

OPI: MPIO

NATIONAL RESIDUE PROGRAM
PART ONE -- BASIC PROVISIONS

I. PURPOSE

This directive identifies FSIS responsibilities in planning, evaluating, supporting, and implementing the National Residue Program which is designed to monitor, detect, reduce, and control residues of drugs, pesticides, and other chemicals and contaminants in meat and poultry products designated for human consumption.

II. (RESERVED)

III. REASON FOR ISSUANCE

The National Residue Program is an essential part of the total inspection efforts to identify and control adulterants in the meat and poultry supply. The effective implementation of the National Residue Program requires thorough planning and timely coordination among numerous FSIS units. This directive establishes and describes functions and relationships of these units.

IV. REFERENCES

Federal Meat Inspection Act
Poultry Products Inspection Act
Parts 309, 310, 311, 318, and 327 of the Federal meat inspection regulations
Section 354.130 of the voluntary inspection and certification regulations
Sections 381.60, 381.70-381.80, 381.91, 381.95, and 381.197 of the poultry products inspection regulations
FSIS Directives 8080.1, 8150.1, 9050.1, 10001.1, 10012.1, 10110.1, 10130.1, 10220.1, 10600.1, 10600.2, 10610.1, 10620.1, and 10625.1

V. ABBREVIATIONS

The following will appear in their shortened form in this directive:

AIIS - Automated Import Information System
CD - Chemistry Division, SCI
CRS - Contamination Response System
EPA - Environmental Protection Agency
EPS - Emergency Programs Staff, MPIO
FDA - Food and Drug Administration
FPD - Foreign Programs Division, IP
FSL - Field Service Laboratories

FSLD - Field Service Laboratories Division, SCI
IAS - Import Analysis Staff, IP
IFO - Import Field Office, IP
IID - Import Inspection Division, IP
IP - International Programs
IRSP - Import Residue Sampling Plan
MARCIS - Microbiological and Residue Computer Information System MD -
Microbiology Division, SCI
MOU - Memorandum of Understanding
MPIO - Meat and Poultry Inspection Operations
MPITS - Meat and Poultry Inspection Technical Services
MSD - Mathematics and Statistics Division, SCI
NRP - National Residue Program
PED - Pathology and Epidemiology Division, SCI
POE - Port of entry
QA - Quality assurance
QC - Quality control
REPD - Residue Evaluation and Planning Division, SCI
ROS - Residue Operations Staff, MPIO
SCI - Science Program
SRC - Standing Residue Committee
SVMO - Supervisory Veterinary Medical Officer
VMO - Veterinary Medical Officer

VI. POLICY

FSIS is responsible for maintaining effective inspection and enforcement programs to assure consumers that domestic and imported meat and poultry products which are distributed to them are safe, wholesome, not adulterated, and properly labeled. An integral part of FSIS's inspection program is the National Residue Program (NRP) which includes monitoring, surveillance, and the Contamination Response System (CRS). Under the NRP, FSIS samples, detects, reduces, and controls residues of drugs, pesticides, and other potentially hazardous chemical adulterants in meat and poultry products. In addition to utilizing regulatory control measures, NRP promotes residue prevention through interagency programs for producer education and through incentives for producers and processors to develop residue quality assurance programs. Samples of meat and poultry are collected for analysis at federally inspected slaughtering establishments producing domestic products and at ports of entry receiving import shipments. The presence of violative residues leads to the investigation and control of the movement of suspected and known adulterated product and to the identification of producers marketing animals with adulterating residues. When a potential or known residue crisis is identified under the NRP, CRS is activated. The CRS utilizes the resources of all relevant FSIS headquarters and field units through an interdisciplinary team whose goal is immediate action for problem resolution.

The NRP demands a concerted effort by all programs within FSIS. The following parts identify the responsibilities of FSIS units to assure that

all aspects of the NRP are well managed and fully integrated.

PART TWO--NATIONAL RESIDUE PROGRAM

SCIENCE PROGRAM RESPONSIBILITIES

I. OVERVIEW

SCI provides the Agency with scientific guidance and planning for the NRP. Included in these functions is the development of the Compound Evaluation and Analytical Capability; Annual Residue Plan which ranks compounds that may be present in meat and poultry (including criteria and methods for setting priorities), lists analytical methods for detecting those compounds, and presents FSIS's sampling plans for the coming year. SCI's support services also include the analyses of meat and poultry samples, the reporting and interpreting of such analytical results, and collaboration with other agencies as defined in relevant MOUs.

II. RESPONSIBILITIES

A. The Deputy Administrator, SCI, has the overall responsibility for managing scientific activities within FSIS, including the planning, evaluation, and reporting of the domestic and import activities of the NRP.

B. Under the direction of the Deputy Administrator, SCI, the units listed below shall perform specific duties under the NRP.

1. The Director, CD:

a. Maintains technical capability of chemistry sections of FSLD.

b. Maintains accreditation program of FSIS accredited laboratories.

c. Develops new, expanded, or improved screening, confirmatory, and in-plant methodology.

d. In cooperation with REPD, ascertains and develops analytical capabilities for each year's annual plan.

e. Participates in IP's SRC.

f. Directs CD support activities involving CRS.

2. The Director, MD:

a. Maintains technical capability of microbiology sections of FSLD.

b. Develops new, expanded, or improved analytical, confirmatory, and in-plant methodology.

c. In cooperation with REPD, ascertains and develops analytical capabilities for each year's annual plan.

d. Participates in IP's SRC.

e. Directs MD support activities involving CRS

3. The Director, PED:

a. Provides epidemiologic services in cooperation with REPD to investigate, characterize, and evaluate residue incidents in animals and products.

b. In cooperation with REPD, provides epidemiologic services necessary to develop plans for residue avoidance and control programs.

c. Provides epidemiologic services for CRS.

d. Participates in IP's SRC.

e. Directs PED support activities involving CRS.

4. The Director, FSLD:

a. Assures that all analyses are completed promptly and that results are transmitted to MARCIS within 30 days after sample collection!

b. Assures that REPD receives prompt, documented notification of laboratory results when violative or unusual findings occur in domestic or import samples.

c. Assures that all analyses for the year are completed and that the results are transmitted to MARCIS by January 31 of the following year.

d. Participates in IP's SRC.

e. Directs FSLD support activities involving CRS.

5. The Director, MSD:

a. Participates with REPD in planning and evaluating programs to assure that procedures are statistically consistent with program purposes.

b. Reviews monitoring and scheduling procedures for statistical accuracy and appropriateness.

c. Assists with the design of data QC procedures and implements these activities associated with MARCIS.

d. Participates in IP's SRC.

e. Directs MSD support activities involving CRS.

6. The Director, REPD:

a. Develops plans for and evaluates the results of residue programs designed to control and eliminate the presence of undesirable substances, the use or presence of prohibited substances, or quantities of authorized substances exceeding the permitted levels in meat and poultry products.

b. Encourages the development of effective residue control programs by States and private industry, both on a cooperative and independent basis, and interacts with FDA, EPA, and other Federal agencies in the development of programs to control and eliminate violative concentrations of residues in meat and poultry products.

c. In consultation with other SCI divisions, MPIO, and IP, designs the annual residue sampling plan and publishes the approved plan by December 15 of each year as the Compound Evaluation and Analytical Capability; Annual Residue Plan.

d. Routinely consults with MPIO on matters that could impact on the annual plan such as laboratory resources, methods development, staffing, and procurement of supplies and equipment.

e. Receives documented notification of laboratory results when violative findings occur in domestic and import samples.

f. In cooperation with MPIO, evaluates each residue violation incident both as an individual occurrence and for a possible pattern in time, geographic distribution, or species. Uses violation data to evaluate the effectiveness of the National Residue Program and to plan and develop new or improved portions of the program.

g. Upon receiving FSLD test results, immediately notifies, as appropriate, MPIO, IP, PED, and FDA and EPA of the occurrence of violative or unusual findings.

h. Serves as the focal point within FSIS for receiving, evaluating, and providing residue-related information and for giving scientific support to MPIO, IP, and MPITS regarding procedures, development, and training for residue control activities.

i. Periodically reviews residue control and sampling activities to assure that they provide adequate information for follow-up actions directed against violators and adulterated product.

j. Publishes the Residue Data Book and other reports, as appropriate.

k. Compiles and evaluates data with associated scientific rationale to support the development of a "systems" approach to residue control, including risk assessment, exposure assessment, and risk management decisions.

1. Participates in IP's SRC.

m. Directs REPD support activities involving CRS.

PART THREE--NATIONAL RESIDUE PROGRAM

MEAT AND POULTRY INSPECTION OPERATIONS RESPONSIBILITIES

I. OVERVIEW

MPIO is responsible for carrying out the inspection requirements specified in the FMIA and PPIA for domestic meat and poultry products and for administering compliance activities to assure regulatory standards are properly enforced at domestic meat and poultry operations. Cooperative interactions with other government agencies are defined in relevant MOUs. Under the NRP, MPIO directs, coordinates, and executes all field inspection activities to assure an effective residue control program for domestic meat and poultry products. In addition, MPIO coordinates the FSIS response under CRS to emergency situations where product is contaminated with residues and other adulterants affecting the wholesomeness and safety of such products.

II. RESPONSIBILITIES

A. The Deputy Administrator, MP10, has the overall responsibility for managing all field operations, including the timely, effective, and uniform execution and maintenance of the NRP.

B. The Assistant Deputy Administrator, Regional Operations, provides guidance, through the Director, ROS, to the Regional Directors on directing and coordinating field inspection activities necessary to provide and execute effective monitoring, surveillance, and CRS functions under the domestic NRP. Under the direction of the Assistant Deputy Administrator, the units listed below shall perform specific duties in implementing the NRP.

1. The Director, ROS:

a. In consultation with REPD, provides guidance to MPIO field personnel to implement appropriate responses to residue contamination incidents and coordinates these actions with other FSIS units.

b. Participates with Extension Services (field representatives) and professional organizations to increase producer awareness of the need to include residue controls in their management programs.

c. Serves as liaison to SCI, Compliance Program, EPS, FDA, EPA, Packers and Stockyards Administration, and other FSIS programs or government agencies to establish lines of communication to assure implementation of an effective residue control program at the field level, in accordance with FSIS policy and interagency MOUs.

d. Receives information from Regional Directors on field

residue problems requiring possible action and, in consultation with REPD and EPS, as applicable, determines the action necessary and notifies appropriate FSIS staffs if residue problems exist.

e. Notifies the Compliance Program of residue problems for possible investigative action.

f. Assures that MPIO staff and field personnel receive appropriate training to carry out their responsibilities in the residue control program.

g. Correlates with Regional Directors on residue-related issues.

h. Assures maintenance of complete and current information on residues within MPIO.

i. Manages procurement and distribution of supplies and materials to conduct inplant residue tests.

j. Prepares the monthly residue monitoring schedule in collaboration with a scheduling team including representatives from SCI and IP.

k. Monitors performance of field activities to assure uniform and consistent implementation of the residue control program.

l. Collaborates with SCI on long-range plans and reviews of the residue control program.

m. Distributes residue-related information to field personnel.

n. Analyzes operational data and information to keep abreast of current residue trends and related issues.

o. Verifies by management information systems the degree and level of application of the various residue-related activities being conducted at the in-plant level by interpreting and analyzing operational reports, information, and data for the purpose of effecting corrective actions in situations where program failure is indicated.

p. Implements a residue violation tracking system.

q. Conducts on-site correlation of residue activities with regional personnel.

r. Provides support for CRS.

s. Participates in IP's SRC.

2. The Director, EPS:

a. Maintains a permanent headquarters-based CRS Control Center.

b. Acts as focal point for reporting contamination problems that are identified by MPIO field personnel, other FSIS programs, other Federal and State government agencies, and industry.

c. Coordinates the FSIS response under CRS to emergency situations affecting the acceptability of meat and poultry products for human consumption.

d. Declares a CRS Residue Action Condition, with concurrence of the Administrator, for control, evaluation, and resolution of large scale chemical contamination emergencies.

e. Directs and coordinates the CRS Residue Action Condition Headquarters and Field Level Response teams which provide expertise in resolving emergency contamination problems and provides guidance to MPIO field personnel in determining the critical nature of contamination situations.

f. Focuses on situations where meat and poultry products are adulterated with drug or other chemical residues which would require the recall of affected products.

g. Manages and accounts for resources utilized in response to CRS and other emergency situations.

3. Field Personnel.

a. The Regional Residue Staff Officer:

(1) Correlates, coordinates, and monitors field activities to assure proper implementation of the residue control program.

(2) Monitors sample collection, supplies, equipment, and residue rates.

(3) Assesses field reports to determine appropriate action.

(4) Assures field personnel receive proper training in residue management.

(5) Conducts on-site assessment of residue programs and violation incidents through contacts including feedlots, farms, and auction markets, as necessary.

(6) Serves as FSIS liaison on residue issues with industry associations, schools, consumer groups, and other governmental agencies.

(7) Sets priorities for field personnel to assure adequate implementation of residue monitoring and surveillance activities.

(8) Communicates with the Director, ROS, as appropriate to assure efficient and effective implementation of the NRP.

(9) Maintains current regulations, issuances, and other relevant material on residue control.

(10) Serves as a CRS field team member.

b. The Area Supervisor:

(1) Coordinates and implements residue program activities at in-plant level.

(2) Collaborates with States having inspection programs for selection of establishments to be sampled each month under the National Residue Monitoring Program.

(3) Collaborates with States, FDA, auction markets, and others, as appropriate, to detect residue violations.

(4) Monitors in-plant residue control performance of inspection personnel.

(5) Assures field personnel receive proper training in residue management.

(6) Determines in-plant staffing needs and sets priorities to assure adequate degree of residue monitoring and surveillance is undertaken.

(7) Maintains current regulations, issuances, and other relevant material on residue control.

(8) Directs support activities involving CRS.

c. The Circuit Supervisor:

(1) Monitors in-plant residue control performance of inspection personnel.

(2) Monitors in-plant staffing needs and sets priorities to assure adequate residue control system; provides feedback to the VMO/SVMO.

(3) Monitors and evaluates the appropriate maintenance and control of supplies, incubators, and other equipment at plant level.

(4) Maintains current material on residue control.

(5) Assures field personnel receive proper training in

residue management.

(6) Provides support for CRS.

d. The VMO/SVMO:

(1) Implements and conducts in-plant residue control program, including CRS.

(2) Sets priorities to assure adequate residue monitoring and surveillance is undertaken.

(3) Assures inspectors and, when appropriate, establishment employees receive proper training in residue monitoring and control.

(4) Properly utilizes in-plant tests.

(5) Maintains current regulations, issuances, and other relevant material on residue control.

(6) Initiates sampling based on ante-mortem and post-mortem information and findings

C. The Assistant Deputy Administrator, Compliance Program, is responsible for providing guidance, through Field Operations Division, to Compliance field area offices regarding direction and coordination of activities necessary to execute investigative action under the NRP. Under the direction of the Assistant Deputy Administrator, Compliance Program, the Director, Field Operations Division:

1. Conducts field investigations, including on-site reviews of violators referred by Regional Operations.

2. Directs the collection and documentation of evidence necessary to support legal actions against alleged violators by FDA or other agencies, including actions defined in interagency MOUs.

3. Directs support activities involving CRS.

4. Monitors compliance with the provisions of MOUs between FSIS and livestock or poultry producers with approved residue control systems.

PART FOUR -- NATIONAL RESIDUE PROGRAM

INTERNATIONAL PROGRAMS RESPONSIBILITIES

I. OVERVIEW

To be eligible for importation into the United States under the FMIA and PPIA, meat and poultry products must be prepared in certified establishments

operating under inspection systems that ensure compliance with requirements at least equal to those applied to domestic establishments and their products. Therefore, imported meat and poultry products must, among other things, comply with applicable U.S. residue standards. Each eligible country is required to provide IP with an annual plan for controlling residues of drugs, pesticides, and other chemicals in products exported to the United States. The SRC, comprised of representatives from IP, SCI, MPIO, and FDA, reviews annual residue plans from eligible exporting countries. After review by the SRC and acceptance of the plan, IP conducts two broad sets of activities to assure that statutory requirements are met: (1) continuing on-site reviews of each inspection system and (2) reinspection of product upon arrival into the United States (POE).

Using the information contained in the country's annual plan, IP tailors on-site reviews to each country's residue status and planned activities. POE testing procedures are designed to verify the continuing successful operation of the country's residue program.

II. RESPONSIBILITIES

A. The Deputy Administrator, IP, manages all activities dealing with foreign inspection systems and exported and imported meat and poultry products. These activities include participation in the NRP which consists in general of cooperating with SCI in developing the annual IRSP for imported meat and poultry products, managing the implementation of the IRSP, reporting data generated by the IRSP, and initiating necessary actions to assure adequate residue control in foreign origin meat and poultry products.

B. Under the direction of the Deputy Administrator, IP, the units listed below shall perform specific duties in executing the NRP for imported products.

1. The Director, FPD, is responsible for the initial and continuing review of foreign inspection systems.

a. Obtains annual residue plans from each foreign inspection system.

b. Manages the review of the annual residue plans by the SRC.

c. Communicates with foreign inspection systems on all residue matters.

d. Conducts activities to assure maintenance in each country of "equal to" residue programs.

e. Consults with SCI on all residue results they report as "non-routine" (violative or unusual findings) to determine need for and extent of corrective action by foreign country.

f. Notifies foreign country of findings indicating a residue

violation and requests report providing explanation and corrective action.

g. Evaluates country response and adjusts review activities as appropriate.

2. The Director, IAS, has analytic responsibility for implementing the IRSP.

a. Receives final IRSP from SCI and programs AIIS by January 1 each year to accomplish plan.

b. Develops and executes reports to permit analysis of:

(1) Progress on implementation of IRSP.

(2) Quality of data in AIIS data base.

(3) Laboratory resource demands.

(4) Country analytical performance.

c. Assures entry of all residue results into AIIS via operation of the MARCIS-AIIS data link, manual entry of laboratory data sent by SCI, or manual entry of non-routine data telecopied to SCI by FSL.

d. Notifies FPD and IID of non-routine residue sample results via telephone immediately upon receiving verified results from SCI.

e. Provides all residue result data to IID field locations via AIIS.

3. The Director, IID:

a. Assures that the IRSP is carried out as directed by this directive and the AIIS;

b. Provides EPS information on lots that have passed inspection when subsequent laboratory results demonstrate that they are in violation; and

c. Sends a copy of the laboratory sample results form to the appropriate IFO.

4. The IFO Supervisor:

a. Immediately notifies inspectors of laboratory results for products on hold,

b. Notifies IID headquarters and monitors the disposition of product which is refused entry because of residue violation,

c. Assures that copies of the laboratory results forms

received from headquarters are filed in the appropriate import case file, and

d. Establishes a retrieval system for residue results data received via AIIS.

5. The inspector:

a. Takes, prepares, and sends samples in accordance with standard operating procedures,

b. Issues refused entry notice on product which is found to be violative,

c. Releases product on hold that has passed laboratory analysis, and

d. Retains any product from a lot still available in the import establishment for product having passed inspection and is subsequently found to be violative.

PART V (RESERVED)

Lester M. Crawford/Acting
Administrator