CHAPTER 04 – PESTICIDES AND CHEMICAL CONTAMINANTS

SUBJECT:	**IMPLEMENTATION DATE**
PESTICIDES AND INDUSTRIAL CHEMICALS IN DOMESTIC AND IMPORTED FOODS (FY 06/07/08) This program has completed a Good Guidance Practices clearance by CFSAN's ORP and OC/DFP/CPB in August, 2006.	September 5, 2006 **COMPLETION DATE** FIELD: 9/30/06,07,08 CENTER: 9/30/06,07,08

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODES: 02-41; 45-47; 50; 52; 54	REPORT SAMPLE COLLECTIONS/ANALYSIS UNDER THE FOLLOWING PACS: 04004A Pesticides and Industrial Chemicals in Domestic and Imported Foods 04004D Dioxin and furans DO NOT report activities relating to Drug Residues in fish against these PACs. Separate assignments and reporting have been issued for these activities.

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 HARD COPY REPORTS TO HEADQUARTERS

A. End of Year Summary of Accomplishments

Program information is still needed by headquarter units for planning and evaluation of the pesticides. Each district/region is requested to submit a summary report covering their prior year's pesticide plan. This summary will be due October 31 after the conclusion of the fiscal year. Submit the summary to Program Monitor, Kaniz F. Shireen, HFS-636.

The Summary Report should cover the following types of information:

1. A summary of the import and domestic district/regional plan accomplishments including: results of district initiated surveys; a summary of actionable samples; significant State and

State/District joint activities and accomplishments; and other program-related highlights or special issues encountered during the year;

2. Recommendations for improving future regional/district plans and suggested modifications that can be incorporated into the guidance contained in the compliance program; and

3. Other data and information the districts/regions would like to include that relates to their pesticide plan/program and/or the compliance program.

Note: CFSAN's Office of Plant and Dairy Foods produces an annual pesticides report and utilizes detailed data retrieved from FACTS to develop the report. The information requested above is used to supplement the FACTS data and is meant to be narrative, highlighting important activities and accomplishments by individual districts, regions, and the field in general. Specific detailed sample data available in FACTS is not needed in the report.

B. Domestic and Imported Foods:

U.S. Department of Agriculture (USDA)/Agricultural Marketing Service (AMS), which coordinates the Pesticide Data Program (PDP) activities, has agreed that they will provide information on instances in which they have found "Presumptive Tolerance Violations" to the appropriate FDA District Offices for further follow-up by FDA. The PDP contracts states to perform pesticide residue surveys to support Environmental Protection Agency (EPA) tolerance reviews. All districts are requested to report a summary (including sample numbers) of all follow-ups as appropriate based on reporting by USDA/AMS of "Presumptive Tolerance Violations" identified by USDA's Pesticide Data Program to CFSAN, Office of Plant and Dairy Foods HFS-308, Attn: Young Lee.

PART I

BACKGROUND

Pesticides are subject to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). The Environmental Protection Agency (EPA) is responsible under FIFRA for the registration of pesticides and setting tolerances if use of a particular pesticide may result in residues in or on food. The tolerances established by the EPA apply equally to domestic food and to imported food. With the exception of meat and poultry, for which the U.S. Department of Agriculture (USDA) is responsible, FDA is charged with enforcing tolerances in imported and in domestic foods shipped in interstate commerce. FDA also carries out incidence and level monitoring to increase FDA's knowledge about particular pesticide/commodity combinations.

The goal of the monitoring program is to carry out selective monitoring to achieve an adequate level of consumer protection. FDA, therefore, remains committed to developing surveillance data on an ongoing basis. The program is conducted under the general guidance of the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Plant and Dairy Foods. The focus of the monitoring is on the raw agricultural foods of dietary importance (i.e. foods that comprise the greater part of the U.S. diet and can most contribute to pesticide exposure) and foods consumed in large amounts by infants and young children.

A summary and detailed analysis of the residue data obtained from the compliance program are prepared annually by the Office of Plant and Dairy Foods and are made available to the public at CFSAN's website. This information is widely used inside and outside the agency including EPA, USDA, Congress, consumers, etc.

The success of the program is dependent on the attention and support given to it by district's investigation, laboratory, and compliance branches. It is equally important that each district's Pesticide Coordination Team (PCT) be fully utilized for the planning, implementation and ongoing evaluation of components of the program.

PART II

IMPLEMENTATION

OBJECTIVE:

To sample and analyze domestic and imported foods for pesticide residues and industrial chemicals.

PROGRAM MANAGEMENT INSTRUCTIONS

Domestic Foods:

The Agency's approach to this program is regulatory in nature with emphasis on intelligence gathering, selective sampling, and aggressive compliance follow-ups. In addition, this program will maintain surveillance sampling to cover gaps in intelligence information, but emphasize finding residues of significance and taking appropriate follow-up to control the immediate problem and deter future violations.

Based upon the district's past experience, identify farmers or growing areas (including bodies of water) for sampling of products that have been associated with residue problems in the past involving foods of dietary significance.

Imported Foods:

The residue monitoring data developed by this program are important since they provide information on the overall incidence and level of pesticide residues in imported foods. Districts should design their individual import monitoring programs by reviewing the following:

- Available pesticide usage data;
- Data from OASIS or other sources concerning the volume of foods imported from various countries;
- Import Alerts:

  99-05 (Automatic Detention of Raw Agricultural Products for Pesticides)
  http://www.fda.gov/ora/fiars/ora_import_ia9905.html

  99-08 (Detention Without Physical Examination of Processed Foods for Pesticides)
  http://www.fda.gov/ora/fiars/ora_import_ia9908.html

  99-14 (Countrywide Automatic Detention of Raw Agricultural Products for Pesticides)
  http://www.fda.gov/ora/fiars/ora_import_ia9914.html

  99-15 (Countrywide Detention Without Physical Examination of Processed Products for Pesticides)
  http://www.fda.gov/ora/fiars/ora_import_ia9915.html

Pesticide Coordination Team:

See ORA Field Management Directive (FMD) No. 134

The investigator/compliance officer/analyst team should coordinate the district's pesticide and other industrial chemical activities (plan and conduct sample collections and investigations, review FACTS reports, and review data from sources other than the FDA). Report time expended on intelligence gathering activities, such as meeting with state/local officials or gathering data on pesticide usage patterns, as coordination/technical assistance (Operation Code 92). The PCT is encouraged to contact CFSAN Program Coordinator, Young Lee, with suggestions on the conduct of the program.

PART III

INSPECTIONAL

A. GENERAL SAMPLING INSTRUCTIONS

Collect sample commodities of dietary importance identified in Attachment B. Do not sample products such as parsley and spices that have little impact on total dietary intakes. Monitoring of these types of food will be directed by headquarters initiated surveys as needed.

Headquarters-initiated assignments related to emerging problems, or other needs, may be issued during the year.

Note that coverage of pesticide residues in foods consumed by infants and children will again be emphasized. These include apples, apple juice, pears, bananas, carrots, green beans, oats/oatmeal, oranges/orange juice, peaches, peas, rice, potatoes, sweet potatoes, corn and wheat products (e.g., farina). If possible, districts should direct at least 50% each of their imported and domestic pesticide sampling resources toward these products.

In addition, unless specifically approved by Headquarters, do not sample raw agricultural commodities such as green coffee beans or hops that undergo extensive processing which either eliminates or significantly reduces pesticide residues before the final food is ready to eat. FDA monitoring of these types of foods will be in the form of headquarters initiated surveys. Medicinal herb formulations should not be sampled at this time. CFSAN will issue assignments for herb formulations as needed.

Although the emphasis for sampling is on raw agriculture commodities, processed foods should be represented. It is recommended that sampling of such products be limited to those situations where there is suspicion that the food may contain an illegal pesticide residue, which is not authorized for any of the individual ingredients. When sampling processed foods, it would be preferable to emphasize foods consisting primarily of one ingredient.

1. Domestic Sample Collections

Samples may be official or investigational. Compliance samples should be official. Strict adherence to IOM requirements is necessary when sampling products for anticipated compliance actions.

Develop district sampling plans based upon the criteria below:

- Commodities of local origin are preferred for surveillance sampling;
- Base coverage on past violative samples, current analytical findings, information obtained through intelligence gathering activities, and on available current pesticide usage information. Investigations Operations Manual (IOM) subchapter 5.8 provides information concerning pesticide intelligence gathering operations;
- Cover the use of pesticides (particularly fungicides) on crops produced in indoor areas such as greenhouses, hydroponic facilities, and mushroom beds;

- Coordinate with state/EPA offices to cover pesticides applied under experimental or emergency use as warranted. Districts should not ordinarily extend sampling coverage to commodities subject to an experimental use permit;

- Develop information not available from previous years with respect to specific pesticides and commodities; and

- Collect surveillance samples of fruits or vegetables at growers or packing sheds, which are the preferred collection sites for these items. Retail samples can be collected but only if the district is unable to meet its sampling obligation at the preferred collection sites **AND** grower information is known so appropriate follow-up can occur if violations are found.

- Do not collect domestic-import samples to satisfy domestic collection obligation.

Each district should:

- Collect shell eggs, milk and/or cheese samples only if district intelligence indicate there is a pesticide usage problem with these products or if the state lacks a viable pesticide program covering these commodities; and

- Give dairy products that are made from pasteurized milk a higher sampling priority than other dairy items. Collect milk and cheese, if not packaged, in clean quart (standard screw-top ring closure) glass jars. Use special Teflon 70mm diameter lid liners to prevent the jar lid from contaminating the samples. If the Teflon liners are temporarily not available, use double layers of contaminant-free aluminum foil. Lid sealing material must not contact the sample. Ensure that milk samples are refrigerated or frozen, since spoilage adversely affects analysis for some analytes.

Based upon local usage, collect and analyze raw agricultural products for:

- Carbamates with emphasis on aldicarb and carbofuran
- Synthetic pyrethroids
- Benomyl and thiophanate-methyl (where post-harvest application of the Fungicides is indicated)
- EBDCs

Note that if analysis of potentially high residue-containing animal feed components (e.g., apple pomace, cannery wastes) under the Center for Veterinary Medicine's program 7371.003 reveals illegal residues, sample the milk and eggs (if any) from herds/flocks which consumed such feed. Residues of persistent pesticides (e.g., dieldrin, heptachlor) present in food processing by-products utilized in animal feed may result in illegal residues in milk/eggs.

Collect fresh produce samples at the early stages of the harvesting season to facilitate compliance follow-up sampling if pesticide residues of significance are found. Sample the products of various growers unless previous experience suggests the need to resample at a particular grower.

2. Import Sample Collections

The program must be flexible in order that the emphasis of district import coverage can be changed to cover problems identified through the Import Bulletins, Alerts and monitoring results.

Pesticide coverage should be based on available pesticide usage information on the commodity in the country of origin. Because the post-harvest use of pesticides may also result in food pesticide residues, consider monitoring pesticides commonly used during the transportation and storage of imported foods.

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Develop sampling plans based on the criteria below:

- Attempt to sample a commodity from all countries offering that particular emphasized product for entry into the district's entry points;
- Imported foods found in the previous season to contain pesticide residues of significance must be sampled in the subsequent year to make certain that the violation is not being repeated;
- Collect samples from those countries for which there is little or no information from previous years sampling activities; and
- Other criteria deemed appropriate by the collecting district.

3. Seafood Sample Collections

a. Domestic Seafood:

All Districts assigned specific seafood collections in the current ORA Field Workplan should collect # samples of fish and/or shellfish locally produced (as close to their origin as possible) of commercial significance. Locally produced seafood, especially non-migratory bottom feeders that may be affected by local pollution, should be targeted. Species harvested close to shore, pollution sources, prior problems, or areas where states have issued advisories due to pesticide pollution, should also be considered. In addition, locally produced shellfish should also be targeted.

The following should be used as additional considerations:

- Choose fresh fish, if available;
- Do not maintain the identity of individual subs of fresh or frozen whole fish;

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b. Imported Seafood:

The seafood sampling results since 1993 shows that measurable pesticide residues are most prevalent in fresh water fish from # (particularly perch yellow, pickerel, lake trout, and whitefish). On the other hand, there is a near total absence of measurable pesticide residues in many ocean fish

species (e.g., sea bass, cod, flounder, fluke, grouper, halibut, ocean perch, pollock, snapper, sole, swordfish, tuna, and whiting) as well as farm raised shrimp from many countries and salmon from #. As a result of this review, districts should sample and analyze the following seafood products for pesticides and PCBs:

- Fresh water species from #, which may have originated from the # (including chubs, perch yellow, lake trout, pike, salmon, whitefish and lake carp);
- Fresh/frozen salmon from #;
- Fresh/frozen aquaculture tilapia, catfish and crayfish;
- Fresh/frozen fresh water species from any country (e.g., catfish, nile perch, basa);
- Shellfish and crustacean; and
- Ocean fish, if specific concerns exist about contamination.

NOTE: When possible, greater priority should be given to collecting samples of import seafood products originating from aquaculture sources. #

B. SAMPLE SIZE/HANDLING (DOMESTIC AND IMPORT)

IOM Sample Schedule Chart 3 lists minimum sample sizes. Refer to IOM subchapter 4.5 for sample handling details.

NOTE: Districts have the option to collect 1 intact shipping case or a total of 20 lbs. from one or more large containers of fresh produce from packing sheds or large produce warehouses. This "one case" option may be used on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the sample as indicated in IOM Sample Schedule Chart 3. This “one case” sampling does not apply to large items such as melons.

If “one case” option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

All surveillance samples of fresh imported produce, except grapes for sulfites, should consist of one case, bag, bale, box, etc.

Collect samples in the container in which the dealer is packaging the product. If no packaging is done, use paper bags, boxes, etc. Clean plastic bags should be used if samples are to be analyzed for metals.

NOTE: Fresh produce samples decompose quickly in plastic bags under warm and hot ambient conditions. Do not use plastic bags for packaging fresh produce samples. Ship the more perishable products (i.e. berries) in a cooler with a cooling agent (i.e. ice packs).

DO NOT maintain the identity of individual subs for other surveillance or compliance samples except when samples are collected from crops growing in the field to document pesticide drift.

C. SAMPLE SHIPMENT (DOMESTIC AND IMPORT)

Submit samples to your Pesticide Servicing Lab except where otherwise instructed in Part IV. Refer to IOM subchapter 4.5.5 for sample shipment details.

Be sure to annotate in the "Remarks Section" of the collection report (CR), the specific pesticide(s) for which the sample is to be analyzed as indicated in the assignment, special survey, or compliance program.

Samples collected under this program, which are related to a particular incident, grower, etc. are to be identified with an episode number. Refer to IOM Section 4.4.10.1.8 for additional guidance.

D. GENERAL REPORTING

Report resources utilized for pesticides into the FACTS as appropriate using the following Problem Area Flags (PAF) and PACs:

PAC	PAF	PAF Description
04004A	PES	Pesticide analysis
04004D	DIO	Dioxin analysis

Note: PAC 04016 is no longer to be used for import pesticide samples; it has been deactivated for FY 03 and beyond. Use PAC 04004A for all general domestic and import pesticide samples.

Flag "Sample Basis" in FACTS either "Pesticide Surveillance" or "Pesticide Compliance".

Surveillance Sampling: "Pesticide Surveillance" samples are collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. All routine sampling should be flagged as surveillance samples.

Compliance Sampling: "Pesticide Compliance" samples are collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a pesticide "Surveillance Sample" that was found to contain actionable levels of pesticides residues. Compliance samples are considered to be "for cause" samples for purpose of CFSAN data evaluation.

Reporting Instructions for Domestic Foods:

- List names and address of the grower/processor if different from the shipper;
- Report information regarding which crops were grown and pesticides used in fields adjacent to the field, which produced the sampled food;
- For selective samples collected from crops growing in the field only to document drift, diagram the field location of each sub on the FDA-464 or FDA-464a form;
- For compliance samples collected because of suspected industrial chemical contaminants, report where the commodity was produced with respect to the

suspected contaminant source. It is imperative that the FDA-464 lists what chemicals or chemical classes are suspected;

- When assigned to collect a soil sample, report what pesticides or other chemical contaminants are suspected. DO NOT routinely collect soil samples;

- In accordance with Field Management Directive No. 129 (based on an MOU between FDA and EPA), FDA districts are to notify the EPA regional offices when FDA investigations or sample analyses reveal pesticide misuse. For this reason, consider the need to collect additional samples or other evidence documenting pesticide misuses when violative residues are encountered. Include information concerning whether misuse has occurred or the potential for drift exists in the "Remarks" section of the FDA-464; and

- Report episode number. Refer to IOM, Section 4.4.10.1.8 for additional information.

Reporting Instructions for Imported Foods:

Time expended on the following activities should be reported as Operation 14, Import Investigation:

- Developing, coordinating, and monitoring district or regional import plans;

- Use of intelligence concerning foreign pesticide usage information;

- Examining import records (entry review);

- Investigation of shipping/warehousing/handling practices to uncover potential routes of contamination; and

- Contact with U.S. Customs Agents, USDA/APHIS (PPQ-280's and imported commodities forecast), commodity brokers, shippers, and importers.

PART IV

ANALYTICAL

Domestic and Imported Foods

Analyzing Laboratories

- See Part I, APPENDIX III of the current ORA Workplan for a listing of Servicing Laboratories;
- See Part I, APPENDIX III of the current ORA Workplan for a listing of Servicing Laboratories except for MA Region – NRL, MW Region – ARL; and
- Carbamates: See Part I, APPENDIX III of the current ORA Workplan for a listing of Servicing Laboratories.

A. Procedural Requirements

1. All analytical packages to support significant residue findings, samples must meet the "Criteria for Analytical Packages to Support Regulatory Action on Pesticide Residues" (For detail information, please see http://web.ora.fda.gov/dfs/programs/pesticides/)

2. In the initial stages of product/area coverage, examine pesticide surveillance samples for as many classes of chemicals as is practicable. At a minimum, examine the sample for organohalogen and organophosphorus residues. Consider using two or more multiresidue and single residue methods to provide broader coverage for pesticide residues.

3. Analyze samples for chemicals applied under emergency exemptions, as appropriate.

4. For the pesticides listed in Attachment D, "Pesticide Reanalysis Criteria," a finding by multiresidue methodology at or above the specified percentage of the tolerance requires reanalysis by a method (such as PAM II) for "total" residues or for complete recoveries.

5. Prepare and analyze raw agricultural commodities on a whole product basis except where impractical (e.g., removal of pits or stones from fruits). Follow the "raw agricultural commodity" definitions and guidance in PAM I, 102. Conduct analyses as soon after collection as practical to minimize the potential for residue deterioration and loss.

6. Use the list of pesticide chemicals subject to Codex maximum residue limits (MRLs), (“international tolerances”), and the Canadian Compilation of MRLs as guide to possible residues on import products.

7. Refer to PAM I, 3rd Edition, for all PAM references. Multi-residue methods should continue to be used for the majority of pesticide samples. Single residue methods (e.g., PAM II, Laboratory Information Bulletins, and other suitable methods), however, must be used when a food is suspected of containing a pesticide not detectable by multi-residue methods or for selective surveys.

B. Methodology

In cases involving a residue level exceeding an official tolerance (40CFR180), an official method must be used for sample analysis when available and appropriate for both the commodity and residue. Methods in Official Methods of Analysis of the AOAC International and Pesticide Analytical Manual, Volumes I & II are official.

Link to PAM: http://www.cfsan.fda.gov/~frf/pami3.html.

1. Organohalogen, Organophosphorus & PCB Residues

When multi-residue GLC methods are used, determine the pesticides and PCB residues by GLC with element and mass selective detection, refer to PAM I, 302 for determination. Refer to PAM I, 105 for determining limits of quantitation for pesticides and PCBs.

(a) Use PAM I, 302 for fresh fruits and vegetables.

(b) Use PAM I, 303 E3 or 302 E4 for low moisture-low fat products.

(c) For fish and shellfish samples, refer to PAM I, 303 and 304. Report residue findings in finfish and mollusks on the edible portion basis. Residue findings in prawns/shrimp should be reported on the whole product basis.

(d) Evaluate chromatograms of all samples for PCBs and pesticides. If presence of PCBs is indicated, complete analysis using the necessary treatment of extract prior to GLC determination. See PAM I, 304 C3 or C4.

(e) Analyze all milk, milk products, and shell eggs for chlorinated hydrocarbons using PAM I, 304.

2. Carbamate Residues

Carbamate residues amenable to gas chromatography can be determined by PAM I, 302 (PAM I, 302 DG4, DG5, and DG17. PAM I tables 302a and 302b lists compounds recovered by these methods.

N-methylcarbamate residues in fruit and vegetable samples may be determined by the PAM I, 401, or 302 (E1-E3 plus C3 or C4 and DL1)

N-methylcarbamate analyses must be conducted on a minimum of 10% of all fresh fruits and vegetables and on 25-50% of all potato/sweet potato and Florida citrus samples.

3. Benomyl and Thiophanate-methyl

Where application on fruits/vegetables is indicated, analyze for the common degradate, carbendazim (methyl 2-benzimidazole carbamate) using PAM I, 404. Consider coverage of produce for post-harvest application of benomyl.

4. Malathion

   Examine grains, peanuts and soybeans using the 50% Florisil elution or elute 3 described in PAM I, 303 C1 or C2 when section 303 extractions and cleanup methods are used.

5. Ethylenebisdithiocarbamates (EBDCs) and Ethylenethiourea (ETU)

   Analyze for EBDCs using JAOAC 54, 528 (1977) (CS2 evolution method), and for ETU using JAOAC 72, 975 (1989).

   When residues of EBDCs exceed an established tolerance, in addition to the check analysis, the laboratory must determine the presence of ETU. Other permitted dithiocarbamates may be erroneously reported as EBDCs without an ETU confirmation.

6. Phenylurea Herbicides

   Use PAM I, 403.

7. Sulfite Residues (Grapes)

   Appropriate screening techniques may be used to determine residual sulfites. However, since all screening techniques may not give results equivalent to the Modified Monier-Williams method, contact the ORA scientific contact for approval before use.

   Conduct check analysis on any samples containing 10 ppm sulfur dioxide or greater using the Modified Monier-Williams method, Fed. Reg., Vol 51, No. 131, p. 25017-20, dated 7/9/86, except DO NOT BLEND GRAPES.

C. Lab Classification/Data Reporting

Some confusion concerning classification of pesticide samples has existed in the past. Be guided by the examples below for pesticides and PCBs.

Lab Class "1": The sample contains no residue or contains residues that are within the limits of an established tolerance or guideline.

Lab Class "2": The sample contains a confirmed residue for which no tolerance or guideline in the sampled food has been established, but the residue level is such that it requires no follow-up (e.g. residue found at trace level).

Lab Class "3": The sample contains a confirmed residue that exceeds a tolerance or guideline or contains a residue at a significant level for which no tolerance in the sample food has been established.

NOTE: For samples coded as Class 3, each residue meeting the criteria for Lab Class 3 must have the appropriate code entered into the violative residue field (i.e., "X" for exceeds tolerance, "N" for no tolerance, or "A" for at or above action level). The code must be entered into the data records for both the original and check analyses.

For samples analyzed under a special emphasis survey, the residue code for each pesticide of interest in the survey must be entered, regardless of whether or not the pesticide was found.

Samples which contain other industrial chemical contaminants (confirmed) above the trace level should be coded "2".

Report all analytical results for pesticides and industrial chemicals in imported and domestic foods into the FACTS as appropriate using the following Problem Area Flags (PAF) and PACs:

PAC	PAF	PAF Description
04004A	PES	Pesticide analysis
04004D	DIO	Dioxin analysis

NOTE: PAC 04016, previously used for pesticides and industrial chemicals in imported foods has been deactivated for FY 03 and beyond.

PART V

REGULATORY/ADMINISTRATIVE STRATEGY

The published Compliance Policy Guide (CPG) 7141.01, section 575.100, which outlines FDA's enforcement policy for pesticides in human foods and animal feeds, is currently under revision (August, 2006) to reflect the amendments in the Food Quality Protection Act (FQPA). For detailed information on the following issues, review the revised CPG, when issued:

A. "Channels of Trade" Provision
B. Charge for Illegal Pesticides in Food
C. Section 18 of FIFRA
D. Unavoidable Pesticide Chemical Residues

Direct Reference Authority for Regulatory Actions:

Districts have direct reference authority for seizure in cases of domestic foods, and detention and the corresponding detention without physical examination (DWPE) in cases of imported foods, without prior consultation from CFSAN, when the required criteria are met. The criteria for direct reference authority for regulatory actions involving pesticide residue violations are in Attachment E. Please refer to this document for specific information when processing enforcement actions for domestic and imported foods.

Domestic Foods:

The most effective way to remove food adulterated with pesticides from domestic channels has been through voluntary recalls. Where voluntary corrective actions are not effective, consider seizure if there is a seizable size lot under embargo or voluntary hold. Otherwise, the District should consider follow-up on each sample classified as "Lab Class 3", either by meeting with the grower/shipper to discuss corrective action, or considering issuing of a Warning Letter.

Preliminary injunctions should be considered only as a last resort because the time required to process such cases usually exceeds the shelf life of the product. Consider injunctions only when the firm has a large inventory of the adulterated food for sale over a few months.

> **NOTE**: Compliance Achievement Reporting System (CARS) should be updated if the firm voluntarily corrects the problem.

Immediately notify the regional EPA office when investigation reveals possible misuse of pesticides. See Memorandum of Understanding, CPG 7155b.04 and FMD 129.

The final disposition of each violative shipment and the action taken **MUST BE REPORTED** on the compliance screen in FACTS for all Lab Class 3 samples.

Imported Foods:

Recommendations for detention and detention without physical examination involving pesticide residues should be forwarded to CFSAN's Division of Enforcement, Import Branch, HFS-606 and DIOP, HFC-172. The recommendations should be made using the form provided as Attachment F.

PART VI

ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTS

ATTACHMENTS

Attachment A - FDA-State Cooperation in the Pesticides and Chemical Contaminants Program

Attachment B - Domestic and Imported Foods for FDA Monitoring

Attachment C - Destination Point Sampling

Attachment D - Pesticide Reanalysis Criteria

Attachment E - Criteria for Direct Reference Seizure or Detention Involving Pesticide Residues

Attachment F – Recommendation for Detention Without Physical Examination

Attachment G - Dioxin, Furans and PCBs in Food

REFERENCES

1. USDA, Weekly Summary Shipments-Unloads, Fresh Fruit and Vegetable Market News.

2. USDA, Usual Planting and Harvesting Dates for Fresh Market and Processing Vegetables (Agriculture Handbook No. 507).

3. USDA, Pesticide Review.

4. USDA, Domestic Pesticide Usage Data (NASS)

5. Code of Federal Regulations, Title 40, Part 180 and 185.

6. Investigations Operations Manual, Sample Schedule

7. Regulatory Procedures Manual

8. Compliance Policy Guide 7141.01

9. Pesticide Analytical Manual, Volume I & II (http://www.cfsan.fda.gov/~frf/pami3.html)

CONTACTS

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Imported Food Regulatory Action Inquiries:	Standra Purnell, Division of Enforcement, Import Branch, HFS-606, Phone: 301-436-1613, Fax: 301-436-2657. Email: standra.purnell@fda.hhs.gov
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Data Input Inquiries:	Judy Lee, Division of Field Program, HFS-615, Phone: 301-436-2063 Email: judy.lee@fda.hhs.gov

PART VII

CENTER RESPONSIBILITIES

The Office of Plant and Dairy Foods will prepare an annual report for publication of the findings of this program.

The Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine have designated individuals to coordinate exchange of residue data and other appropriate information, since residue findings in feeds and in foods derived from animals is often interrelated.

FDA-STATE COOPERATION IN THE PESTICIDES AND CHEMICAL CONTAMINANTS PROGRAMS

PURPOSE

To provide guidance to FDA field offices for the establishment of cooperative FDA-State pesticides and chemical contaminants programs. Such programs enhance FDA and state monitoring and enforcement activities, achieve optimal coverage of human foods and animal feeds, and provide for the most efficient use of available resources.

BACKGROUND

The FDA has a long history of cooperation with state agencies on a variety of food and feed safety issues. As part of this relationship, we routinely share information and are involved in cooperative programs or partnerships with states in the area of pesticide and other chemical residues in food and feeds. This guidance provides the groundwork for each district to establish FDA/State cooperative programs or partnerships.

APPROACH

This document provides a fairly comprehensive matrix for FDA/State cooperative programs or partnerships in the pesticide area, including a step-by-step procedure from initial contact with State agencies through actual joint planning, work sharing, and data exchanging. While all field offices have progressed beyond the initial stages, it is useful to periodically consider whether some of the first steps need repeating as personnel turnover occurs.

It is imperative that FDA districts establish and maintain close, mutually beneficial working relationships with their state counterparts. Viable, comprehensive FDA/State cooperative programs or partnerships should be the goal for each district. At the very least, districts should establish with each State within district boundaries, a system of communication and information exchange on domestic food monitoring and, if appropriate, imported foods

A. General

1. Make contact with agencies or organizations in a state that are involved in monitoring food and/or feed commodities for pesticides and industrial chemicals or regulate pesticides or industrial chemicals. These state agencies or organizations may include: health, environmental protection, agriculture, fisheries and university or college extension services.

2. Obtain information on each agency's responsibilities regarding pesticides and industrial chemicals and their applicable state laws and regulations. Describe the FDA's responsibility and how a cooperative program can benefit all organizations and ultimately improve consumer protection.

3. Follow-up meetings and contacts should be scheduled to formulate the program with those state agencies that have expressed an interest in this cooperative effort. It may be appropriate at this point to include regional EPA and USDA personnel in these meetings.

4. Prepare a listing of contact persons from each of these involved agencies and the FDA that include address, work and home telephone numbers. Copy all agencies.

5. Use meetings, newsletters and committees of AFDO regional associations, (e.g., CASA and AFDOSS), and AAFCO, to publicize FDA/State cooperative programs or partnerships and to encourage participation of states not yet involved. Seminars, workshops and committees of these associations can be effective tools for information and data sharing, laboratory methods discussions, etc.

6. Request and acquire pesticide usage reports from state contacts.

7. Provide assistance as may be requested by state and USDA personnel who are participating in the recently initiated USDA Pesticide Data Program (PDP).

B. Joint Planning

1. Schedule at least one planning meeting annually with the involved agencies. The following information should be considered each year in formulating FDA/State monitoring of domestically produced foods and feeds:

    a. Pesticide usage information, both historic and recommendations for the coming year, including possible experimental uses and emergency exemptions (county extension offices may be a useful source of this information);

    b. Predicted insect and other pest problems;

    c. Crop production data, including approximate harvest times;

    d. How to handle specific types of operations, e.g., hot house and hydroponic facilities, aquaculture, etc.;

    e. Landfills and hazardous waste sites that may affect crops, foods;

    f. Animal grazing areas or commercial fishing or other FDA regulated operation;

    f. Special surveys to be done by the state and/or FDA;

    g. Coordination with State/USDA programs; and

    h. Seafood consumption advisories.

2. Utilize joint planning for maximum coverage of commodities (i.e. foods and feeds for food producing animals) and pesticides. Do not ignore foods or feeds that have not had a past problem. Consider both short and long-term planning to assure comprehensive coverage.

3. Ensure that sampling procedures and analytical methods are as consistent as feasible. A laboratory quality assurance program is an excellent way to assure consistency among laboratories. This can be accomplished by agreeing to split one or more samples collected

each year for analysis by different laboratories using the same method. Joint FDA and state sampling can be one method to obtain consistency in sampling procedures.

4. Use imaginative approaches to make the best use of available state and FDA resources. For example, states that do not have laboratory facilities to analyze samples of food or feed may be willing to collect samples for FDA analysis with the results shared with those states. Or, state labs may have the capability of conducting certain types of pesticide analyses but not others. In this situation analytical work could be shared.

5. An FDA district/state-sampling plan should be formulated using all available information and incorporating all aspects of agreed upon cooperation. This plan should be in writing and include the reason behind the selection of foods or feeds for sampling.

6. Establish a system for exchange of information during the year such as information on violative samples (including actions taken), periodic feedback on non-violative results, new regulations or policies, emergency situations, i.e., drift reports, spills, etc.

C. Program Monitoring and Coordination

The district's pesticide coordination team (PCT) (described in Field Management Directive 134) serves as the focal point for the district's pesticide sampling and analytical activities, including primary contact with state, county and local government agencies.

The pesticide coordination team should be responsible for the day-to-day monitoring and coordination for the district's FDA/state pesticide sampling cooperative program. This responsibility may include but is not limited to the following:

1. Ensuring that the joint sampling plan is being followed or appropriate revisions are being made;

2. If changes are made in the sampling plan, assuring that the changes are justified and have been discussed with cooperating state agencies;

3. Coordinating follow up investigations to samples with significant residue findings.

4. Tracking accomplishments, including analytical and inspection results, compliance and other activities;

5. Planning and scheduling meetings as necessary;

6. Coordinating training; and

7. Providing the region with district/state sampling plan information.

D. Compliance Activities

Regulatory activities of each agency will be in accordance with each agency's statutory authority and regulatory policies. Actions taken by one agency do not preclude another agency from taking action. The following items should be considered:

1. If possible and appropriate, establishes a system whereby inspection and/or analytical results can be used to eliminate or minimize duplicative efforts;

2. Establish a system that provides for the immediate notification of cooperating agencies when a sample is found to contain residues of significance. Coordinate follow-ups to remove the commodity from the market, determine if other shipments or food or feed producers are affected, and obtain evidence for possible action against the producer;

   The USDA/State Pesticide Data Program includes a mechanism, which notifies FDA districts when violative samples are found. Districts should make arrangements with states participating in this program (currently 6 – 10 states) to receive such information in a timely manner;

3. Regulatory action will not always be available to the FDA because of lack of interstate movement or some other reason. However, action can often be taken by state agencies; and

4. Keep in mind that there may be agencies other than a state health or agricultural department that can take an appropriate action (e.g., a state agency that regulates pesticides has the authority to fine producers or remove a pesticide applicator's license).

In addition to FDA and state regulatory action, alternative means to promote compliance should be considered using the cooperative program.

The following examples can be used to, among other things, inform growers and applicators of the FDA/state regulatory action taken against violators:

1. Bulletin or newsletter issued by state agriculture agencies or county agents;

2. Training sessions given by extension services; and

3. Food and feed producer meetings.

E. Training

Cooperative training programs have a number of benefits and should be considered as a part of the overall cooperative FDA/state programs. When necessary and resources and personnel are available, training can be given or received by the FDA or state personnel such as:

1. Training courses on pesticides and industrial chemicals;

2. Sampling and inspection procedures; and

3. Methods of analysis and laboratory techniques.

The FDA's Division of Human Resource Development (DHRD) can conduct training identified in the annual training need survey. The FDA regional or district offices and the states through the regional affiliates of AFDO or AAFCO may meet other training needs through development of local courses.

F. Data Exchanges

1. In those cases where states log their program findings by computer, the states should be encouraged to have compatible information fields with the FDA's data fields so that data can be extracted from one system and coded into another.

2. FDA and state analytical data should be freely exchanged among cooperating agencies on a routine basis.

3. Actions taken by the FDA or a state as follow-up to a violative sample must be tracked and recorded under the Shipment Disposition Data System.

DOMESTIC AND IMPORTED FOODS FOR FDA MONITORING

Except when advised otherwise by headquarters, the FDA's sampling of domestic and imported foods for pesticide residues on a surveillance basis should be directed toward the following food commodities list (list is not in priority order), which may be in either the raw or processed form:

Root and Tuber Vegetables:	beets (garden and sugar), carrots, potatoes, radishes, sweet potatoes, yams, rutabagas, turnips, artichokes and cassava (bitter or sweet).
Bulb Vegetables:	onions, green onions and leeks.
Leaf, stem & Vegetables:	celery, lettuce (all varieties), cress, endive, spinach and asparagus.
Brassica Vegetables:	broccoli, Brussels sprouts, cabbage, cauliflower, collards, mustard greens and kale.
Legume Vegetables:	succulent and dried form of beans and peas (all varieties).
Fruiting Vegetables:	eggplant, peppers, okra, tomatillos and tomatoes.
Cucurbit Vegetables:	cucumbers, pumpkins, squash (summer and winter).
Citrus Fruits:	grapefruit, lemons, limes, oranges, tangeloes, clementines and tangerines.
Pome fruits:	apples, pears.
Stone Fruits:	apricots, cherries (sweet and sour), nectarines, peaches, plums, and prunes.
Small Fruits and Berries:	blackberries, blueberries, boysenberries, cranberries, grapes, raspberries, and strawberries.
Tropical/Subtropical Fruits:	avocadoes, mangoes, olives, pineapples, papayas, guavas, bananas, kiwi fruit.
Vine Fruits (melons):	cantaloupes, honeydew melons, muskmelons, watermelon and others.
Tree Nuts:	almonds, pecans, and walnuts (black and English), pistachios, peanuts, cashews. (Analyze primarily for post harvest fumigants).
Cereal Grains:	barley, corn, oats, rice, wheat, rye, wild rice, and farina.
Oilseeds:	soybeans, peanuts and cottonseed.

Refined Vegetable Oils:	shipped in bulk and examined primarily for industrial chemicals due to contamination during transit.
Fish and Shellfish:	locally produced of commercial significance including aquaculture species (see Part III, Page 4) plus Gulf Coast finfish, Sand Sea trout, Silver Sea trout, Spot, Gulf Coast crabs, Chesapeake finfish (Striped Bass and Spotted Sea trout), California marine species (Cod, Sablefish and Rockfish-sebastes species), and Great Lakes finfish.
Aquaculture Products:	commercially significant species (e.g., Catfish, Crawfish, Trout) from aquaculture producers throughout the district's geographical area.
Milk Products:	milk, cheese, dried milk, dried whey.
Miscellaneous:	mushrooms

DESTINATION POINT SAMPLING

These procedures are designed to insure the effective and efficient handling of regulatory actions against foods bearing illegal pesticide residues that may degrade rapidly. "Destination point sampling" is not required for pesticide residues for which there is no tolerance or when misuse is documented. (These procedures apply only when the origin district collects the official sample that is used as the basis for the seizure recommendation.)

The originating district is responsible for recommending the seizure action to Chief, Domestic Branch (DB), HFS-607, and for alerting DB when the recommendation is being prepared for submission. Where DB assistance is required other than during normal working hours, contact DB as indicated in the emergency procedures.

Once the originating district decides to recommend seizure, they will request the destination point district to collect and analyze a sample of the lot to corroborate the original findings while the seizure recommendation is being processed.

Seizure recommendations should include all the necessary documents, such as the investigational findings and a complete analytical package for the official sample collected at the origin.

DB will process the seizure recommendation and transmit the seizure documents to the Office of Enforcement (HFC-200) if tentative approval is granted. The tentative approval will be conveyed by telephone. HFC-200 and OCC will process the seizure recommendation on the basis of the tentative approval. The seizure will be transmitted to the destination district for filing after DB grants final approval, which will be based on analytical results, obtained for the destination sample.

The servicing laboratory for the destination point district is responsible for conducting a single analysis (no check analysis necessary) to corroborate the initial findings and for providing the analytical results directly to DB, first by telephone, and then by submission of the analytical package for Center review.

DB will notify the destination and originating districts and HFC-200 of the final decision based on the analytical results for the destination point sample.

PESTICIDE REANALYSIS CRITERIA

A. For various reasons, certain pesticides are only partially recovered using commonly employed multiresidue methodology. As a general guideline, when the residue level determined by the multiresidue method exceeds # of the tolerance level, the sample should be reanalyzed using alternate elution systems, higher or lower column temperatures or other methods such as those in PAM II, which give acceptable recoveries.

Because of their frequent occurrence, or toxicological concern, the above guideline applies particularly to the following pesticides:

PAM I Methods Used Initially	Pesticide
303, 304	linuron dicloran methidathion
304	dialifor hexacholorobenzene (HCB)
303	captafol chlorothalonil chlorobenzilate
302	methamidophos

B. Metabolites of the following pesticides are of significant toxicological concern, are expected to constitute major portions of the total residues covered by the tolerance, and are only partially recovered (or are not recovered) by commonly used multiresidue methodology. Perform reanalysis by a method for "total residues" such as that given in PAM II whenever the pesticide or any one of its metabolites is found at the indicated percentage of tolerance. (This list is restricted to those pesticides of most concern, and does not include all pesticides posing the problem of incomplete determination of regulated metabolites.)

Pesticide	Metabolites	#
pronamide	those which can be converted to methyl-3,5 dichlorobenzoate using acid reflux	#
phorate	sulfoxide; sulfone; O-analog; O-analog sulfoxide; O-analog sulfone	#
disulfoton	sulfoxide; sulfone; demeton-S (O-analog of disulfoton); demeton-S sulfoxide; demeton-S sulfone	#

Pesticide	Metabolites	#
demeton	-O sulfoxide; demeton-O sulfone; demeton-O; O-analog; demeton-S sulfoxide; demeton-S sulfone	#
fenamiphos	sulfoxide; sulfone	#
terbufos	sulfoxide; sulfone; O-analog; O-analog sulfoxide; O-analog sulfone	#
nitrofen	metabolites containing the diphenylether moiety	#
alachlor	metabolites containing the 2,6-diethylaniline moiety	#
diuron	those which can be converted to 3,4-dichloroaniline by alkaline hydrolysis	#
linuron	those which can be converted to 3,4-dichloroaniline by alkaline hydrolysis	#

U.S. registration of nitrofen has been canceled. Foreign use is believed to be still extensive.

CRITERIA FOR DIRECT REFERENCE SEIZURE OR DETENTION INVOLVING PESTICIDE RESIDUES

Districts have direct reference authority for seizure in cases of domestic foods, and detention and the corresponding detention without physical examination (DWPE) in cases of imported foods, without prior consultation from CFSAN, when the following required criteria are met.

Note: Direct Reference Authority does not apply to cases based on "Action Levels". Action Levels represent levels at which FDA will consider whether it should exercise enforcement discretion. All domestic and import regulatory actions based on Action Levels must be submitted to CFSAN, Division of Enforcement, for review and concurrence consideration.

A. General Requirements

1. The sample of food was collected in accordance with all instructions provided in the Investigations Operations Manual, Sample Schedule, Chart 3; or other CFSAN guidance documents, i.e. assignment/Compliance Programs (CP).

2. The portion of food commodity analyzed was in accordance with PAM I.

3. A confirmatory or check analysis of a second test portion that demonstrates the presence of the residue of interest was performed.

4. In cases involving a residue level exceeding an official tolerance (40CFR180), an official method must be used for either the original or check analysis when available and appropriate for both the commodity and residue. Methods in Official Methods of Analysis of the AOAC International and Pesticide Analytical Manual, Volumes I & II are official. Miniaturized versions of these methods are considered equivalent to the official version.

   In cases where a residue is present for which there is no established tolerance, a non-official method may be used. However, use of an official method is preferred.

5. In situations, where the pesticide residue exceeds a tolerance, the residue amount determined in both the original and check analyses agree within 30%.

6. The pesticide residue was measured and the level was calculated in accordance with the residue expression (the appropriate parent compounds and metabolites) found at the applicable tolerance regulation or action level citation in the CPG.

7. The amount was calculated following the calculation criteria specified in PAM.

8. The analytical work and work sheets must conform to the Criteria for Analytical Packages outlined in attachment F.

9. The district must provide CFSAN's Division of Enforcement, Domestic Branch (HFS-607, with a copy of each direct reference Warning Letter as it issues and courtesy copies of seizure documents for all direct reference cases as they are recommended to OCC. In cases of

imported products, the district must provide CFSAN's Import Branch (HFS-606) with a copy of recommendation for Detention Without Physical Examination Pesticide Sample Worksheet (see Attachment F) for all direct reference import cases as soon as action is taken.

B. Tolerance Exists for a Particular Pesticide/Commodity Combination.

In addition to the General Requirements, a direct reference is authorized only when the lower of the residue amounts determined by either the original or check analysis exceed the established tolerance by a least 15%.

NOTE: For cases where a tolerance is exceeded, but the criteria for direct reference seizure authority has not been met, e.g., a finding less than 15% above the tolerance refer the case to Division of Enforcement, Domestic Branch for consultation and approval. Enclose the complete analytical worksheets and other pertinent documentation.

Recommendation for detention without physical examination due to pesticide residues for which there is an established tolerance should be submitted directly to DIOP.

C. No Tolerance, Tolerance Exemption, Emergency Exemption Exists

1. Direct reference is authorized only when the districts make the following determinations:

   - Determine whether the food belongs to a particular crop grouping (refer to Title 40 CFR 180.1, 180.34 and 180.41).

   - The district must also determine that no Section 18 tolerance is in effect for the use of the pesticide (see http://www.epa.gov/opprd001/section18/) in the food. If a Section 18 tolerance is or has been in effect, and the residue found exceeds EPA's tolerance, refer the case to Division of Enforcement, Domestic Branch.

   Cases for imported products that have a pesticide residue detected and there is no tolerance, tolerance exemption, or Section 18 tolerance, the complete analytical package shall be forwarded to Division of Enforcement, Imports Branch for review when the level of residue detected is below **0.05 ppm**.

2. In cases where there is no tolerance for the residue, the level must equal or exceed the limit of quantitation (Lq) of the target pesticide. Quantitation of the residue in the confirmatory analysis is not required. The limit of quantitation must be determined in accordance with PAM I. As stated in the "General Requirements" a confirmatory analysis must be performed to demonstrate the identity of the residue of interest.

   NOTE: For cases where the residue is not covered by a tolerance or tolerance exemption, but the criteria for direct reference seizure has not been met, refer the case to Division of Enforcement, Domestic Branch for consultation and approval. Include the complete analytical worksheets and other pertinent documentation.

RECOMMENDATION FOR DETENTION WITHOUT PHYSICAL EXAMINATION

DATE: _____

FROM: District/Mail Code_____

Case Contact _____

Phone _____ FAX_____

TO:Chief, Import Branch, DOEP (HFS-606), FAX # (301) 436-2657

Pesticide Monitor, DIOP (HFC-170), FAX #(301) 594-0413

SUBJECT: Recommendation for Detention Without Physical Examination

____ Import Alert 99-05, (Raw Agricultural Products)

____ Import Alert 99-08, (Processed Foods)

_____ This recommendation is being sent to CFSAN for concurrence OR

_____ This sample meets the criteria for direct reference

Sample Number: _____ Entry Number: _____

Product:_____ Product Code:_____

Grower/Shipper: _____

Street Address:_____

City:_____ Country:_____

FEI #:_____

Pesticide(s):_____

Findings: _____pm original analysis _____ppm check analysis

_____exceeds tolerance OR _____no tolerance

Analyzing Lab:_____

_____

CFSAN/DIVISION OF ENFORCEMENT AND PROGRAMS DECISION

Note: CFSAN decision is not required for direct reference actions

_____ Approved _____ Disapproved

DOE Signature_____

Date DIOP notified_____

DIOXIN, FURANS AND PCBS IN FOOD

OBJECTIVE:

To obtain more comprehensive data on background levels of dioxin in a wide variety of foods so that the Agency can more accurately estimate dioxin exposure and better determine how to reduce dietary dioxin levels to protect the public health.

BACKGROUND:

Environmental dioxins occur in many animal foods and feeds. Because dioxins accumulate in food-producing animals, consumption of animal-derived foods (e.g., meat, poultry, eggs, fish, dairy products) is considered to be the major route of human exposure. The U.S. Food and Drug Administration (FDA) has been concerned about dioxins in foods for more than 30 years and has been monitoring certain foods with the goal of identifying ways to reduce dietary exposure.

In the past, the FDA's monitoring program for dioxins (a group of compounds known as dioxins/furans/coplanar polychlorinated biphenyls or PCBs) has consisted of determining background levels in certain foods. These foods have been identified as potential pathways of dietary dioxins. The FDA has also investigated individual events of unusual levels of dioxins, such as ball-clay, with naturally high levels of dioxin used as a feed ingredient. Because dioxin analysis is costly and time consuming, data on background levels in foods are limited. For many foods, the Agency has no data. With limited data, it has been difficult to determine how dioxin levels in foods can be further reduced. The purpose of the dioxin-monitoring program is to obtain more comprehensive data on background levels of dioxin in a wide variety of foods so that the Agency can more accurately estimate exposure and better determine how to reduce dietary dioxin levels to protect the public health. The FDA will use the data on background levels to:

1. Identify unusual levels of dioxin in more foods. Currently, it is difficult to determine unusual levels of dioxin in foods because the Agency has limited information on typical background levels;

2. Ascertain how to reduce exposure of unusual levels of dioxin by:

    a. Determining the source of contamination through trace-back investigations;
    b. Determining whether a health hazard exists that may warrant appropriate enforcement action. This will be done on a case-by-case basis.

3. Improve exposure assessments of dioxin by providing better information on:

    a. Exposure trends over time;
    b. Average levels in foods that provide a large portion of dioxin exposure;
    c. Regional variability;
    d. Various diets.

APPROACH:

A. Investigational

1. Collecting districts: All except SJN. For district sampling obligation, please refer to the appropriate quarterly Sampling Instructions and Collection Schedule developed jointly by CFSAN (Office of Plant and Dairy Foods and Office of Compliance; Division of Field Programs) and ORA (Division of Field Science). The Sampling Instructions and Collection Schedule are issued by CFSAN/Division of Field Programs, Compliance Programs Branch, HFS-636 and lists monthly district sampling obligations.

2. Priority should be given to collecting aquaculture fish samples (catfish, salmon and striped bass) with associated finished feed samples for all aquaculture fish samples. These samples should be collected as soon as they become available. **DO NOT** collect aquaculture fish samples if the associated finished feed samples are unavailable.

3. A unique sample number must be assigned to all aquaculture finished feed samples. FACTS does not allow for multi-subsample reporting of lab results.

4. **ALL** domestic products, including produce items, should be collected at **retail establishments,** except aquaculture fish, corresponding finished feed samples and requested feed components. Aquaculture fish and corresponding finished feed samples must be collected at the grower. Additionally, feed components, as requested in the quarterly Sampling Instructions and Collection Schedule, must be collected at feed mills.

5. **DO NOT** sample products of import origin (i.e., cashews) while in import status. Products should be collected in commerce after they have been released from import status. Shipments should be released via OASIS after location of goods is determined to allow sample collection. The Collection Report should include reference to the entry/line number.

6. Each fiscal year KAN-DO laboratory will send a portion of approximately 232 food items from the Total Diet Study market basket collection to the Arkansas Regional Laboratory for dioxin analysis. These samples will have been cooked, processed or otherwise prepared as appropriate for Total Diet Study pesticide analysis. The composite portions will be dispensed into *dioxin-free* jars.

7. Samples are to be collected and analyzed for 17 dioxin/furan congeners and 3 PCB congeners (as methods become available) when analyzed by high resolution mass spectrometry (HRMS), for 15 dioxin/furan congeners and 3 PCB congeners (as methods become available) when analyzed by ion trap mass spectrometry (ITMS).

Sampling Instructions:

For specific sampling instructions, see the appropriate Sampling Instructions and Collection Schedule.

Where applicable, refer to IOM, Sample Schedule, Chart 3, Part 1, for sample size of domestic and domestic-import foods that have no specialized sampling instructions indicated.

Sample Shipment:

DO NOT COLLECT/SHIP SAMPLES BEFORE THE DATE INDICATED BY THE SAMPLING INSTRUCTIONS AND COLLECTION SCHEDULE.

Follow directions as provided in the Sampling Instructions and Collection Schedule as to which lab(s) samples should be submitted to.

Mark the outside of each parcel PERISHABLE except for canned and packaged dry foods. Ship samples packed in ice by overnight service. Refer to IOM 4.5.3.5.1 for instructions on shipping frozen samples and IOM 4.5.3.6 for instructions on shipping refrigerated samples.

Do not ship on Fridays.

For samples destined for ARL, ship to:

Arkansas Regional Laboratory, HFR-SW500
Attn: Mr. William "Kirk" Wilkes, Sample Custodian (Phone: 870-543-4012)
3900 NCTR Rd., Building 26
Jefferson, AR 72079-9502.

Please Note: FedEx will add a sur- charge to shipments that are sent to the old building (building 14).

For samples destined for KAN-DO, ship to:

FDA, KAN-DO District Laboratory HFR-SW360
Attn: Lloyd Ingram, Sample Custodian – Dioxins (Phone: 913-752-2483)
11510 West 80th Street
Lenexa, KS 66214

B. Analytical

Analyzing Laboratories:

- Arkansas Regional Laboratory (HRMS and ITMS)
- KAN-DO (only ITMS capability)

The fat content of all whole milk samples should be determined.

The following is the list of dioxin, furan, and coplanar-PCB congeners of interest. The PCB congeners should be reported as methods are developed and implemented into routine procedures.

Dibenzodioxins	*"Non-ortho" PCBs*
2,3,7,8-TCDD	3,3',4,4'-TCB (PCB #77)
1,2,3,7,8-PeCDD	3,3,'4,4',5-PeCB (PCB #126)
1,2,3,4,7,8-HxCDD	3,3',4,4',5,5'-HxCB (PCB #169)
1,2,3,6,7,8-HxCDD	

1,2,3,7,8,9-HxCDD	
1,2,3,4,6,7,8-HpCDD	
OCDD	
Dibenzofurans	
2,3,7,8-TCDF	
1,2,3,7,8-PeCDF	
2,3,4,7,8-PeCDF	
1,2,3,4,7,8-HxCDF	
1,2,3,6,7,8-HxCDF	
1,2,3,7,8,9-HxCDF	
2,3,4,6,7,8-HxCDF	
1,2,3,4,6,7,8-HpCDF	
1,2,3,4,7,8,9-HpCDF	
OCDF	

CDD = chlorinated dibenzodioxin
CDF = chlorinated dibenzofuran
CB = chlorinated biphenyl

Methodology:

All samples, except aquaculture finished feed samples, will be prepared and analyzed for 2,3,7,8-substituted dioxins and furans using either the ion trap methodology (ITMS) (LIB 4084 or 4203), or high-resolution mass spectrometry (HRMS) methodology (EPA Method 1613, LIBs 3981, 3990, or 4084 as appropriate) as directed in the quarterly Sampling Instructions and Collection Schedule.

Fat determination should be performed on all whole milk samples. The following fat determination method should be used in conjunction with LIB 4084: On page 9, paragraph 1, LIB 4084 states: "the eluting solvent flows to waste collection flask." Fat content in the analytical portion can be determined by collecting this material and reducing to constant weight: To determine fat content in milk samples, collect all eluting solvent and washings (before toluene elution) from the carbon column in a weighed, clean, dry 1000 mL 24/40 short-necked round bottom flask or turbo-evaporator tube. Reduce combined solvent and washings to dryness by rotary vacuum under vacuum or by using a turbo-evaporator. When the flask has reached constant weight, determine weight of fat by difference. Use this fat weight as the denominator for all dioxin calculations for lipid adjusted values.

Fish samples must be prepared consistently. Fish samples must be skinless, headless fillets prior to developing composites.

ITMS analysis should be confirmed by random selection and re-analysis of 10% of samples by HRMS.

Analyze all samples including all aquaculture finished feed samples.

REGULATORY/ADMINISTRATIVE FOLLOW-UP:

However, CFSAN will evaluate sample results from this program to determine if further follow-up investigation is necessary. CFSAN will develop and with ORA concurrence issue follow-up assignments as needed.

CONTACTS:

General Assignment Contacts (CFSAN):

Kaniz Shireen, OFP/CPB, HFS-636, (301) 436-2775
William Baczynskyj, OFP/CPB, HFS-636, (301) 436-1612 (if Ms. Shireen is unavailable)

Analytical Methods Contacts (CFSAN):

Alex Krynitsky, OPDFB/DPIC, HFS-336, (301) 436-2098
Doug Hayward, OPDFB/DPIC, HFS-336, (301) 436-1654

Regulatory Policy Contacts (CFSAN):

Paul South, OPDFB/DPPS, HFS-306, (301) 436-1640
Henry Kim, OPDFB/DPPS, HFS-306, (301) 436-2023

Regulatory Contact (CFSAN):

Crystal McKenna, DOE/DB, HFS-607, (703) 719-5718

CVM Contact

Randall Lovell, OSC/DAF, HFV-222, (301) 827-0176

DFS Analytical Contact:

Steve Robbs, DFS, HFC-140, (301) 827-9555

DFI Contact:

Barbara Marcelletti, DFI, HFC-132, (301) 827-5635

Field Laboratory Contact:

Arkansas Regional Laboratory:

Himansu Vyas, Director Chemistry Branch, ARL
(870) 543-4023

Paula Barnes, Dioxin Supervisor
(870) 543-4056

Vincent Litman, Dioxin Supervisor
(870) 543-4025

Jeff Archer, Dioxin Team Leader
(870) 543-4076

Sina Shojaee, Lead Chemist
(870) 543-4616

KAN-DO Laboratory

Marvin Hopper, (913) 752-2126

REPORTING:

Report all samples collection time and analytical time and results in FACTS under PAC 04004D and PAF = DIO.

PRIORITY:

All sample collections should be completed within the time frames established by the Sampling Instructions and Collection Schedule. All analysis should be completed within 60 days of receipt of sample.