

CHAPTER 04 – PESTICIDE AND CHEMICAL CONTAMINANTS

<b>SUBJECT:</b>  TOXIC ELEMENTS IN FOOD AND FOODWARE, AND RADIONUCLIDES IN FOOD - IMPORT AND DOMESTIC (FY 03/04/05)	<b>IMPLEMENTATION DATE</b>  UPON RECEIPT						
	<b>COMPLETION DATE</b> FIELD: 9/30/03,04,05 CENTER: 9/30/03,04,05						
<b>DATA REPORTING</b>							
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES						
FOODS: ALL FOOD CODES EXCEPT 52	<p style="text-align: center;"><u>REPORT INSPECTIONS UNDER THE FOLLOWING PACS:</u></p> <table> <tr> <td style="padding-left: 40px;">04019A</td> <td>TOXIC ELEMENTS IN FOOD</td> </tr> <tr> <td style="padding-left: 40px;">04019B</td> <td>TOXIC ELEMENTS IN FOODWARE</td> </tr> <tr> <td style="padding-left: 40px;">04019C</td> <td>RADIONUCLIDES IN FOOD</td> </tr> </table>	04019A	TOXIC ELEMENTS IN FOOD	04019B	TOXIC ELEMENTS IN FOODWARE	04019C	RADIONUCLIDES IN FOOD
04019A	TOXIC ELEMENTS IN FOOD						
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**Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.**

FIELD REPORTING REQUIREMENTS

1. Report all applicable FACTS operations (i.e., sample collections/analyses, field exams).
2. Report import field exam using OASIS Activity # 23.
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 dietary intake 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 heavy metals), 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 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 dietary intake of toxic elements and radionuclides.

**NOTE:** The program is now organized in three distinct sections that address the major routes of dietary intake of these contaminants: Toxic Elements in Food, Toxic Elements in Foodware, and Radionuclides in Food. The sections for each contaminant/product combination has specific instructions regarding sample collection, analysis, data reporting, and regulatory follow-up, unique to each section.

Note that certain Center and Office contact information applies to all three sections of the program; these contacts are listed only once in Part VI of Section I (Toxic Elements in Foods). Additional contact information specific to each section of the program is listed in Part VI of that section.

**TOXIC ELEMENTS IN FOOD****PART I - BACKGROUND**

As part of its responsibilities for ensuring food safety, the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) monitors levels of certain toxic elements in foods. CFSAN uses this information to estimate dietary exposure to these contaminants and to identify the relative contributions of these foods to total exposure. With this knowledge, CFSAN can take steps to reduce or eliminate the concentrations of toxic elements in both domestic foods and foods imported to the U.S.

Lead and cadmium are the toxic elements of concern at this time. The foods of interest are those known to be major dietary sources of these elements, particularly in the diets of sensitive populations.

With regard to lead, particular emphasis is placed on foods consumed by children, who are the most sensitive to its adverse health effects. Program resources are directed at four significant sources of lead in the diets of children: grape juice, baby carrots (baby cut carrots), raisins, and canned fruit cocktail.

Environmental contaminants, including lead and cadmium have been found to accumulate in certain aquatic organisms. Selected species of finfish and shellfish are of particular interest to CFSAN at this time. Data on levels of cadmium in bivalve molluscs and lead in canned tuna are important for supporting FDA's position on proposed standards for foods in international trade.

To implement the program, District personnel are directed to collect samples of selected foods and analyze them for specific elements as noted in the Sample Collection Schedules (Attachments A and B). The schedules for the first fiscal year of the three-year period are included in this program document; schedules for subsequent years will be distributed to the collecting Districts prior to the start of each fiscal year. (#) for toxic elements in foods, laboratory results that are found to exceed the normal concentrations in these foods are brought to the attention of CFSAN. The Center will evaluate these on a case-by-case basis and will recommend follow up as appropriate.

**TOXIC ELEMENTS IN FOODS****PART II - IMPLEMENTATION****A. OBJECTIVES**

- To generate information on the concentration of toxic elements in selected foods.
- To estimate dietary exposure to those elements, particularly for sensitive populations.
- To identify the major dietary sources of these contaminants, which will aid CFSAN in directing its efforts to reduce these levels.

**B. PROGRAM MANAGEMENT INSTRUCTIONS**

In general, emphasis is placed on sampling and analysis of foods that are significant dietary sources of the toxic elements cadmium and lead, particularly in the diets of young children.

**TOXIC ELEMENTS IN FOODS****PART III – INSPECTIONAL****A. GENERAL SAMPLING INSTRUCTION**

Sampling schedules (Attachments A and B) for both nonseafood and seafood will be issued at the beginning of each Fiscal Year. Please contact the CFSSAN Compliance Program Contact if collecting districts feel that adjustments are necessary.

**1. Domestic Foods**

Samples are surveillance. Collect domestic samples, as identified in the Attachments at the retail level. If the districts have reason to believe that there is a toxic element problem with specific foods and consumed by infants and children, other than those listed in the Attachments, districts may choose to collect these foods.

Document the brand name, manufacturer, batch or lot number, and any other pertinent identifying information.

Collect samples in the container in which the dealer is packaging the products. Ensure that perishable samples are refrigerated or frozen, since spoilage affects analysis adversely.

**2. Domestic-Import Foods**

Samples as identified in the Attachments should be collected in domestic import status immediately after a “May Proceed” notice has been issued. The sample type in FACTS will be "I", and the country of origin must be entered into the FACTS record as well.

If there is a suspicion or indication of a problem with an imported food product, districts may choose to collect samples in import status and hold the lot pending results of analysis.

Domestic Import samples can be collected in two ways:

- a. 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 can be determined.

**OR**

- b. 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 it is released.

**B. NON SEAFOOD PRODUCTS**

Refer to Attachment A for non-seafood collection schedule.

**Sample size**

Samples should consist of 12 randomly selected subs from a lot. Each sub 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 subs of at least 4 ounces each. No 702 (b) portions required.

**C. SEAFOOD PRODUCTS**

Refer to Attachment B for seafood sample collection schedule.

Collect molluscs for cadmium analysis and canned tuna for lead analysis under this program.

**Molluscs (for cadmium analysis)**

1. Molluscan shellfish (oysters, clams, mussels, scallops) and squid should be collected from retail establishment only. Document the origin of each species collected (i.e., body of water where harvested).
2. Molluscan shellfish (except scallops) must consist of whole, in-shell fresh, frozen or refrigerated product.
3. Avoid contaminating the samples with analytes of interest. The district may wish to consult with the analyzing laboratory on the prevention of sample contamination during sampling and transportation to the laboratory.
4. Refer to IOM 452.5 for instructions on shipping frozen samples and IOM 452.6 for instructions on shipping refrigerated samples. Submit samples to the collecting district servicing laboratory.
5. Each sample will consist of sufficient shellfish or seafood to provide at least 1 lb. (454g) of edible meat. No 702 (b) portions required.
6. Flag each collection report Surveillance.

**Canned Tuna (for lead analysis)**

Refer to Attachment B for sample collection schedule.

1. Collect samples in domestic import status
2. Collect twelve (12) subsamples, minimum 6-oz retail containers per sub selected at random from the same manufacturing code. No 702 (b) portions required.

3. Report the brand name, manufacturer, country of origin, and description of tuna (i.e. solid albacore, chunk light, chunk white, etc.), description of the pack (i.e. in water or in oil)
4. Flag each collection report Surveillance.

**Sample shipment:**

Submit samples to your servicing laboratory except where other wise instructed. Refer to IOM subchapter 454 for sample shipment details. See the ORA Field Workplan to determine servicing labs.

**TOXIC ELEMENTS IN FOOD****PART IV - ANALYTICAL****A. CRITERIA FOR ANALYTICAL PACKAGES**

All food and foodware samples considered for regulatory action under this program must meet the "Criteria for Analytical Packages to Support Regulatory Action on Toxic Elements in Food and Food-Related Products," July, 1998. This document has been distributed to the field; copies can be obtained from the CFSAN Compliance Program Contact or viewed on the Office of Compliance Intranet site (when activated).

**B. ANALYZING LABORATORIES**

See Part I of the current ORA Workplan for a listing of Servicing Laboratories.

**C. ANALYSIS**

Do not analyze individual subsamples. Composite an equal weight portion of the edible part of each subsample. Water (ASTM Type I Grade) may be used to aid homogenization but analytical results must be corrected for any added water.

Thoroughly homogenize analytical sample before taking analytical portion.

Analyze the analytical portion for lead or cadmium (see Attachment A & B) using graphite furnace atomic absorption spectrometry as described in *AOAC Int.* method 999.10 or 999.11.

**D. DATA REPORTING**

Report sample results, including blanks, reference materials, and recoveries, into the FACTS Data Reporting System using the Problem Area Flag (PAF): ELE.



**TOXIC ELEMENTS IN FOOD**

**PART V - REGULATORY/ADMINISTRATIVE STRATEGY**

(#) CFSAN scientists in the Office of Plant, Dairy Foods and Beverages (OPDFB), Division of Risk Assessment, will review analytical findings through FACTS and conduct an assessment of potential health hazards from the quantity of the toxic element found in the food based upon food consumption of the product. CFSAN's Office of Compliance; Compliance Program Branch, in conjunction with OPDFB, will issue assignments if further follow up is warranted based on the sample results.

**However, the analyzing labs and/or district compliance branches should promptly notify the CFSAN Compliance Program Contact of atypically high results for foods analyzed under this program for Center evaluation.** In most cases, these levels cannot be precisely defined because of the many foods and exposure rates involved. Historical data may be used as a guide.

**TOXIC ELEMENTS IN FOOD****PART VI - ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTS****ATTACHMENTS**

Attachment A Non-seafood sample collection schedule

Attachment B Seafood sample collection schedule

**REFERENCES**

IOM Chapter 4, Sample Schedule Chart 3, for minimum sample size

IOM 452.5 for instructions on shipping frozen samples

IOM 452.6 for instructions on shipping refrigerated samples

IOM 454 for sample shipment details

Analytical methods for lead and cadmium:

Official Methods of Analysis of AOAC INTERNATIONAL (2002), 17<sup>th</sup> Edition, Revision 1, Official Method 999.10 and Official method 999.11.

Criteria for Analytical Packages to Support Regulatory Action on Elements in Food and Food-Related Products

**GENERAL CONTACTS FOR THREE SECTIONS**

Compliance Program Contact: Kaniz Shireen, CFSAN/ Division of Field Programs/Compliance Programs Branch, HFS-636, Phone: (301) 436-2775, Fax: (301) 436-2657 Email: [kshireen@cfsan.fda.gov](mailto:kshireen@cfsan.fda.gov)

Regulatory Contact (Import): Thushi Amini, Ph. D., CFSAN/ Division of Enforcement/ Import Branch, HFS-606, Phone: (301) 436-2077, Fax: (301) 436-2657 Email: [tamini@cfsan.fda.gov](mailto:tamini@cfsan.fda.gov)

Regulatory Contact (Domestic): Priya Joy, CFSAN/ Division of Enforcement/Domestic Branch, HFS-607, Phone: (301) 436-2078 Fax: (301) 436-2716 Email: [pjoy@cfsan.fda.gov](mailto:pjoy@cfsan.fda.gov)

## CFSAN Scientific Contact:

Toxic Elements in Foods

Stephen Capar, CFSAN/OPDFB/DPIC,  
HFS-338, Phone: (301) 436-2003  
Email: [scapar@cfsan.fda.gov](mailto:scapar@cfsan.fda.gov)

## ORA Scientific Contact:

Charles Parfitt, ORO/Division of Field Science,  
HFC-141, Phone: (301) 827-1033  
Email: [cparfitt@ora.fda.gov](mailto:cparfitt@ora.fda.gov)

## ORA Import Operations Contact:

Ted Poplawski, ORO/Division of Import Operations &  
Policy, HFC-172, Phone: (301) 443-6553  
Email: [tpoplaws@ora.fda.gov](mailto:tpoplaws@ora.fda.gov)

## ORA Investigations Contact:

Barbara Marcelletti, ORO/Division of Emergency and  
Investigational Operations, HFC-132,  
Phone: (301) 443-3340  
Email: [bmarcell@ora.fda.gov](mailto:bmarcell@ora.fda.gov)

## Food List Inquiries:

Katie Egan, CFSAN/OPDFB/DRA,  
HFS-308, Phone: (301) 436-1946  
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**TOXIC ELEMENTS IN FOOD**

**PART VII - CENTER RESPONSIBILITIES**

The Director, Office of Plant and Dairy Foods and Beverages, will prepare an annual evaluation of this program except for the seafood samples by April 1 of the following fiscal year. The Director of the Office of Seafood will prepare a similar evaluation for seafood by April, of the following fiscal year. The evaluations should be submitted to the Chief, Compliance Programs Branch, HFS-636.

**TOXIC ELEMENTS IN FOODWARE****PART I - BACKGROUND**

This segment of the program focuses on ceramicware and silver-plated hollowware used for eating, storing, holding and cooking foods, particularly liquids. Lead and cadmium are components in some pigments used to decorate ceramicware, and ceramicware may be coated with glazes containing lead and/or cadmium. Glazes that are improperly formulated, applied, or fired may permit unacceptable amounts of lead and/or cadmium to leach into food. Some of these products have been found to release lead and/or cadmium when used for food purposes.

Monitoring of ceramicware is conducted in two steps. First, screening tests are conducted in the field to identify items that are likely to contain leachable lead. Based on the results of the screening tests, official samples are collected and sent to the laboratory for further testing. If the test results exceed action levels stated in relevant Compliance Policy Guides, a regulatory action recommendation may be initiated and forwarded to CFSAN for review.

There are no validated screening tests for detecting cadmium in ceramicware or lead and cadmium in silver-plated hollowware. Items identified for testing for leachable lead and cadmium are sampled and sent to the laboratory for analysis without conducting screening tests.

A Sample Collection Schedule is not provided for this section of the program. Guidance regarding the types of products that should be inspected and considered for screening is provided in Parts II and III of the program. The number of field tests, sample collections and analyses to be conducted is indicated in the program workplan.

**TOXIC ELEMENTS IN FOODWARE****PART II - IMPLEMENTATION****A. OBJECTIVES**

- To examine and analyze domestic and imported ceramic and silver-plated hollowware to determine whether they contain excessive levels of leachable lead and cadmium.
- To investigate the rate of compliance for Chinese ceramic tableware from both certified and non-certified factories.
- To audit the effectiveness of the China certification program in improving the safety of ware exported to the United States.

**B. PROGRAM MANAGEMENT INSTRUCTIONS****General Instructions**

When selecting items for inspection and analysis, emphasis should be placed primarily on ceramicware, and secondarily on silver-plated hollowware. Other types of foodware should not be collected for analysis without first consulting with the CFSAN Compliance Program Contact (refer to section - A, Part VI).

FDA's enforcement strategy for ceramicware has generally been to sample products at domestic manufacturing/retail firms or products in import status. Emphasis is placed on products from firms and countries with histories of exceeding applicable FDA action levels.

**Domestic samples**

- Concentrate sampling on firms with a violative history. Conduct follow-up with manufacturers found to be violative.

**Import samples**

- Concentrate sampling on firms/countries/shippers/importers with a history of prior violations. Be particularly attentive to small shipments entering from Mexico. Use On-Line Detention Data for planning compliance coverage for imported products under this program.
- Based on volume imported and/or past problems, ceramicware from the following countries should be considered for sample collection before other countries:

(#)

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**Ceramicware from the People's Republic of China**

The FDA and the State Administration of Entry/ Exit Inspection and Quarantine of China (recently renamed the China National Certification and Accreditation Administration or CNCA) implemented a Memorandum of Understanding (MOU) pertaining to the safety of ceramic tableware produced in China and exported to the United States. Under this agreement, CNCA certifies facilities whose products will satisfy FDA action levels for leachable lead and cadmium.

The MOU specifies, among other provisions, that CNCA, through its network of provincial, municipal, and local inspection offices (called CCIBs or CIQs), institute a certification system for ceramic tableware production facilities in China. This certification system is expected to provide FDA with reasonable assurance that ceramicware produced in these facilities and exported to the United States will not exceed FDA action levels for leachable lead and cadmium. CNCA has provided FDA with a list of the names, addresses, and unique factory codes of certified factories and will update the list as necessary to maintain a current list of CNCA certified factories. FDA has incorporated the list into the Agency's automated import entry examination system (Operational and Administrative System for Import Support, OASIS) to determine at the time of entry, the eligibility of the shipment to proceed into U.S. commerce under terms of the MOU.

FDA believes that consignments of ceramic tableware originating from CNCA-certified factories should have a higher probability of satisfying applicable FDA action levels than those originating from other non-certified manufacturing factories in China. For that reason, emphasis should be placed on shipments that appear to be from facilities that have not been certified and therefore do not bear CCIB stickers. For further information on sampling and this MOU, please see **Import Alert # 52-06 - "Surveillance of Ceramicware from the People's Republic of China."** Certified manufacturing firms are identified in this document.

**TOXIC ELEMENTS IN FOODWARE****PART III – INSPECTIONAL GUIDANCE****A. GENERAL GUIDANCE**

This program focuses on two types of foodware that are potential sources of lead and cadmium: ceramicware and silver-plated hollowware.

The term ceramicware as used in this document refers to tablewares 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. Inspection of ceramicware is conducted in two steps: Samples are first screened in the field (field exams) for the presence of lead in glazes or decorations. Based on the results of the screening tests, official samples are collected and sent to the laboratory for additional testing.

In addition, samples of ceramicware that are suspected of containing leachable cadmium may be collected and sent to the laboratory for analysis. Since there is no screening test for cadmium, investigators should rely on visual observations to select official samples for cadmium leach testing. The following colors in the glaze or decorations are often indicative of ceramicwares that release cadmium:

- Red
- Orange
- Yellow

For inspection of silver-plated hollowware, samples are collected and sent to the laboratory for analysis of lead and cadmium. There are no screening tests for these products.

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. Emphasis for sample screening and collection should be placed on:

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

For Chinese ceramicware CCIB stickers affixed to both the shipping carton and the retail carton should accompany shipments from certified factories. Since a high proportion of entries are shipped by distributors, not by manufacturers, the CCIB sticker (<http://www.cfsan.fda.gov/~comm/ceramic.html>) becomes an important aspect in recognizing ware from certified and non certified firms.

Generally, do NOT collect the following types of products:

- Lead crystal
- Enameled metalwares
- 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
- Drinking glasses with exterior decorations in the lip and rim area. (Ceramicware cups and mugs with exterior decorations in the lip and rim area may be sampled to determine the levels of lead leaching from the food contact (interior) surface of the vessel, however, testing of the exterior portion or the cup or mug should not be conducted.)

## **B. FIELD EXAMS FOR SCREENING CERAMICWARE FOR LEAD**

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.

The following characteristics are sometimes, but not always, indicative of ceramicware that releases excessive amounts of lead:

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

Ceramicware items considered for lead analysis are screened using a rapid screening test [Quick Color Test (QCT) or Rapid Abrasion Test (RAT)] according to the protocol in LIB 4127. The screening tests are appropriate only for testing silicate-based wares only (e.g., ceramicware); they are not appropriate for silver-plated hollowware. District servicing laboratories will provide the inspectional staff with supplies and instructions for the QCT and RAT when possible. LIB 4127 "Ceramic Foodware Lead Screening Using Test Kits" is also available via the DFS Intranet at:

<http://web.ora.fda.gov/dfs/LIB/Lab%20Info%20Bulletins/libhome.htm>

Commercially available QCT (e.g., LeadCheck Swab) and RAT are referenced in FDA LIB 4127. If using these kits, the investigator may need to purchase sandpaper separately to abrade the foodware when conducting the RAT.

Perform the screening test as directed in FDA LIB 4127. 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.

### **C. SAMPLE COLLECTION**

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

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 samples for cadmium testing. If results of the screening test for lead are negative, visually inspect the ware for the possibility that it may contain cadmium.

When sets of foodware (whether ceramicware or silver-plated holloware) are considered for sampling, priority should be given to those items with the lowest actionable lead level (i.e., cups, mugs, and pitchers).

**Domestic samples**

- Collect an official sample that consists of twelve (12) units of identical size, shape, color, and design.

**Import samples**

- Collect an official sample consisting of six (6) units of identical size, shape, color, and design.

**D. FACTS REPORTING REQUIREMENTS**

Report all lead screening tests conducted by investigators (i.e., positive, negative, or inconclusive) under FACTS/Field Examinations/Test.

Report sample type C (audit/certification) in the Collection Report for samples from certified Chinese manufacturers and include PAF: CDW.

Report the import sample collection into OASIS.

**TOXIC ELEMENTS IN FOODWARE****PART IV – ANALYTICAL GUIDANCE****A. CRITERIA FOR ANALYTICAL PACKAGES**

All food and foodware samples considered for regulatory action under this program must meet the “Criteria for Analytical Packages to Support Regulatory Action on Toxic Elements in Food and Food-Related Products,” July, 1998. This document has been distributed to the field; copies can be obtained from the Compliance Program Contact or viewed on the Office of Compliance Intranet site (when activated).

**B. ANALYZING LABORATORIES**

See Part I of the current ORA Workplan for a listing of Servicing Laboratories.

**C. SAMPLE PREPARATION AND ANALYSIS**

Check analyses are not required.

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).

Determine lead concentrations first. If violative levels of lead are found, do not determine cadmium concentrations. If non-violative levels of lead are found, proceed with cadmium determinations.

Samples are analyzed using FDA Elemental Analysis Manual (EAM) Method 4.1 or 4.2 as appropriate.

**D. DATA 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.”

**E. DISPOSITION OF SAMPLES**

Samples of ceramicware that have been analyzed for leachable metals and found to be in compliance may be returned to the consignees provided the consignees agree that FDA did no damage.

Attempt to return any saleable items of "Sterling" quality silver-plated hollowware or other expensive metalware to the dealer for reimbursement if found to be NAI. 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

Districts should dispose of those samples locally, which are of less than "sterling" value.

**TOXIC ELEMENTS IN FOODWARE****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 – Lead in Silver-plated Hollowware.

**Specimen Charge**

Article (namely flatware, hollowware, cups and mugs, pitchers or silver-plated hollowware-as applicable) adulterated (when introduced into and while in interstate commerce) (while held for sale after shipment in interstate commerce), within meaning of Section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act, in that it contains a food additive, namely lead (and/or cadmium-as applicable) which is unsafe within the meaning of Section 409(a), because its use and intended use are not in conformity with a regulation or exemption established pursuant to Section 409.

**Imports**

If the ceramicware or silver-plated hollowware tested exceeds the action levels stated in the CPGs, the districts should forward a recommendation for Detention Without Physical Examination (DWPE) to the Imports Branch (HFS 606). The DWPE must be accompanied by all analytical worksheets and other appropriate documentation (e.g. entry paperwork, collection report).

**Domestic**

If the ceramicware or silver-plated hollowware tested exceeds the action levels stated in the CPGs, the districts should forward a complete regulatory action recommendation package, including sample analyses to the Domestic Branch (HFS-607). CFSAN will review to determine Center support for the recommended action.

**TOXIC ELEMENTS IN FOODWARE****PART VI – REFERENCES****REFERENCES**

LIB 4127: Ceramic Foodware Lead Screening Using Test Kits

FDA Elemental Analysis Manual (EAM) Method 4.1  
(<http://vm.cfsan.fda.gov/~acrobat/eam4-1.pdf>)

FDA Elemental Analysis Manual (EAM) Method 4.2  
(<http://vm.cfsan.fda.gov/~acrobat/eam4-2.pdf>)

Compliance Policy Guide Section 545.400 – Pottery (Ceramics) Imported and Domestic – Cadmium Contamination. ([http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg545-400.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg545-400.html))

Compliance Policy Guide Section 545.450 – Pottery (Ceramics) Imported and Domestic – Lead Contamination. ([http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg545-450.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg545-450.html))

Compliance Policy Guide Section 545.500 – Lead in Silver-plated Hollowware.  
([http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg545-500.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg545-500.html))

Import Alerts # 52-01, 52-06 (Surveillance of Ceramicware from the PRC), 52-08, 52-10, 52-11, 52-12, 52-14  
([http://www.fda.gov/ora/fiars/ora\\_import\\_alert\\_list.html](http://www.fda.gov/ora/fiars/ora_import_alert_list.html))

**FOR GENERAL CONTACTS**

See Toxic Elements in Foods, PART VI.

CFSAN Scientific Contact

Toxic Elements in Foodware

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**TOXIC ELEMENTS IN FOODWARE**

**PART VII – CENTER RESPONSIBILITIES**

The Director, Office of Plant and Dairy Foods and Beverages will prepare an annual evaluation of this program by April 1 of the following fiscal year. The evaluation should be submitted to the Chief, Compliance Programs Branch, HFS-636.

**RADIONUCLIDES IN FOOD****PART I – BACKGROUND**

Routine analysis of foods for the presence and levels of radionuclide 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 abroad. 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 respond to nuclear accidents and to identify sources of radionuclide contamination.

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 all three fiscal years are specified in the Sample Collection Schedule (Attachment C). 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 monitoring import samples, no specific sample collection schedule is provided. Guidance is provided to District 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).

If a sample is found to have a radionuclide concentration that exceeds regulatory limits, the laboratory conducts a confirmatory analysis. The analytical results are forwarded to CFSAN for review to determine whether a follow-up investigation is warranted.



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**RADIONUCLIDES IN FOOD****PART II – IMPLEMENTATION****A. 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.

**B. 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. If increasing concentrations of radionuclides are observed, this information will help to target sources of radionuclide contamination.

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**RADIONUCLIDES IN FOOD****PART III – INSPECTIONAL GUIDANCE****A. SAMPLE COLLECTION****1. Domestic Samples**

Refer to Attachment C for sample collection locations and collecting districts.

Each collecting district will collect four samples of products harvested, produced, or caught as near as possible (within 10 miles) from the nuclear power plants.

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.”

**2. Import Samples**

Specific sample collection schedules are not provided for import samples.

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

Collect products originating from European countries potentially affected by accidental contamination. Examples of such countries, in rough order of priority, include 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 contain potentially affected fruits, vegetables, or grains 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.
- Grain/cereal type products such as pasta and macaroni
- Nuts and fruit/vegetable products such as dates, mushrooms, herbs, spices, tea

- Game animals such as reindeer, venison, and rabbit
- Powdered milk

Import samples should be flagged “I” on the collection report and must be coded as sample type “I”. Flag the collection report “RADIONUCLIDES IN FOODS.”

Sampling districts 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.

#### **B. SAMPLE SIZE**

Sample size is 4 pounds (**edible portion**) for solids; 1 gallon for liquids. No 702 (b) portions required.

#### **C. 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 all foods to arrive at WEAC by COB Thursday of the week of collection. Ship samples to:

Food and Drug Administration  
Winchester Engineering and Analytical Center, HFR-NE400  
ATTN: Radionuclide Monitor  
109 Holton Street  
Winchester, MA 10890

Contact WEAC at 781-729-5700 if there are questions about shipping requirements.

#### **D. FACTS REPORTING REQUIREMENTS**

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

For domestic samples, sample type is V (investigational)

Import samples should be flagged “I” on the collection report and must be coded as sample type “I”

Report the import sample collections into OASIS.

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**RADIONUCLIDES IN FOOD****PART IV – ANALYTICAL GUIDANCE****A. ANALYZING LABORATORIES**

The Winchester Engineering and Analytical Center (WEAC) will perform all analyses.

**B. SAMPLE PREPARATION AND ANALYSIS**

Analyze all **domestic samples** for tritium and gamma-ray emitters. Analyze two samples collected near each power plant for strontium-90.

Analyze all **import samples** for cesium-134 and cesium-137. For all samples having a total cesium-134 and cesium-137 radioactivity concentration of 110 Bq/kg (3,000 pCi/kg) or more, analyze also for strontium-90.

The analytical methods to be used are as follows:

- Determination of Gamma-ray Emitting Radionuclides in Foods, WEAC SOP TD RN-1.
- E. J. Troianello (1978), Dehydration of Food Samples for Assay of Tritium in Free Water FDA Laboratory Information Bulletin 1913, Food and Drug Administration, Division of Field Science, Rockville, MD.
- Determination of Strontium-90 in Foods, WEAC SOP TD RN-2.

**C. DATA 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.

**RADIONUCLIDES IN FOOD****PART V – REGULATORY/ADMINISTRATIVE STRATEGY**

WEAC should immediately notify the Compliance Program Contact (CFSAN) and proceed with a confirmatory analysis whenever potentially violative levels of radionuclides in foods are found. To determine compliance, WEAC should use the Derived Intervention Levels (DILs) cited in the 1998 FDA guidance document “Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies” and summarized below. Please note that DILs supercede Levels of Concern found in Compliance Policy Guide Section 560.750 Radionuclides in Imported Foods – Levels of Concern. A new CPG will be issued to replace Levels of Concern with DILs.

**Derived Intervention Levels (DILs)  
for Radionuclides in Food<sup>(a),(b)</sup>**

**All Components of the Diet**

Radionuclide Group	(Bq/kg)
Strontium-90	160
Iodine-131	170
Cesium-134+Cesium-137	1200
Plutonium-238 + Plutonium-239 + Americium-241	2
Ruthenium- 103 + Ruthenium- 106 <sup>(c)</sup>	$\frac{C_3}{6800} + \frac{C_6}{450} < 1$

<sup>(a)</sup> The level for each radionuclide group is applied independently. Each level applies to the sum of the concentrations of the radionuclides in the group at the time of measurement.

<sup>(b)</sup> Applicable to foods as prepared for consumption. For dried and concentrated products such as powdered milk or concentrated juices, adjust by a factor appropriate to reconstitution, and assume the reconstitution water is not contaminated. For spices, which are consumed in very small quantities, use a dilution factor of 10.

<sup>(c)</sup> Due to the large difference in levels for Ru-103 and Ru-106, the individual concentrations of Ru-103 and Ru-106 are divided by their respective levels and then summed. The sum must be less than one.  $C_3$  and  $C_6$  are the concentrations, at the time of measurement, for Ru-103 and Ru-106, respectively.

Upon confirmation of the initial findings, CFSAN will review the data and determine whether a follow-up investigation is warranted.

**RADIONUCLIDES IN FOOD****PART VI – ATTACHMENT AND REFERENCES****A. ATTACHMENTS**

Attachment C: Radionuclides Sampling Schedule

**B. REFERENCES**

Determination of Gamma-ray Emitting Radionuclides in Foods. WEAC SOP TD RN-1.

E. J. Troianello (1978). Dehydration of Food Samples for Assay of Tritium in Free Water. *FDA Laboratory Information Bulletin* 1913, Food and Drug Administration, Division of Field Science, Rockville, MD.

Determination of Strontium-90 in Foods. WEAC SOP TD RN-2.

Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. *Federal Register* August 13, 1998 (63 FR), pp. 43402-43403. (Also found at the following website: <http://www.fda.gov/cdrh/dmqrp/84.html>)

**FOR GENERAL CONTACTS**

See Toxic Elements in Foods, PART VI.

CFSAN Scientific Contact

Radionuclides in Foods

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**RADIONUCLIDES IN FOOD****PART VII – CENTER RESPONSIBILITIES**

The Director, Office of Plant and Dairy Foods and Beverages, will prepare an annual evaluation of this program by April 1 of the following fiscal year. The evaluation should be submitted to the Chief, Compliance Programs Branch, HFS-636.

**ATTACHMENT A****NON-SEAFOOD SAMPLE COLLECTION SCHEDULE****(For lead analysis only)****FY 03**

<b>DISTRICT</b>	<b>PRODUCT</b>	<b>DSC</b>	<b>DI</b>
<b>(#)</b>	Grape Juice Conc.	4	
	Baby carrots	4	
	Canned Fruit cocktail	3	
	Raisins		4
<b>(#)</b>	Grape Juice Conc.	5	
	Baby carrots	5	
	Canned Fruit cocktail	4	
	Raisins		5
<b>(#)</b>	Grape Juice Conc.	5	
	Baby carrots	4	
	Canned Fruit cocktail	5	
	Raisins		5
<b>(#)</b>	Grape Juice Conc.	5	
	Baby carrots	5	
	Canned Fruit cocktail	4	
	Raisins		5
<b>(#)</b>	Grape Juice Conc.	3	
	Baby carrots	2	
	Canned Fruit cocktail	3	
	Raisins		3
<b>(#)</b>	Grape Juice Conc.	5	5
	Baby carrots	6	
	Canned Fruit cocktail	6	
<b>(#)</b>	Grape Juice Conc.	2	
	Baby carrots	2	
	Canned Fruit cocktail	3	



**ATTACHMENT A (cont.)****NON-SEAFOOD SAMPLE COLLECTION SCHEDULE****(For lead analysis only)****FY 03**

<b>DISTRICT</b>	<b>PRODUCT</b>	<b>DSC</b>	<b>DI</b>
(#)	Grape Juice Conc.	6	
	Baby carrots	6	
	Canned Fruit cocktail	8	
	Raisins		6
(#)	Grape Juice Conc.	8	
	Baby carrots	8	
	Canned Fruit cocktail	8	
	Raisins		6
(#)	Grape Juice Conc.	8	
	Baby carrots	22	
	Canned Fruit cocktail	22	
	Raisins		8
(#)	Grape Juice Conc.	6	5
	Baby carrots	6	
	Canned Fruit cocktail	7	
	Raisins		6
(#)	Grape Juice Conc.	6	
	Baby carrots	9	
	Canned Fruit cocktail	9	
	Raisins		6
(#)	Grape Juice Conc.	8	5
	Baby carrots	10	
	Canned Fruit cocktail	10	
	Raisins		8
(#)	Grape Juice Conc.	6	
	Baby carrots	13	
	Canned Fruit cocktail	12	
	Raisins		6

**ATTACHMENT A (cont.)****NON-SEAFOOD SAMPLE COLLECTION SCHEDULE****(For lead analysis only)****FY 03**

<b>DISTRICT</b>	<b>PRODUCT</b>	<b>DSC</b>	<b>DI</b>
<b>(#)</b>	Grape Juice Conc.	3	
	Baby carrots	6	
	Canned Fruit cocktail	6	
<b>(#)</b>	Grape Juice Conc.	3	5
	Canned Fruit cocktail	3	
<b>(#)</b>	Grape Juice Conc.	6	
	Baby carrots	12	
	Canned Fruit cocktail	13	
	Raisins		6
<b>(#)</b>	Grape Juice Conc.	5	5
	Raisins	4	5
<b>(#)</b>	Grape Juice Conc.	6	5
	Baby carrots	10	
	Canned Fruit cocktail	10	
	Raisins		6
<b>TOTAL</b>		<b>370</b>	<b>115</b>

**ATTACHMENT B****SEAFOOD SAMPLE COLLECTION SCHEDULE****FY 03**

<b>DISTRICT</b>	<b>ANALYSIS</b>	<b>PRODUCT</b>	<b>DSC</b>	<b>DI</b>
(#)	Lead	Canned Tuna		10
(#)	Cadmium	Oysters	4	
(#)	Cadmium	Oysters	4	
	Cadmium	Squid		2
	Lead	Canned Tuna		20
(#)	Cadmium	Oysters	2	12
	Cadmium	Clams	2	10
	Cadmium	Mussels	1	10
	Cadmium	Squid	8	5
	Cadmium	Scallops		4
	Lead	Canned Tuna		10
(#)	Cadmium	Oysters	4	
(#)	Cadmium	Oysters	2	5
	Cadmium	Clams	3	
	Cadmium	Mussels	2	
	Cadmium	Scallops	3	12
	Lead	Canned Tuna		10
(#)	Cadmium	Oysters		5
	Cadmium	Clams		5
	Cadmium	Mussels		4
	Cadmium	Scallops		4
	Lead	Canned Tuna		20

ATTACHMENT B (cont.)SEAFOOD SAMPLE COLLECTION SCHEDULEFY 03

<b>DISTRICT</b>	<b>ANALYSIS</b>	<b>PRODUCT</b>	<b>DSC</b>	<b>DI</b>
<b>(#)</b>	Cadmium	Oysters		6
	Cadmium	Clams	2	4
	Cadmium	Mussels	1	3
	Cadmium	Squid	2	3
	Lead	Canned Tuna		20
<b>(#)</b>	Cadmium	Oysters	4	12
	Cadmium	Clams	3	7
	Cadmium	Mussels	3	7
	Lead	Canned Tuna		10
<b>TOTAL</b>			<b>50</b>	<b>220</b>

PROGRAM

ATTACHMENT C

(%)