UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

10,800.4

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THE NATIONAL RESIDUE PROGRAM ROLES, FUNCTIONS, AND RESPONSIBILITIES

I. PURPOSE

This document describes the roles, functions, and responsibilities of Agencies and FSIS offices involved in the control of residues in meat and poultry products as part of the National Residue Program (NRP).

II. BACKGROUND

A. The United States National Residue Program for meat, poultry, and egg products is an interagency program designed to identify, prioritize, and analyze chemical residues and contaminants in meat, poultry, and egg products. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) administers this program. The NRP is an important component of the FSIS mission to protect the health and welfare of the consumers by regulating domestic meat, poultry, and egg products and to prevent the distribution into commerce of any such products that are adulterated or misbranded.

B. The Food and Drug Administration (FDA) is responsible for administering and enforcing the Federal Food, Drug and Cosmetic Act (FFDCA). Under this Act, FDA is responsible for ensuring that human foods and animal feeds are safe and, among other things, do not contain illegal residues of drugs, pesticides or environmental contaminants. FDA also approves drugs used for food producing animals, establishes tolerances for drug residues and may establish action levels for unavoidable contaminants that may adulterate food.

C. The Environmental Protection Agency (EPA) is responsible for administering and enforcing the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Under this Act, EPA has the authority to protect humans and their environment from unreasonable adverse effects of pesticide chemicals by regulating the sale and use of pesticide products. EPA samples pesticide chemicals to verify label claims concerning content and safety and investigates incidents where the misuse of pesticides has occurred. EPA is responsible under the FFDCA for establishing tolerances for residues of pesticides in food and has the authority to monitor the effectiveness of surveillance and enforcement. Under the Toxic Substances Control Act (TSCA), EPA also regulates other chemical substances (e.g., industrial chemicals) that can adulterate food.

D. The *Federal Register* notice: <u>Residue Control in a HACCP Environment</u> describes how FSIS adapted its approach to the control of chemical residues in or on meat and poultry products in light of the implementation of the regulation in the Agency's Pathogen Reduction-Hazard Analysis and Critical Control Point Systems final rule.

III. RESPONSIBILITIES OF THE OFFICE OF PUBLIC HEALTH SCIENCE (OPHS)

- A. OPHS Headquarters staff is to:
 - 1. Receive, evaluate, and provide residue-related information and scientific support to the Office of Field Operations (OFO) and the Office of Policy and Program Development (OPPD), other program areas regarding chemical residue control activities;
 - Coordinate the Surveillance Advisory Team (SAT), which functions to develop sampling and testing priorities and reviews chemical residue prevalence and intelligence information, including exposure assessments, from EPA, FDA, and the Centers for Disease Control and Prevention (CDC);
 - 3. Coordinate the Interagency Residue Control Group (IRCG) monthly meetings with FDA. These interagency meetings are the means for FSIS, FDA, EPA, CDC, other USDA agencies, such as Agriculture Research Service (ARS), the Agricultural Marketing Service (AMS), and the Animal and Plant Health Inspection Service (APHIS), as well as other Federal partners as needed, to discuss emerging chemical residue exposure issues, and follows up on detected findings in domestic or imported meat, poultry, and egg products;
 - Coordinate activities that may arise concerning NRP violative samples in accordance with the existing Memorandum of Understanding (MOU), <u>FSIS-FDA-EPA MOU (MOU</u> <u>225-85-8400): Regulatory activities concerning residue of drugs, pesticides and</u> <u>environmental contaminates in food.</u>
 - 5. Compile, analyze, and evaluate chemical residue data collected under the NRP and discuss with the Chemical Residue Workgroup (CRWG);
 - 6. Annually publish the U.S. National Residue Sampling Plan;
 - 7. Annually publish the chemical residue data in the U.S. National Residue Program summary report;
 - 8. Design and coordinate routine and exploratory residue sampling programs under the NRP, in collaboration with other Federal partners; and
 - 9. Provide updates, as requested by OFO, on chemical residue results reported in the LIMS Direct inclusive of carcass or part disposition.
- B. FSIS Field Service Laboratories are to:
 - 1. Conduct laboratory tests and provide the test results of those tests in accordance with Agency objectives, guidelines, and OPHS SOP *Interpretation of Chemical Test Results in FSIS- Regulated Products*; and
 - 2. Assess and update modifications to laboratory methodologies in support of scheduled, inspector-generated, and other chemical residue-related sampling.

IV. RESPONSIBILITIES OF THE OFFICE OF FIELD OPERATIONS (OFO)

A. OFO Headquarters Staff is to:

- 1. Provide data analysis and oversight of the NRP for OFO Headquarters and the Districts;
- 2. Participate in the monthly residue meetings, IRCG, SAT, and other residue-related activities, such as the Dioxin Survey Committee;
- 3. Communicate follow-up information requested from the Districts or from inspection program personnel (IPP) for other program areas outside OFO and outside agencies (e.g., OPPD, OPHS, Office of Planning, Analysis, and Risk Management (OPARM), FDA); and
- 4. Collaborate with the Office of Employee Experience and Development (OEED) in the design and delivery of residue-related training to the IPP and Supervisory Public Health Veterinarians (SPHVs).
- B. District Office (DO) and Frontline Supervisor (FLS) Personnel are to:
 - Receive notification of chemical residue violations and violators' information from FSIS Field Laboratories and the Policy Development Staff (PDS) through the Residue Violator Tracking System (RVT), and cooperate with residue violation investigations that may involve FSIS, FDA, and EPA;
 - 2. Verify the various chemical residue-related activities conducted at the in-plant level for notification received through RVT and FDA. DO and FLS personnel are to interpret and analyze operational reports, data, and other information to assess corrective actions in situations where the establishment's program failed to prevent violative residues;
 - 3. Inform OFO leadership of actions taken in response to repeat violators, per <u>FSIS</u> <u>Directive 10,800.1</u> *Residue Sampling, Testing, and Verification Procedures under the National Residue Program for Meat and Poultry Products,* Chapter Two, Section IV;
 - 4. Evaluate and assess OFO field personnel performance of in-plant residue sampling and other verification activities related to the NRP to ensure uniform and consistent implementation of the NRP; and
 - 5. Ensure training is provided to field personnel responsible for residue sampling and related verification tasks and maintain and disseminate current information to IPP on residue sampling and other verification tasks.
- C. IPP, including the SPHVs, are to:
 - Conduct residue sampling and other verification activities as described in <u>FSIS</u> <u>Directives 10,800.1, 10,800.2</u>, <u>Residue Sampling and Testing under the National</u> <u>Residue Program for Meat and Poultry Products</u> and <u>10,800.3</u>, <u>Prioritizing Inspector-Generated Sampling Under the National Residue Program for Meat and Poultry</u> <u>Products</u>;
 - 2. Determine the disposition of carcass/parts from the information provided in LIMS-Direct; per <u>FSIS Directive 10.800.1</u> Chapter 4, Section IX; and
 - 3. Participate in training in chemical residue sampling and testing procedures and ensure appropriate action is taken for chemical residue violations.

V. RESPONSIBILITIES OF THE OFFICE OF POLICY AND PROGRAM DEVELOPMENT (OPPD)

OPPD Headquarters Staff is to:

- 1. Coordinate activities related to policy issues for violative samples and the dissemination of chemical residue-related information among FSIS, FDA, and EPA in accordance with the existing Memorandum of Understanding (MOU);
- 2. Perform administrative functions for the residue tracking system. Enter and manage residue violation cases using an Agency database that serves as a:
 - a. Repository for residue violations sampled by OFO;
 - b. System for tracking repeat violator producers; and
 - c. Method for sharing information with FDA and EPA per the MOU;
- 3. Evaluate, interpret, and provide policy guidance for internal and external customers, develops new science-based policies in collaboration with other Program Areas, and as necessary, provides instructions to the field and guidance documents for industry; and
- 4. Communicate with producers (farmers), veterinarians and veterinary pharmaceutical companies to clarify residue violations and the NRP. Respond to residue violation questions submitted by internal (District Offices and IPP) and external customers (FDA and EPA).

VI. RESPONSIBILITIES OF THE OFFICE OF PLANNING, ANALYSIS, AND RISK MANAGEMENT (OPARM)

OPARM Headquarters Staff is to:

- 1. Provide statistical design and schedule sampling for chemical residues;
- 2. Create the data tables for the monthly, quarterly, and yearly chemical residue reports;
- 3. Provide statistical analysis and data visualization of the chemical residue inspection data; and
- 4. Create and maintain a chemical residue database repository with historical and current data that is updated nightly.

VII. RESPONSIBILITIES OF THE OFFICE OF INVESTIGATION, ENFORCEMENT AND AUDIT (OIEA)

A. The Compliance and Investigations Division (CID) is to conduct surveillance, investigations, and other compliance activities concerning residues; and

1. The Enforcement Operations Staff (EOS) is to conduct evaluation and analysis of case evidence and recommendation from OFO, CID, and other offices to initiate criminal, civil, or formal administrative enforcement action concerning residue violations in appropriate cases.

VIII. QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, complete the <u>web form</u> and select Residue as the Inquiry Type.

NOTE: Refer to <u>FSIS Directive 5620.1</u>, *Using askFSIS*, for additional information on submitting questions.

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