CHAPTER 04 – PESTICIDE AND CHEMICAL CONTAMINANTS

SUBJECT:	**IMPLEMENTATION DATE**
TOXIC ELEMENTS IN FOOD AND FOODWARE, AND RADIONUCLIDES IN FOOD - IMPORT AND DOMESTIC (FY 08, 09, 10)	UPON RECEIPT
	COMPLETION DATE 09/30/10

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
	REPORT INSPECTIONS UNDER THE FOLLOWING PACS:	
FOODS: ALL FOOD CODES EXCEPT 53	04019A	TOXIC ELEMENTS IN FOOD
	04019B	TOXIC ELEMENTS IN FOODWARE
	04019C	RADIONUCLIDES IN FOOD

FIELD REPORTING REQUIREMENTS

1. Report all applicable FACTS operations (i.e., sample collections/analyses, field exams).

2. Report import field exam using OASIS Work Type 'FEX'.

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"

4. For results where no regulatory action is anticipated, no hardcopy worksheets are needed.

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 section 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 (e.g., lead, cadmium, inorganic arsenic, and methylmercury) in both domestic foods and foods imported in to the U.S.

The Program monitors the foods of interest are those can be major dietary sources of certain toxic elements. 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 foods that may be significant sources of lead in the diets of children. As an example, recent concerns about exposure to lead from certain candies has led FDA to propose new guidance on recommended maximum levels for lead in candy (http://www.cfsan.fda.gov/~dms/pbguid2.html).

Toxic elements, including lead, cadmium, and methylmercury 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 these contaminants in bivalve molluscs, finfish and lobster are important for supporting FDA's position on proposed standards for foods in international trade.

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, this 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 (e.g., lead, cadmium, inorganic arsenic, and methylmercury) in the diets of young children.

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. The sample collection schedules for both seafood and non-seafood will be distributed to the collecting Districts prior to the start of each fiscal year. Although there are no regulatory limits for toxic elements in foods, laboratory results that are found to exceed the normal concentrations in these foods are to be brought to the attention of CFSAN. The Center will evaluate these situations on a case-by-case basis and may recommend follow up as appropriate.

TOXIC ELEMENTS IN FOODS

PART III – INSPECTIONAL

A. GENERAL SAMPLING INSTRUCTION

The sample collection schedules for both non-seafood and seafood, consistent with the current ORA Field Workplan, will be issued at the beginning of each fiscal year. Please contact the CFSAN Compliance Program Contact early in the fiscal year if collecting districts feel that there may be difficulties in completing the workplan directed collections.

Unpackaged (bulk) samples for metals analysis should be collected in new plastic bags or other plastic containers and sealed in a manner so as to prevent contamination during handling and storage. Factory packaged foods in cans, glass, plastic, and other materials are satisfactory for collection if unopened and sealed.

1. **Domestic Foods**

   Samples are surveillance. Collect domestic samples, as identified in the sample collection schedule. If districts have reason to believe that there is a toxic element problem with specific foods which may be consumed by infants and children, and the foods that are not listed in the collection schedule, 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. **Import Foods**

   Collect import food samples, as identified in the collection schedule, at the port of entry. The district may use their discretion to collect and follow-up on other foods, which may be consumed by infants and children from the countries that they have reason to suspect, may not be in compliance.

   See Import Alerts for foods under DWPE and Import Bulletins for special sampling consideration.

   Submit samples to per the National Sample Distributor (NSD).

B. NON-SEAFOOD PRODUCTS

Refer to sample collection schedule for non-seafood collections. No 702 (b) portions required.

Sample size

Samples should consist of twelve (12) randomly selected subsamples from a 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.

C. SEAFOOD PRODUCTS

Refer to sample collection schedule for seafood collections. No 702 (b) portions required.

Collect molluscs, finfish and lobster for arsenic, cadmium, lead, and mercury analysis under this program.

Sample Size

Each fish sample should consist of twelve (12) subsamples, minimum 1/2-lb per subsample. Each sample of lobster should consist of a total of 1 lb (454g) of tail meat.

Finfish

Collect samples from the distributor, cold storage warehouse, or fish processing facility. The samples can be aquaculture or wild. Document the size, the species and any other pertinent identifying information.

Molluscs

1. Molluscan shellfish (oysters, scallops) and squid should be collected from retail establishments 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 4.5.3.5 for instructions on shipping frozen samples and IOM 4.5.3.6 for instructions on shipping refrigerated samples. Samples may be frozen prior to shipping. Submit samples per NSD.

5. Each sample should consist of sufficient shellfish (approximately 12 shellfish) or seafood to provide at least a total of 1 lb. (454g) of edible meat.

6. Flag each collection report Surveillance.

Sample Shipment:

Submit samples per NSD. Refer to IOM subchapter 4.5.5 for sample shipment details. See the ORA Field Workplan to determine servicing labs. Do not ship samples on Friday.

TOXIC ELEMENTS IN FOOD

PART IV-ANALYTICAL

A. ANALYZING LABORATORIES

Per NSD.

B. ANALYSIS

Non-seafood:

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 using FDA Elemental Analysis Manual (EAM) Method 4.3 [Revision draft E, January 2002], microwave digestion and graphite furnace atomic absorption spectrometry, available in FDA eRooms at http://eroom.fda.gov/ [Elemental Analysis > EAM methods > EAM4-3dE.pdf]. Please contact the CFSAN Scientific Contact for questions related to the method or accessing the Elemental Analysis eRoom. Report results in FACTS using Method Code 703 and enter the following in the Method Remarks field of the Method Applied screen: EAM 4.3dE.

Alternatively, analyze the analytical portion for lead by inductively coupled plasma-mass spectrometry using Draft Method for Analysis of Seafood by ICP-MS, available at http://eroom.fda.gov/ [Elemental Analysis > EAM methods > Draft EAM Procedures: Seafood ICPMS 16Nov06.pdf]. Report results under Method Code 998 (Other) and enter the following method remarks**:** Draft Seafood ICP-MS method, CFSAN/ERB November 16, 2006.

Seafood:

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 cadmium, lead and mercury by Draft Method for Analysis of Seafood for As*, Cd, Hg, and Pb by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) available in FDA eRooms at http://eroom.fda.gov/ [Elemental Analysis > EAM methods > Draft EAM Procedures: Seafood ICPMS 16Nov06.pdf]. (Note that samples are not to be analyzed for arsenic.) Report results under Method Code 998 (Other) and enter the following in the Remarks field of the Method Applied screen: Draft Seafood ICP-MS method November 16, 2006.

C. DATA REPORTING

Report sample results, including blanks, reference materials, and recoveries, into the FACTS Data Reporting System using the Problem Area Flag (PAF): ELE. For results where no regulatory action is anticipated, no hardcopy worksheets are needed.

See Regulatory/Administrative Strategy (Part V) for further guidance on reporting.

TOXIC ELEMENTS IN FOOD

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Regulatory action is not anticipated in this area. CFSAN scientists in the Office of Food Safety (OFS), Risk Assessment Staff, will review analytical findings through FACTS and conduct an assessment of potential health hazards based on the quantity of the toxic element(s) found in the food and consumption levels of the product. CFSAN's Office of Compliance, Field Programs Branch, in conjunction with OFS, may 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 if any results for bottled water exceed the quality standards (CFR 165.110), or, if atypically high results are encountered for foods analyzed under this program. In most cases, atypically high results cannot be precisely defined because of the many foods and exposure rates involved. Some examples of toxic element levels in specific foods that CFSAN requests to be notified about appear below. For other foods and elements, historical data may be used as a guide.

The analyzing labs are requested to notify the CFSAN Seafood Contact, Barbara Montwill at 301-436-1426 (email: Barbara.Montwill@fda.hhs.gov) if the original analytical results for the seafood products noted below equal or exceed the stated levels. Inquiries for all other products should be made to Kaniz Shireen, Compliance Program Contact.

The seafood products and toxic element levels are:

Lead:	
Finfish:	0.4 ppm
Crustacean	0.4 ppm
Bivalve Mollusc	0.8 ppm
Cadmium:	
Finfish:	0.4 ppm
Crustacean (except lobster)	0.2 ppm
Lobster	6.0 ppm
Bivalve Mollusc (except oyster)	0.4 ppm
Oyster	1.5 ppm

TOXIC ELEMENTS IN FOOD

PART VI - ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTS

REFERENCES

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

IOM 4.5.3.5.1 for instructions on shipping frozen samples

IOM 4.5.3.6 for instructions on shipping refrigerated samples

IOM 4.5.5 for sample shipment details

FDA Elemental Analysis Manual (EAM) for Food and Related Products (http://www.cfsan.fda.gov/~dms/eam-toc.html)

GENERAL CONTACTS FOR THREE SECTIONS

Compliance Program Contact:	Teja Patel, CFSAN, Office of Compliance Division of Filed Program and Guidance Program Assignment & Monitoring Branch, HFS-615, Phone: 240-402-2339 Email: Teja.Patel@fda.hhs.gov
Regulatory Contact (Import):	Doriliz De Leon, CFSAN/Division of Enforcement/ Product Adulteration Branch, HFS-606, Phone: (301) 436-2772 Email: Doriliz.DeLeon@fda.hhs.gov
Regulatory Contact (Domestic):	Priya Rathnam, CFSAN/Division of Enforcement/Manufacturing and Storage Adulteration Branch, HFS-607, Phone: (301) 436-2078, Fax: (301) 436-2716, Email: Priya.Rathnam@fda.hhs.gov
CFSAN Scientific Contact:	Toxic Elements in Foods William Mindak, CFSAN/OCD/ORS/DBC/CHCB, HFS-716, Phone: (301) 436-2005 Email: william.mindak@fda.hhs.gov
ORA Scientific Contact:	Steven Robbs, ORO/Division of Field Science, HFC-141, Phone: (301) 827-9555 Email: steven.robbs@fda.hhs.gov
ORA Import Operations Contact:	Ted Poplawski, ORO/Division of Import Operations & Policy, HFC-172, Phone: (301) 594-3849 Email: ted.poplawski@fda.hhs.gov
ORA Investigations Contact:	Barbara Marcelletti, ORO/Division of Field

	Investigations, HFC-132, Phone: (301) 827-5635 Email: barbara.marcelletti@fda.hhs.gov
Food List Inquiries:	Katie Egan, CFSAN/OFS, HFS-301, Phone: (301) 436-1946 Email: katie.egan@fda.hhs.gov

TOXIC ELEMENTS IN FOOD

PART VII - CENTER RESPONSIBILITIES

The Office of Food Safety is responsible for evaluation of this program. The program summaries will be available on the OC intranet website (http://intranet.cfsan.fda.gov/OC/pages/progrevaln.htm), and likely the CFSAN Internet, when available.

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 and/or decals 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 for lead is conducted in two steps. First, products are screened in the field using a Rapid Abrasion Test (RAT) to identify items that are likely to contain leachable lead. If the results of the screening tests are positive, 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 separate 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 ORA Field 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 non-certified factories.

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 Toxic Elements in Foods, 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:
  Hong Kong, Indonesia, Italy, Japan, Republic of Korea, Mexico, People's Republic of China, Poland, Taiwan, Thailand, and United Kingdom.

Ceramicware from the People's Republic of China

The FDA and Certification and Accreditation Administration (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 the China Entry-Exit Inspection and Quarantine Bureaus (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. All shipping cartons and retail cartons in each lot are identified by a CIQ sticker/logo that is imprinted with the standardized factory code of the CNCA/CIQ factory. 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 CIQ stickers/logos.

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 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. 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 ceramicware that releases 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, CIQ 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 CIQ 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
- Rough unprotected surface decals
- 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 (200 grit silicon carbide paper) 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 performs 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.
            Φ IF the RAT on the decoration is positive or inconclusive, collect a sample.
            Φ 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 hollowware) 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 units total, 6 units for analysis and 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

- Collect an official sample that consists 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. ANALYZING LABORATORIES

Per NSD.

B. 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. The link to EAM is http://www.cfsan.fda.gov/~dms/eam-toc.html.

C. 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." For results where no regulatory action is anticipated, no hardcopy worksheets are needed.

D. 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 (CPG 7117.06) – Pottery (Ceramics) Imported and Domestic – Cadmium Contamination.

CPG Section 545.450 (CPG 7117.07) - Pottery (Ceramics) Imported and Domestic – Lead Contamination.

CPG Section 545.500 (CPG 7117.05) - Silver-Plated Hollowware - Lead Contamination.

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 Division of Import Operations and Policy (DIOP). 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 DE/MSAB, 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) for Food and Related Products
http://www.cfsan.fda.gov/~dms/eam-toc.html.

Compliance Policy Guide Section 545.400 – Pottery (Ceramics) Imported and Domestic – Cadmium Contamination (CPG 7117.06). (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 (CPG 7117.07). (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg545-450.html)

Compliance Policy Guide Section 545.500 – Silver-plated Hollowware – Lead Contamination (CPG 7117.05). (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg545-500.html)

FOR GENERAL CONTACTS

See Toxic Elements in Foods, PART VI.

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TOXIC ELEMENTS IN FOODWARE

PART VII – CENTER RESPONSIBILITIES

The Office of Food Safety is responsible for evaluation of this program. The summary will be available on the OC intranet website (http://intranet.cfsan.fda.gov/OC/pages/progrevaln.htm), and likely the CFSAN Internet, when available.

RADIONUCLIDES IN FOOD

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 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 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 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. If the test results exceed action levels stated in CPG Section 560.750 - Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14), a regulatory action recommendation is considered and forwarded to CFSAN for review.

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 and to target sources of radionuclide contamination.

RADIONUCLIDES IN FOOD

PART III – INSPECTIONAL GUIDANCE

A. SAMPLE COLLECTION

1. Domestic Samples

Refer to sample collection schedule for sample collection locations and collecting districts.

Each collecting district 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 702 (b) portions 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."

2. Import Samples

Specific sample collection schedules are not provided for 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.
- Grain/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 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.

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 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

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.

RADIONUCLIDES IN FOOD

PART IV – ANALYTICAL GUIDANCE

A. ANALYZING LABORATORIES

The Winchester Engineering and Analytical Center (WEAC) is assigned to 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, When cesium-137 is detected, analyze also for strontium-90.

The analytical methods to be used are as follows:

- 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 Determination of Strontium-90 in Foods by Internal Gas-Flow Proportional Counting, WEAC.RN.Method 2.0.
- WEAC SOP for Analysis of Strontium-90 in Food by Liquid Scintillation Counting, SOP-000450.

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. For results where no regulatory action is anticipated, no hardcopy worksheets are needed.

RADIONUCLIDES IN FOOD

PART V – REGULATORY/ADMINISTRATIVE STRATEGY

For regulatory guidance refer to CPG Section 560.750 - Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14).

RADIONUCLIDES IN FOOD

PART VI – ATTACHMENT AND REFERENCES

REFERENCES

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-RN-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.

FOR GENERAL CONTACTS

See Toxic Elements in Foods, PART VI.

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Radionuclides in Foods

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RADIONUCLIDES IN FOOD

PART VII – CENTER RESPONSIBILITIES

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