CHAPTER 04 – Pesticides and Chemical Contaminants

SUBJECT	PESTICIDES IN HUMAN FOODS - DOMESTIC AND IMPORT
IMPLEMENTATION DATE	05/28/2026
PRODUCT CODES	INDUSTRY CODES: 02-26
PRODUCT/ASSIGNMENT CODES	REPORT PROGRAM ACTIVITIES UNDER THE FOLLOWING PACs: **04004A** Pesticides in Domestic and Imported Foods

FIELD REPORTING REQUIREMENTS:

1. Domestic sample collections are reported in the Regulatory Operations Management System (ROMS).
2. Import sample collections are reported in the System for Entry Review and Imports Operations (SERIO).
3. All analytical results (domestic and import) are reported in ALIS (Automated Laboratory Information System) with automatic transfer to FACTS.
4. Pursuant to requirements described in the Pesticide Monitoring Improvements Act, 21 U.S.C. §§ 1401-1403 (1988), FDA produces an annual pesticide report and utilizes detailed data retrieved from FACTS to develop the report.

NOTE: This compliance program does not address dioxin/other industrial chemicals or drug residues/chemotherapeutics in fish/fishery products, which are addressed in separate assignments/compliance programs under separate PACs (04004D and 04018, respectively).

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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 under FFDCA for setting of tolerances if the use of a particular pesticide may result in residues in or on food. With the exception of meat and poultry, for which the U.S. Department of Agriculture (USDA) is responsible, FDA is charged with enforcing pesticide tolerances in imported and 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 FDA's pesticide residue monitoring program is to carry out selective monitoring of human and animal foods for consumer protection. Therefore, FDA remains dedicated to continuously developing surveillance data. The program is conducted under the general guidance of the Human Foods Program (HFP)/Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI)/Office of Post Market Assessment (OPMA). Monitoring focuses on 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 in people) and foods consumed in large amounts by infants and young children. Most of the tolerances EPA establishes are for raw agricultural commodities, with a limited number of tolerances on some processed foods.

Pursuant to requirements described in the Pesticide Monitoring Improvements Act, 21 U.S.C. §§ 1401-1403 (1988), a summary and detailed analysis of the residue data obtained from the compliance program (CP) are prepared annually by OPMA and are made available to the public on FDA's website. This information is widely used inside and outside the agency including by EPA, USDA, Congress, industry, and consumers.

PART II - IMPLEMENTATION

1. Objectives

- To enforce pesticide residue tolerances in foods established by the EPA
- To determine the incidence and level of pesticide residues in domestic and imported foods
- To fulfill requirements described in the Pesticide Monitoring Improvements Act, under 21 U.S.C. §§ 1401-1403 (1988)

2. Program Management Instructions

Domestic Foods

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

Consistent with the sampling instructions in this program and guidance by the program office through the annual Sample Collection Operation Planning Effort (SCOPE), and based upon the Division'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. The Office of Import Operations (OIO) import monitoring should be consistent with the sampling instructions provided in this CP and by reviewing the following:

- Sampling instructions provided in this program and the annual SCOPE issued at the beginning of each Fiscal Year
- Data concerning the volume and types of foods imported from various countries
- Import Alerts (IAs):

  IA 99-05, Detention Without Physical Examination of Raw Agricultural Products for Pesticides
  http://www.accessdata.fda.gov/cms_ia/importalert_258.html

IA 99-08, Detention Without Physical Examination of Processed Human and Animal Foods for Pesticides
http://www.accessdata.fda.gov/cms_ia/importalert_259.html

IA 99-14, Countrywide Detention Without Physical Examination of Raw Agricultural Products for Pesticides
http://www.accessdata.fda.gov/cms_ia/importalert_261.html

IA 99-15, Countrywide Detention Without Physical Examination of Processed Products for Pesticides
http://www.accessdata.fda.gov/cms_ia/importalert_262.html

NOTE: Firms/products should not be sampled based solely on a previous listing on one of the IAs above. EPA tolerances can change over time, and these changes impact what commodities are of highest priority. Please refer to SCOPE when determining which products to collect. If there are questions, please contact the Pesticides CP monitor.

Interactions with Other Compliance Programs

Use the appropriate PAC when reporting sample collections under this CP. If a sample is collected under this program and the food is subject to additional regulations, compliance programs, or assignments outside the scope of this CP, then additional requirements should be covered per the respective interacting programs. This CP may have interactions with the following:

- Preventive Controls and Sanitary Human Food Operations (CP 7303.040)

  The pesticides CP (7304.004) covers sampling of domestic and imported human foods to enforce pesticide residue tolerances in foods established by the EPA. Samples collected for pesticide analysis during an inspection should be reported under CP 7304.004.

  Incorrect application and storage of industrial and household chemicals in food facilities covered under the Current Good Manufacturing Practices (CGMP) & Preventive Controls for Human Foods (PCHF) rule are covered under the Preventive Controls and Sanitary Human Food Operations compliance program (CP 7303.040).

  Misuse of pesticide chemicals (did not follow label instruction when applied) observed during a domestic inspection should be shared with EPA in accordance with the requirement for disclosure to other federal government departments and agencies, as provided under 21 CFR 20.85. (see PART V - Regulatory/Administrative Strategy).

- Produce Safety Inspections (CP 7303.080)

  The pesticides CP (7304.004) covers, in part, sampling of foods including covered produce. Samples collected for pesticides analysis during Produce Safety inspections should be reported under CP 7304.004.

- Foreign Supplier Verification Programs Inspections (CP 7303.878)

  The pesticides CP (7304.004) covers sampling, analysis, and enforcement instructions for pesticides in human food. The Foreign Supplier Verification Programs Inspections (FSVP) CP (7303.878) covers, in part, hazards including pesticides. Inspections conducted under the FSVP CP will consider the risk of the food and previous pesticides sample results. An inspection performed under the FSVP CP may yield observations that warrant follow-up sample collection for pesticides analysis (e.g., during the entry admissibility process). Samples are not typically collected during FSVP Inspections. Samples collected for pesticide analysis should be reported under CP 7304.004.

- Chemotherapeutics in Aquaculture Seafood (CP 7304.018)

  Chemotherapeutics and pesticides represent distinct categories of contaminants in seafood. Chemotherapeutics primarily enter seafood through intentional use in aquaculture to treat fish infections. Secondary contamination occurs through pharmaceutical waste.

  Samples of seafood to be analyzed for approved and unapproved drug residues should be reported under the Chemotherapeutics in Aquaculture Seafood CP (7304.018). Samples of seafood to be analyzed for pesticides should be reported under the pesticides CP (7304.004).

- Comprehensive Animal Food Sampling Program (CP 7371.100)

  The Center for Veterinary Medicine (CVM) monitors a broad range of contaminants in imported and domestic animal food commodities including ingredients and finished foods under the Comprehensive Animal Food Sampling Program (CP 7371.100). Pesticide sample collections of food/feed intended for animal use should be reported under CP 7371.100 or as specified by CVM.

Resource Instructions

Resources for sample collections and analysis for Pesticides in Human Foods are provided in the Office of Inspections and Investigations (OII) Field Workplan.

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

1. State and Local Counterparts:

   States and local officials are valuable sources of information on current and potential pesticide problems in foods. Divisions should coordinate activities with State and local officials to prevent duplication of efforts in domestic food sampling. State laboratories may share violative results with FDA. After reviewing the results, FDA may follow up.

2. The FDA Laboratory Flexible Funding Model (LFFM):

   LFFM is a comprehensive emergency response and surveillance cooperative agreement program (CAP) between FDA and the Food Emergency Response Network (FERN) partner laboratories. This program allows FDA to further support a National Integrated Food Safety Support (IFSS) by increasing national ability to detect, prevent, respond to, and recover from threats to the Country's food supply. Under LFFM, states may pursue their own regulatory action in addition to alerting FDA of potentially violative findings.

3. Other Federal Agencies:

   U.S. Department of Agriculture

   USDA's Pesticide Data Program (PDP) is a statistically based national monitoring and database program for pesticide residues in food. The PDP collects pesticide residue data on a wide variety of domestic and imported foods with an emphasis on the foods most likely consumed by infants and children. In accordance with MOU 12-25-MU-277, USDA alerts FDA monthly of presumptive tolerance violations they find in the PDP. FDA may provide ad hoc data to USDA divisions upon request.

   U.S. Environmental Protection Agency

   Under FIFRA, EPA is responsible for ensuring that pesticide applicators are properly trained and that growers are not using any registered pesticide in a manner inconsistent with its labeling. Pesticide residue results should be shared with EPA in accordance with the requirement for disclosure to other federal government departments and agencies, as provided under 21 CFR 20.85 when FDA investigations or domestic sample analyses reveal pesticide misuse. See PART V - Regulatory/Administrative Strategy.

4. Foreign Authorities:

   The FDA works with foreign governments and international standard-setting bodies to harmonize food safety laws, regulations and standards based on science. More information can be found at International Cooperation on Food Safety.

PART III - INSPECTIONAL

1. Operations

A. Inspections

An inspection is a careful, critical, official onsite examination of a facility to determine its compliance with federal law. See IOM subchapter 5.1.1. Inspections are not planned under this CP; refer to PART II - Interactions between Compliance Programs.

B. Investigations

An investigation is an information-gathering activity conducted for several reasons. Information obtained during an investigation may lead to other operations such as sample collections or inspections. See IOM subchapter 8.1.1.

C. Sample Collections

(1) General Sampling Instructions (Domestic and Import)

Collections should focus on unprocessed, single-ingredient, raw agricultural commodities (RACs) identified in the current year's SCOPE.

The SCOPE is based upon multiple factors including dietary significance, past history of violations, findings from partner agencies, and foreign or regional intelligence. Emphasis is given to foods highly consumed by infants and children, such as apples, bananas, carrots, corn, green beans, oats, oranges, peaches, pears, peas, potatoes, rice, sweet potatoes, and wheat products (e.g., farina). Examples of commodities appropriate for pesticide sampling are listed in the appropriate foods resource document.

Processed foods that are primarily a single ingredient food may be sampled (e.g., raisins, wheat flour). It is recommended that sampling of processed products be limited to those situations where there is suspicion that the food may contain an illegal pesticide residue. RAC foods are preferred.

HFP-initiated sampling schedules and field assignments related to emerging problems, or other needs, may be issued during the fiscal year.

Do not collect samples of:

- Teas, herbs, and spices.
- Heavily processed foods (e.g., protein powders, fruit syrups and foods that are fried, baked, or pickled (except olives)).

- Multi-ingredient foods.
- Medicinal herb formulations, extracts, or foods intended to be used as dietary supplements. This does not include whole ginseng which is classified as a root crop by EPA.
- RACs that must undergo extensive processing which either eliminates or significantly reduces pesticide residues before the food is eaten, such as coffee beans and hops.
- Foods labeled or marketed as organic foods unless there is suspicion of pesticide misuse. Regulations that qualify foods as organic are under the purview of the USDA National Organic Program, and FDA resources should not be used to determine compliance with USDA regulations.
- Multiple samples of one type of product from the same manufacturer/grower within a short period of time, unless otherwise instructed.

(a) Domestic Sample Collections

Samples may be official or investigational. Compliance samples should be official if evidence of interstate commerce is known or available. Strict adherence to IOM requirements is necessary when sampling products for this program. Collect domestic samples as identified in the SCOPE. If divisions have reason to collect samples that are not included in the pesticides SCOPE, see the Non-SCOPE Sample Collections section below.

Collect samples at or after harvest; EPA pesticide tolerances and FDA Action Levels do not apply to pre-harvest field samples.

Do not collect domestic samples known to be of import origin (i.e., domestic-import samples). Domestic-import samples will be classified as import samples and will not be used to satisfy domestic collection obligations.

When planning sample collections under this CP, consider prioritizing based upon the criteria below:

- Prioritize commodities of local origin for surveillance sampling.
- Base coverage on past violative samples, current analytical findings, information obtained through inspections and investigations, and on available current pesticide usage information. Investigations Operations Manual (IOM) Exhibit 5-22 provides information concerning pesticide inspections and investigations.

- 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.

- Consider collecting samples from 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. Divisions should not ordinarily extend sampling coverage to commodities subject to an experimental use permit.

- 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 division 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.

- Refer to guidance on collection of seafood samples given by HFP through SCOPE.

(b) Import Sample Collections

Collect samples of imported foods at ports of entry or during any stage of the import admissibility process.

Collection Priorities:
1. Focus primarily on commodities identified in the SCOPE
2. Prioritize SCOPE samples from shipments with higher values and/or larger quantities/volumes
3. For seafood samples, follow specific guidance provided by HFP through SCOPE

(c) Non-SCOPE Sample Collections

Surveillance samples of domestic commodities that are not listed in the SCOPE may be collected after consultation with the HFP Pesticides CP Monitor (see Program Contacts). CSOs should provide their rationale for the non-SCOPE collection. If the non-SCOPE sample collection is pre-authorized by HFP, the Investigator must note this in the "Remarks" section of the collection report (C/R).

Surveillance samples of domestic or imported commodities that do not follow the criteria in the General Sampling Instructions above, or do not have HFP concurrence, may not be accepted by the laboratory for analysis.

(2) Sample Size/Handling (Domestic and Import)

IOM Sample Schedule Chart 3 lists minimum sample sizes for pesticides analysis. Refer to IOM subchapter 4.7 for sample handling details.

NOTE: Use the Sample Schedule Chart 3 only for determining sample size; use SCOPE for selecting appropriate commodities for sampling.

Collect and pack samples in the container(s) the dealer uses to package the product. If dealer packaging is not available, package samples into containers that best maintain sample integrity (e.g., plastic bags, boxes, coolers, etc.). Avoid the use of paper containers (bags, boxes, etc.) to package high moisture commodities that may leak moisture and compromise the integrity of the package.

DO NOT maintain the identity of individual units for samples for pesticides analysis, except when collecting samples from crops growing in the field to document pesticide drift.

(3) Sample Shipment (Domestic and Import)

Submit samples to a servicing laboratory per the Lab Servicing Table (LST) Dashboard, specifically for the Pesticides (PES) program. Refer to IOM subchapter 4.7.5 for sample shipment details.

Be sure to annotate in the "Reason for Collection" section of the C/R if the sample is to be analyzed for a specific assignment, special survey, or compliance program.

Shipping instructions to maintain the integrity of frozen and refrigerated samples and the procedure to notify the receiving laboratory can be found in the most recent version of the IOM subchapter 4.7 - Sampling: Preparation, Handling, Shipping.

Samples should be packaged with the appropriate refrigerant and shipped to the laboratory no later than Thursday of each week. Unless prior arrangements are made, shipping on Fridays should be avoided as staff may not be present on the weekends to ensure proper sample receipt.

D. Import Activities

Related import activities, such as entry review and field/label examinations, are covered under IOM subchapters 6.2 and 6.3.

2. Reporting

Report resources utilized for sample collection using the following Program Assignment Code (PAC) and Problem Area Flag (PAF):

PAC	PAF	PAF Description
04004A	PES	Pesticides Sample Collection

A. Additional Reporting Instructions for Domestic Samples:

- List names and address of the grower/processor if different from the shipper.
- For all domestic samples, the name of the county and state where the sample was grown or collected must be entered in the appropriate fields in the Collection Record (ROMS).
- Report information regarding which crops were grown and pesticides used in fields adjacent to the field which produced the sampled food.
- Include information regarding any potential pesticide misuse collected during an investigation. Please also advise the HFP program contact when evidence of intentional misuse is apparent (see PART V - REGULATORY/ADMINISTRATIVE STRATEGY).
- 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 C/R.

PART IV - ANALYTICAL

1. Analyzing Laboratories

See LST Dashboard for pesticide laboratories.

2. Analyses to be Conducted

All laboratories will perform the GC-MS DRS Method, Harmonized Pesticide Method, and at least one Single Residue Method (SRM). Please refer to the specific methodology listed under Section 3 (Methodology), Part B (Methods) for the scope of analytes.

3. Methodology

A. General Information

i. Prior to beginning analysis, review the C/R to verify the collected products are listed in the Sample Collection Operation Planning Effort (SCOPE). If the product is not on the list of SCOPE requests but is preauthorized by HFP, as noted in the C/R, the laboratory should proceed with the analysis. If the product is not listed on the SCOPE and is not preauthorized, it may not be appropriate for analysis under the pesticide program. The laboratory should contact HFP program contacts before proceeding with the analysis.

ii. 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 the Pesticide Analytical Manual (PAM) I, Chapters 1 and 2 (https://www.fda.gov/food/laboratory-methods-food/pesticide-analytical-manual-volume-i-pam-3rd-edition). Conduct analyses as soon after collection as practical to minimize the potential for residue deterioration and loss.

> NOTE: Although various analytical methods and techniques are described in other chapters of PAM I, the determination methods listed in this document Part B (Methods) below should be used for routine regulatory testing.

iii. All methods of analysis must be validated, and samples shall be defined within the scope of the selected method. When required, method extensions shall be completed prior to the submission of regulatory sample results following the FDA Foods Program Guidelines for the Validation of Chemical Methods (https://www.fda.gov/science-research/field-science-and-laboratories/method-validation-guidelines).

iv. Over tolerance violations (Laboratory Classification 3, LC3) will be confirmed by check analysis and the check analysis should be performed by an experienced second analyst using the same method. Appropriate quality control measurements are required in all analyses to document method performance.

B. Methods

The following validated methods are used by the FDA/HFP/Office of Laboratory Operations and Applied Science (OLOAS)/Office of Regulatory Testing and Surveillance (ORTS) laboratories for routine regulatory analysis. Methods are available as an FDA standard operating procedure (internal) or referenced in the Foods Program Compendium of Analytical Laboratory Methods | FDA.

i. GC-MS DRS Method – GC-MS Full Scan with Deconvolution Reporting Software (DRS) (qualitative analysis only)

ii. Harmonized Pesticide Method – Determination of Pesticides and Industrial Chemicals Using Modified QuEChERS and GC-MS/MS and LC-MS/MS

iii. Selective Residue Methods (SRMs)

a. Glyphosate and Related Residues in Food – Harmonized Method for Detection and Quantitation (Foods Program Compendium of Analytical Laboratory Methods | FDA: C-013)

b. Acid Herbicides – Analysis of Acid Herbicides in Human and Animal Foods

4. Lab Classification and Reporting

A. Lab Classification

i. Lab Class 1 (LC1): The sample contains no positive residue finding or contains residues that are within the limits of an established tolerance, tolerance exemption, or action level.

ii. Lab Class 2 (LC2): One of the following scenarios applies:

a. The sample contains a detected residue for which no tolerance or guideline in the sampled commodity has been established, but the residue level is such that it requires no follow-up. For example, trace findings which are above the limit of detection (LOD) but below the limit of quantitation (or 0.010 ppm, whichever is higher).

b. The sample contains an unavoidable residue at or above the limit of quantitation (or 0.010 ppm, whichever is higher) for which no action level has been established for the sampled commodity. For example, findings for commodities listed under CPG Sec 575.100 may require HFP review (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-575100-pesticide-residues-food-and-feed-enforcement-criteria).

c. The sample contains a residue for which Channels of Trade provisions may apply. Refer to HFP guidance issued for specific residues under the Channels of Trade Guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-channels-trade-policy-commodities-residues-pesticide-chemicals-which-tolerances).

d. The sample contains a detected residue at or above the limit of quantitation (or 0.010 ppm, whichever is higher) and the lab would like clarification from HFP on determining appropriate regulatory follow-up.

iii. Lab Class 3 (LC3): The sample contains a detected residue that exceeds a tolerance or action level, or contains a residue at a concentration equal to or above the limit of quantitation (or 0.010 ppm, whichever is higher) for which no tolerance or tolerance exemption in the sampled commodity has been established.

NOTE: Import samples classified as LC3 are subject to direct reference authority (see Attachment A). If laboratory quality criteria specific for direct reference authority are not met for a given sample, or if HFP consultation is required before enforcement action is recommended, laboratories should classify the sample as LC2.

B. Reporting

i. All sample results, regardless of lab classification, are to be reported in ALIS or other data reporting software using the following PAC and PAF codes:

PAC	PAF	PAF Description
04004A	PES	Pesticides Analysis

NOTE: Consumer complaint and LFFM samples are not covered by this compliance program and should be reported under their respective PAC codes (04R800 and 04R834).

a. For residues meeting the violation criteria for a particular pesticide, the appropriate code must be entered into the violative residue field in FACTS/ALIS (i.e., "X" for exceeds tolerance, "N" for no tolerance, or "A" for exceeds action level). The code must be entered into the data records for the original and check analysis (if applicable). Samples are then assigned Lab Classifications based on the criteria specified in Section 4, Part A (Lab Classification) above.

b. LC2 and LC3 import samples will be reported to the respective OII import compliance division. LC2 and LC3 domestic and domestic import samples will be reported to HFP/Office of Compliance and Enforcement (OCE)/Division of Compliance Consultation (DCC) for appropriate regulatory follow-up (HFPOCESampleResults@fda.hhs.gov). LC2 samples that contain only trace findings (Section 4, Part A.ii.a) should not be reported to HFP. When criteria for Direct

Reference Authority are met (see PART V - Regulatory/Administrative Strategy), OII import divisions do not require prior consultation from HFP.

c. 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 the pesticide was found.

ii. Results for quality control measurements (e.g., method blanks, fortified analytical portions, reference materials) are not required to be entered into ALIS (or other data reporting software) system but the laboratory must maintain this information to document analytical methods performance.

iii. Worksheet packages of LC3 samples are required to be uploaded to CMS. Worksheet packages of LC2 samples should be uploaded to CMS if the information is needed to support enforcement cases; for example, if HFP consultation was requested. Worksheet packages of LC1 samples are not required to be uploaded to CMS.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

The published Compliance Policy Guide (CPG) 7141.01 (section 575.100) outlines FDA's enforcement policy for pesticides in human and animal foods. In 2008, FDA issued as draft guidance a revised CPG Sec. 575.100 that, when finalized, will represent FDA's current thinking on enforcement criteria for pesticide residues in food and feed, taking into account the provisions of the Food Quality Protection Act (FQPA). For detailed information on the following topics, review the draft revision of the CPG:

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

Direct Reference Authority (DRA) for Regulatory Actions:

OII Import Divisions have DRA for detention and the corresponding detention without physical examination (DWPE) in cases of imported foods, without prior consultation from HFP, when the required criteria are met. The criteria for DRA for regulatory actions involving pesticide residue violations are in Attachment A. Please refer to this document for specific information when processing enforcement actions for imported foods.

Domestic Foods:

For LC2 or LC3 domestic or domestic import samples, HFP Office of Compliance Intervention and Consultation (OCIC)/Division of Compliance Consultation (DCC) will create a CMS Work Activity (District – Worksheet/Other Exam Review), via CMS with a link to the related sample number for review by HFP.

The most effective way to remove food adulterated with pesticides from domestic channels has been through voluntary recalls. Otherwise, consider follow-up on each sample classified as LC3, either by meeting with the grower/shipper to discuss corrective action, or considering issuance of a Warning Letter (WL).

Pesticide residue results should be shared with EPA in accordance with the requirement for disclosure to other federal government departments and agencies, as provided under 21 CFR 20.85, when FDA investigations or domestic sample analyses reveal pesticide misuse.

Imported Foods:

For LC2 or LC3 imported food samples, OII import field division compliance officers should send recommendations for detention and refusal of a specific entry and/or DWPE involving pesticide residues that do not meet criteria for DRA to HFP's OCE, Office of Enforcement, Imports Enforcement Branch for evaluation. The OII/OIO field compliance officer should create a CMS case

type “Center review of detained shipment for Refusal (a.k.a. Detn Recom)” with a link to the related sample number.

Recommendations for DWPE involving pesticide residue levels with DRA (see Attachment A for direct reference criteria) should be forwarded only to OII/OIO/Division of Import Operations (DIO), Import Compliance Branch for placement on DWPE for a specific Import Alert. These recommendations should be created and sent via CMS Case (Import Alert – Add to RED List) under the appropriate Import Alert.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. References

Major guidance and reference materials pertaining to this program are listed below. Additional guidance may be found on the Pesticides in Human Foods Resource Page.

A. USDA Pesticide Data Program Annual Summary Reports

B. USDA National Agricultural Statistics Service (NASS) Domestic Pesticide Usage Data

C. Code of Federal Regulations, Title 40, Part 180.

D. Investigations Operations Manual (IOM), Chapter 4

E. Regulatory Procedures Manual

F. MOU 225-15-004
"Memorandum of Understanding on Information Sharing between U.S. Environmental Protection Agency Office of Chemical Safety and Pollution Prevention and Department of Health and Human Services Food and Drug Administration Foods and Veterinary Medicine Program"

G. Pesticide Analytical Manual, Volume I & II

2. Attachments

A. Criteria for Direct Reference Detention Involving Pesticide Residues

3. Program Contacts

A. Compliance Program Monitor/Inquiries

Dennis N. Hoang, HFP/OCE/OCOI/DCI/CPAB
Email: dennis.hoang@fda.hhs.gov

B. Domestic and Imported Food Regulatory Action Inquiries

OCE/OE Chemical Contaminants Team
Email: HFP-OCE-OE-CHEMICALCONTAMINANTS@fda.hhs.gov

C. Program Coordinator/Method and Residue Code Inquiries

HFP/Lead Coordinator, Plant Commodities

Sara C. McGrath, Ph.D., HFP/OFCSDSI/OPMA/DCC
Email: sara.mcgrath@fda.hhs.gov

HFP/Seafood Commodities
Emanuel Hignutt, HFP/OMFS/ODSS/DSS
Email: emanuel.hignutt@fda.hhs.gov

CVM/Animal Food Questions/Inquiries related to Pesticides:
CVMAnimalFoodContaminants@fda.hhs.gov

D. HFP Analytical/Methods Inquiries

Christine Parker, Ph.D., HFP/OLOAS/OCT/DBC
Email: christine.parker@fda.hhs.gov

Jessica Beekman, Ph.D., HFP/OLOAS/OCT/DAC/MDB
Email: jessica.beekman@fda.hhs.gov

E. HFP Scientific Inquiries

Moh (Mohammed) R. Islam, HFP/OLOAS/ORTS/DSPC/CB
Email: mohammed.islam@fda.hhs.gov

F. OII Investigations Inquiries

Byron Beerbower, OII/OHFI/OGSHFI/DCSF/HFPEB
Email: byron.beerbower@fda.hhs.gov

G. OII Import Operations Inquiries

OII OIO Import Support Form (for FDA staff use only)
For general import operational questions contact imports@fda.hhs.gov

PART VII - CENTER RESPONSIBILITIES

HFP/OFCSDSI/OPMA will provide subject matter expertise in the maintenance and evaluation of the compliance program and provide guidance to the Office of Compliance and Enforcement (OCE) with regard to program priorities, relevant evaluation questions, and recommended program changes. OPMA will review sample collections and findings monthly to ensure accuracy of collection reports and violative assignments. OPMA will prepare an annual report for web publication summarizing the findings of this program. Existing reports may be accessed at https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data.

OCE will lead the effort and work in conjunction with OPMA to prepare routine compliance program evaluations. Evaluation will be conducted on a periodic basis and outline the program office's current objectives, general and specific program evaluation questions, list recommendations for process improvement, and highlight data patterns and trends for better targeting and resource allocation. OCE will make these evaluations available internally to FDA. In addition, OCE will prepare an annual summary report of this compliance program which will be available at Compliance Program Summaries.

HFP and CVM have designated contacts (see Program Contacts) to coordinate exchange of residue data and other appropriate information, since residue findings in feeds and in foods derived from animals is often interrelated.

ATTACHMENT A - CRITERIA FOR DIRECT REFERENCE DETENTION INVOLVING PESTICIDE RESIDUES

Import divisions have DRA for detention and the corresponding DWPE of imported foods, without prior consultation from HFP, when the following required criteria are met. Recommendation for DWPE due to pesticide residues should be submitted directly to OII/OIO/DIO.

1. 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 HFP guidance documents, i.e. assignment/compliance programs (CP).

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

3. The analysis was performed using an FDA official method, and all quality elements were met in accordance with the current laboratory SOP.

4. The laboratory calculated the pesticide residue level in accordance with the residue expression (the appropriate isomers, parent compounds, and metabolites) found at the applicable tolerance regulation and classified the sample as LC3 (see PART IV – ANALYTICAL, Section 4).

5. The individual commodity, commodity crop group (Title 40 CFR 180.1, 180.34 and 180.41) and Food Handling Establishment tolerances (tolerances for pesticide residues resulting from pesticide applications where food and food products are held, processed, prepared and/or served) have been considered when determining if a residue is violative.

6. DRA does not apply to cases based on “Action Levels” (see CPG 575.100, Section VI for unavoidable pesticide residues).

2. Tolerance Exists for a Particular Pesticide/Commodity Combination

In addition to the General Requirements, for cases where a tolerance is exceeded, 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 at least 15%.

3. No Tolerance, Tolerance Exemption, Emergency Exemption Exists

Direct reference is authorized only when the above general considerations are met and the violative finding is at or above 0.010 ppm.