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

FSIS DIRECTIVE

10,800.1
Rev. 3

6/23/22

RESIDUE SAMPLING, TESTING AND OTHER VERIFICATION PROCEDURES UNDER THE NATIONAL RESIDUE PROGRAM FOR MEAT AND POULTRY PRODUCTS

CHAPTER ONE – GENERAL

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP), on conducting verification procedures in accordance with the National Residue Program (NRP) for meat, and poultry products. FSIS has revised this directive to remove the prescriptive frequency for show animal residue testing and update the definition of a show animal lot.

KEY POINTS:

Provides instruction to IPP on:

- *Selecting carcasses for the NRP surveillance sampling*
- *Situations that warrant inspector-generated residue sampling*
- *Conducting* Public Health Information System (*PHIS) tasks to verify the establishment's residue control program*

II. CANCELLATION

FSIS Directive 10,800.1, Revision 2, *Residue Control Program Verification Procedures Under the U.S. National Residue Program for Meat and Poultry Products*, 2/14/22

III. RESTRUCTURE OF THE RESIDUE DIRECTIVES

A. FSIS has replaced the previous version of FSIS Directive 10,800.1 with a series of directives (Directives 10,800.1, *Residue Sampling, Testing, and Other Verification Procedures under the National Residue Program for Meat and Poultry Products,* 10,800.2, *Residue Sampling and Testing under the National Residue Program for Meat and Poultry Products,* and 10,800.3, *Prioritizing Inspector-Generated Sampling under the U.S. National Residue Program for Meat and Poultry Products)*.

B. Information related to residue policy and verification tasks performed as part of the NRP (including Hazard Analysis Verification (HAV) and Hazard Analysis and Critical Control Points (HACCP) verification tasks, Other Regulatory Requirements tasks) to verify an establishment's residue control program are included in FSIS Directive 10,800.1.

C. Information related to sample collection methodologies are included in FSIS Directive 10,800.2.

D. Information related to pathologies and conditions warranting carcass retention and sampling are included in FSIS Directive 10,800.3.

NOTE: Instructions for egg product residue sampling are found in FSIS Directive 10,230.3, *FSIS Verification Testing of Domestic Egg Products*. Instructions for Siluriformes fish residue sampling are found in FSIS Directive 14,010.1, *Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments*. Instructions to import inspection personnel on imported products residue sampling are found in FSIS Directive 9900.6, *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products.*

IV. BACKGROUND

A. The United States has a robust residue control system with rigorous processes for approval, sampling, testing, and enforcement activities. Three principal agencies are involved in the control of residues in meat and poultry products: FSIS, Food and Drug Administration (FDA), and Environmental Protection Agency (EPA). FSIS works with EPA and FDA to implement the NRP. FSIS's primary responsibility is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat and poultry products through sampling programs within the NRP. The NRP also provides national data on chemical residue testing results to support risk assessment, enforcement, and educational activities. In accordance with FDA and EPA regulations, the NRP is designed to prevent the occurrence of violative levels of chemical residues in meat and poultry products.

B. Under 9 CFR 9 CFR 417.2, establishments are required to conduct a hazard analysis and consider the food safety hazards that are reasonably likely to occur in their production processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level. In a slaughter establishment, the possible sources from which chemical food safety hazards may arise include chemical contamination, veterinary drug residues, and pesticides. An establishment is required to maintain documentation that supports the decisions made in its hazard analysis as part of its records under 9 CFR 417.5(a) (1). An establishment that determines in its hazard analysis that chemical residues are a hazard not reasonably likely to occur (NRLTO) is required under 9 CFR 417.3(b)(4) to reassess its HACCP plan each time a violative drug residue is found by FSIS. With repeated violations it becomes increasingly difficult for establishments to support the decision that drug residues are not reasonably likely to occur. Regulations require that an establishment verify the effectiveness of its residue control program under HACCP per 9 CFR 417.4(a) on an ongoing basis.

CHAPTER TWO – DOMESTIC RESIDUE SAMPLING PLAN

I. SURVEILLANCE SAMPLING

A. Surveillance sampling (also known as scheduled or directed sampling) is the sampling of specified slaughter subclasses at the time of slaughter, after passing ante-mortem inspection. Under this program, IPP randomly select carcasses within a given production class for sampling as part of a nationally representative sample. Sample requests for NRP surveillance residue testing appear as directed tasks on the establishment task list in the Public Health Information System (PHIS). The sampling task provides information to IPP on the slaughter class to sample and the sample collection window.

B. IPP are to follow the instructions provided in FSIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System,* for accepting, scheduling, and completing a directed sampling task using PHIS. IPP are to follow the instructions for collecting tissue samples for residue testing provided in FSIS Directive 10,800.2.

II. SPECIAL PROJECT SAMPLING

FSIS periodically conducts special residue sampling projects. These projects may focus on residue testing for a specific slaughter class or a specific chemical compound (e.g., dioxin survey) or testing at a herd level. IPP will receive notification of a special project residue sampling project") through an FSIS notice.

III. INSPECTOR-GENERATED SAMPLING

A. IPP conduct inspector-generated sampling whenever they suspect that an animal presented for slaughter may contain a violative level of one or more chemical residues. Inspector-generated sampling includes:

1. Kidney Inhibition Swab (KIS™) Test: The Public Health Veterinarian (PHV), or Inspection Program Personnel (IPP) under the direction of the PHV, are to conduct a KIS™ test on any carcass that, based on herd history or ante-mortem or post-mortem inspection findings, may contain a violative drug residue.

NOTE: PHV and IPP are to note that the KIS™ test does not detect non-antimicrobial drugs (i.e., beta-agonist drugs or nonsteroidal anti-inflammatory drugs (NSAIDs)).

2. Confirmatory Tissue Testing: The PHV, or IPP under the direction of the PHV, are to collect and submit tissue samples to the FSIS Laboratory for inspector-generated residue testing when:

    a. A KIS™ test result is positive;

    b. An animal is suspected of having violative levels of a chemical residue, other than an antibiotic (e.g., NSAIDs, beta agonists);

    c. A producer is listed on the Residue Repeat Violator List for a chemical residue other than an antibiotic; or

    d. Ante-mortem or post-mortem examination findings indicate a condition where violative residues may be present, regardless of KIS™ test results.

B. IPP are to retain all carcasses and parts from animals selected for KIS™ testing until all test results are completed.

C. IPP are to refer to FSIS Directive 10,800.3 for information on pathologies and conditions which may warrant carcass retention and sampling and FSIS Directive 10,800.2 for performing KIS™ tests.

D. IPP are to refer to FSIS Directive 6100.1, *Antemortem Inspection of Livestock* for actions to take on downed/ disabled livestock to determine their eligibility for KIS™ testing. IPP are to note that non-ambulatory disabled cattle are not eligible for slaughter and therefore would not be KIS™ tested.

IV. INCREASED KIS™ TESTING

A. There are several circumstances that warrant increased KIS™ testing. The PHV, or IPP under the direction of the PHV, are to increase the frequency of KIS™ testing when the PHV is notified through supervisory channels or otherwise determines that an establishment:

1. Purchases or receives animals from a supplier on the Residue Repeat Violator List (had two (2) or more FSIS laboratory-confirmed chemical residue violation in the previous 12 months);

NOTE: The term "supplier" may include a producer, broker, or livestock market.

2. Does not have a residue control program designed to control residue violations or the establishment's residue control program has been determined to be ineffective in design or implementation to continue to support decisions in the establishment's hazard analysis;

3. Fails to collect the name and address or other type of credible certification of the source of animals it slaughters that demonstrates the supplier is not on the Residue Repeat Violator List;

4. Receives dairy cows or bob veal from any unknown source, even if the animal appears normal. For bob veal, this increased testing rate is *in addition* to the rates described in 9 CFR 310.21 (See Section F. of this Chapter); or

5. Receives animals with pathologies listed in FSIS Directive 10,800.3.

B. The list above is not all-inclusive. The PHV is to use sound professional judgment and consult with supervisory channels to determine when increased inspector-generated sampling is warranted. The PHV is to consider all aspects of an establishment's residue control program, including previous residue sampling results, to determine whether increased sampling is warranted. IPP are to refer to Chapter Four, for instructions for verification of the establishment's residue control program.

C. IPP are to refer to the Residue Repeat Violator List found on the FSIS website to determine whether a supplier is listed as a repeat violator. IPP are to note that a firm or person listed on the Residue Repeat Violator List remains eligible to market its livestock for slaughter provided it does not bear or contain violative levels of chemical residues.

D. The PHV is to discuss the circumstances that warranted increased sampling with the establishment at the weekly meeting and provide the link to the Residue Repeat Violator List to the establishment.

E. If an increased rate of testing is warranted, IPP are to:

1. Test at least two (2) animals each time the establishment receives animals from an unknown source or from a supplier with a known residue violation history, and the establishment does not have controls in place that minimize the possibility that the animals have violative residues;

2. Correlate with the PHV to determine whether additional sampling is necessary, based on the effectiveness of the establishment's residue control program at reducing or eliminating the occurrence of FSIS violative residue findings;

3. Continue this level of testing on all livestock from suppliers listed on the FSIS Residue Repeat Violator List; and

4. Continue increased testing rate on all dairy cows and bob veal if the establishment lacks an effective residue control program. IPP are to refer to Chapter IV for instructions on how to verify an establishment's residue control program.

F. IPP are to correlate through supervisory channels for guidance on increasing the rate of testing.

G. The PHV is to refer to Chapter IV for instructions on test results reporting and actions to take in situations of laboratory-confirmed chemical residue violations.

H. IPP are to retain all carcasses and parts from animals selected for KIS™ testing until all test results are completed.

I. When a KIS™ test result is positive, IPP are to maintain regulatory control of the carcass testing positive and submit muscle, kidney, and liver tissue samples to the FSIS laboratory for further residue testing, using the instructions provided in FSIS Directive 10,800.2.

V. TESTING FOR NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

A. Ante-mortem and post-mortem findings that may indicate possible NSAID (e.g., flunixin and phenylbutazone) use in all livestock (particularly dairy cattle) include, but are not limited to:

1. Any inflammatory conditions, including arthritis, mastitis, metritis, pneumonia, and peritonitis;

2. Injection sites showing marked local inflammation or necrosis; and

3. Chronic traumatic injuries, or lameness.

B. If the use of NSAIDs is suspected in any livestock, the PHV, or IPP under the direction of the PHV, are to collect tissue samples for submission to the FSIS laboratory using the instruction provided in FSIS Directive 10,800.2.

C. The PHV is to use sound professional judgment to determine when testing for NSAIDs is warranted. The PHV is to consider herd history, the establishment's residue control program effectiveness, and previous FSIS confirmed violative and non-violative NSAID test results in making this determination.

VI. TESTING FOR BETA-AGONISTS

A. IPP are to collect tissue samples for beta-agonist testing (e.g., ractopamine clenbuterol) under conditions when:

1. Livestock presented for slaughter exhibit signs of beta-agonist use or abuse, such as excessive or unusually heavy muscle development and hyperexcitability; and

2. As requested by a State Health or Agriculture official or Fair Board for selected show animals, such as the Grand Champion, or based on reports of beta-agonist use in show animals.

B. When the PHV suspects beta-agonist use, the PHV is to tag these animals as "U.S. Suspect," perform a KIS™ test, and submit tissue samples to the FSIS laboratory for beta-agonist testing, using the instruction provided in FSIS Directive 10,800.2. IPP are to note the request for beta-agonist testing in the Remarks box provided in the Sample Collection Data tab in the Sample Management – Sample Collection field in PHIS.

VII. TESTING OF SHOW ANIMALS

A. For the purposes of this directive, a "lot" of show animals (cattle, hogs, sheep, goats) is defined as all animals presented for inspection from a single fair or livestock show that are otherwise healthy and have an equal chance of being selected for testing. The lot could be comprised of a single or multiple slaughter classes.

B. IPP are to submit tissue samples whenever an establishment presents show animals, including steers, heifers, market hogs, mature sheep, and lambs for slaughter, using the instruction provided in FSIS Directive 10,800.2.

C. When show animals appear otherwise healthy, the PHV, or IPP, under the direction of the PHV, based on their direct knowledge of the establishment history, show history, and professional judgement, are to select the number of healthy show animals from the entire lot of show animals for testing.

D. When show animals appear unhealthy or are suspected of having antibiotic residues (e.g., injection sites, evidence of a disease process), they should be handled as "US Suspects". The PHV will tag as "US Suspect" to conduct a KIS™ test and, if warranted, submit tissue samples for residue testing. These samples are not counted toward the healthy show animal testing requirement.

NOTE: Live animal testing performed at fairs does not change FSIS requirements for show animal testing.

E. For antibiotics (including sulfonamides), IPP are to submit samples to the Midwestern Laboratory (MWL) and select the "CG_SHOW_MWL" task from the drop-down menu in the Sample Management window of PHIS.

VIII. KIS™ TESTING OF BOB VEAL CALVES

A. Under 9 CFR 310.21(b) (1), a "calf" is defined as "up to 3 weeks of age or up to 150 lbs."; this includes "bob veal calves". These calves have a non-functional rumen.

NOTE: IPP are to note that certified groups (calves) described in 9 CFR 310.21(b) (2) no longer exist.

B. IPP are to select bob veal calf carcasses for KIS™ testing from apparently healthy calves, as determined by the IPP or PHV, during ante-mortem inspection.

C. The number of healthy-appearing bob veal calves to sample is based on the percent of the day's estimated slaughter, as indicated in Table 2.

Table 2: Testing of Healthy-Appearing Bob Veal Calves (9 CFR 310.21(b)(4))

Level of testing of healthy-appearing calves	Percent of daily slaughter heads to sample (%)
A	100
B	50
C	30
(start) D	10
E	5
F	2

D. Upon initiation of the slaughtering of bob veal calves at the establishment, IPP are to begin testing at Level D, as shown in Table 2.

E. IPP are to **increase** the testing rate to the next higher level, on the following production day, when three (3) carcasses out of 100 or fewer consecutively tested have a violation for drug residue confirmed by an FSIS laboratory.

F. IPP are to **decrease** the testing rate to the next lower level when no more than two (2) bob veal calves out of 500 bob veal calves consecutively tested have a violation for drug residues confirmed by an FSIS laboratory or when no more than two (2) bob veal calves are confirmed to have a confirmed violative residue by a FSIS laboratory from all bob veal calves tested over a sixty (60) working-day period.

NOTE: Only residue test results reported by FSIS laboratories from the sampling of healthy bob veal calves are used in this calculation.

G. IPP are to retain all carcasses and parts from the bob veal calves selected for KIS™ testing until all test results are completed.

H. When a KIS™ test is positive, IPP are to continue to retain only those bob veal calf carcasses testing positive and submit muscle, kidney, and liver tissue samples to the FSIS laboratory for further residue testing, using the instructions provided in FSIS Directive 10,800.2.

I. IPP are to continue to perform KIS™ tests on bob veal calf carcasses that exhibit disease lesions or signs of treatment but are not to use any of these violative test results in calculating the bob veal calf residue testing rate.

CHAPTER THREE – ANIMAL IDENTIFICATION AND SUPPLIER INFORMATION

I. COLLECTING ANIMAL IDENTIFICATION INFORMATION

A. IPP are to be aware that establishments are required to collect all man-made animal identification (ID) devices and maintain such identification identifiable with the carcass and parts until the completion of post-mortem inspection, including the reporting of FSIS residue test results, in accordance with FSIS Directive 6100.2, Chapter VIII.

B. IPP are to refer to the Animal Identification: Examples of Official Ear Tags document for examples of animal ID tags. Types of animal ID include, but are not limited to:

1. Livestock market or sale barn backtags;
2. Producer ear tags;
3. Feedlot identification tags;
4. Canadian tags;
5. Vaccination (e.g., calf-hood “Bangs” or Brucellosis) tags;
6. Tattoos and brands; and
7. Any special ID used on cattle imported from Mexico and presented for slaughter.

C. IPP are to obtain from the establishment all animal ID information and devices for animals selected for all directed and inspector-generated samples submitted for chemical residue testing.

D. IPP are to document all alphanumeric information from all types of ID tags that are present on the animal selected for sampling and maintain the animal ID information identifiable with the carcass.

E. IPP are to hold all collected identification tags until KIS™ test results report as negative or,

F. For positive KIS™ test results and other samples submitted to the FSIS field service laboratories, IPP are to document all animal ID information in the appropriate data fields in the Sample Collection – Sample Management page in PHIS.

G. For carcasses selected for chemical residue testing that are also subject to blood sample collection for the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) surveillance sampling programs, IPP are to record the animal ID information in PHIS and submit the animal ID tags with the blood sample to the designated State testing laboratory.

H. IPP are to perform one "Other Inspection Requirements" task every month during slaughter operations to verify miscellaneous requirements, including that establishments are collecting and maintaining identification of animals in accordance with 9 CFR 310.2.

I. The Frontline Supervisor (FLS) may allow the use of any alternative method proposed by the slaughter establishment for handling the types of animal ID devices to meet the regulatory requirements if the alternative method provides a ready means of identifying a specific carcass with the corresponding animal ID devices at post-mortem (9 CFR 310.2(b)(4)). The FLS is to determine whether the establishment's alternative method consistently and accurately identifies each animal and its origin as required by 9 CFR 320.1.

II. COLLECTING SUPPLIER INFORMATION

A. IPP are to be aware that an establishment is required to maintain records of each transaction involving its purchase of livestock or poultry, including, but not limited to, the name and address of the livestock or poultry supplier (9 CFR 320.1 and 381.175).

B. IPP are to request from the establishment the animal producer information for all surveillance samples and inspector-generated samples submitted to FSIS laboratories for residue testing.

1. If the producer information is not known at the time of sample collection, IPP are to enter the establishment's name and address into PHIS as the producer and submit the tissue samples for testing. IPP are NOT to hold these samples or delay their submission to the laboratory pending receipt of producer information; or

2. If producer information on a violative result is later determined, IPP are to submit the information to the Office of Policy and Program Development's (OPPD) Policy Development Staff (PDS) by e-mail to residue@usda.gov or by phone at 1-800-233-3935. IPP are to include the establishment name, establishment number, establishment phone number, the laboratory form number for the violative residue result, and the producer information in their correspondence to PDS.

C. IPP are to document a noncompliance report (NR) when an establishment fails to provide information about the violator upon reporting of a violative residue on FSIS testing. IPP are to cite the noncompliance under 9 CFR 417.2(c), if the establishment addresses residues in its HACCP plan; 417.5(a)(1) , if they address residues in a pre-requisite program; or 416.16, if they address residues in their Sanitation Standard Operating Procedures (SSOP).

CHAPTER FOUR - VERIFYING AN ESTABLISHMENT'S RESIDUE CONTROL PROGRAM

I. REPORTING OF TEST RESULTS AND FSIS ACTIONS

A. IPP are to monitor PHIS and review the test results for any residue samples submitted (surveillance and inspector-generated). The PHV is to make a final disposition on the carcass and parts (liver and kidney tissues) and take any necessary regulatory enforcement actions based on the results.
B. PHVs are to condemn the tissues identified as violative in the test results for:

1. Violations in muscle or in parts and muscle – condemn parts and carcass; or

2. Violations in parts but no violation in muscle – condemn parts, pass carcass.

C. For residue results reported as "Not Detected" or "Detected – non-violative," the PHV is to release the carcass and its parts.

D. For residue test results reported as "Detected but not Quantified, Violation" or those that have a quantified violation for some part (such as organ tissue) without a quantified muscle result, the PHV is to condemn the carcass and all parts.

E. IPP are to notify the establishment of residue test results as soon as they are reported and the final disposition of any carcass and its parts. IPP are to discuss any developing trends in violative residue results at the weekly meeting.

F. An establishment that determines in its hazard analysis that chemical residues are a hazard NRLTO is required under 9 CFR 417.3(b)(4) to reassess its HACCP plan each time a violative drug residue is found by FSIS. IPP are to verify that an establishment takes corrective actions in response to violative test results that meet all applicable requirements of 9 CFR 417.3(b) for an unforeseen hazard, including:

1. Performing a reassessment of the hazard analysis;

2. Documenting the reassessment.

G. If IPP verify that appropriate corrective actions were followed including adequate measures to prevent recurrence, and the establishment has a history of having an adequate residue control program, IPP are NOT to issue an NR.

H. If IPP determine that the establishment has failed to take corrective actions, IPP are to document an NR in PHIS and cite 9 CFR 417.5(a) (1) and 417.3(b).

I. When IPP are notified that the establishment had more than one (1) FSIS laboratory-confirmed residue violation from animals purchased from a single source (Residue Repeat Violator), IPP are to:

1. Discuss this finding with the establishment at the next weekly meeting, and

2. Inform the establishment that its failure to prevent this hazard from recurring raises questions about the adequacy of the establishment's HACCP system.

J. IPP are to issue an NR if it is determined that the establishment has not maintained adequate support for decisions in their hazard analysis as outlined in Chapter IV.

K. IPP are to issue an NR for each occurrence of additional residue violations between an establishment and a source listed on the Residue Repeat Violator List. IPP are to associate the NRs in accordance with FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System,* and include a description of developing trends of noncompliance, the number and date of previous associated NRs, and a description of previous corrective actions.

L. If IPP determine that the establishment has failed to address the chemical residues in its hazard analysis at animal receiving, IPP are to document an NR under 9 CFR 417.5(a)(1) and 417.2(a). IPP are to verify the establishment's reassessment of its hazard analysis under 9 CFR 417.4 and verify whether any modifications to the hazard analysis were made.

M. When an establishment demonstrates a trend of noncompliance, the PHV is to raise concerns, through supervisory channels, to the District Office (DO) for potential enforcement action.

II. SLAUGHTER HACCP VERIFICATION TASK

A. IPP are to perform a Slaughter HACCP Verification Task in establishments that include residues in their HACCP plan for animals it receives for slaughter. IPP are to follow the instructions in FSIS Directive 5000.1, including verification of the implementation of the establishment's controls that are cited as support for decisions in the hazard analysis regarding chemical residues at receiving and collection of supplier information.

B. IPP are to verify that the establishment's prerequisite programs continue to support the decisions in the hazard analysis for chemical residues at animal receiving. Examples of prerequisite programs an establishment may use include: purchase specifications, an industry quality assurance certification program, attestation from the herd veterinarian ensuring the livestock were treated under a valid client – patient relationship (VCPR), individual animal or herd treatment records, or certification from the seller or livestock market that the animals purchased are not from a producer on the Residue Repeat Violator List. These examples are not intended to be an exhaustive list.

III. HAZARD ANALYSIS VERIFICATION

A. When performing the HAV task as described in FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task* in a slaughter establishment, IPP are to evaluate the design of the establishment's hazard analysis and HACCP plan. The following steps describe additional information for IPP verification in a slaughter establishment when conducting a HAV task.

B. Flowchart (9 CFR 417.2(a) (2)): IPP are to verify that the establishment has included animal receiving as a step in its flow chart.

C. Hazard analysis (9 CFR 417.2): IPP are to verify that the establishment has considered chemical residues (e.g., drugs, pesticides, and chemical contaminants) as a potential hazard at animal receiving.

1. If the establishment determines that chemical residues are a hazard reasonably likely to occur at animal receiving, IPP are to verify that the establishment has included one or more Critical Control Points (CCPs) to control the hazard in its HACCP plan.

2. If the establishment determines that chemical residues are a hazard not reasonably likely to occur at animal receiving because it implements a prerequisite program (e.g., purchase specifications, certification from the seller or livestock market that the animals purchased are not from a producer on the Residue Repeat Violator List), IPP are to verify that:

    a. The slaughter establishment has procedures in place to avoid slaughtering animals that contain illegal residues through its prerequisite program;

    b. The prerequisite program is written;

    c. The program is designed to prevent the hazard from being reasonably likely to occur;

    d. The establishment maintains supporting documentation that the program has been validated (i.e., scientific or technical support and in-plant validation data);

    e. The records are sufficient to demonstrate that the program is being implemented as written;

    f. The records are sufficient to demonstrate the program effectively prevents the hazard (i.e.,

on-going verification of the decision that the hazard is not reasonably likely to occur); and

g. The program describes actions that the establishment will take when it fails to implement the program, or when it finds that the program has failed to prevent the hazard (i.e., corrective actions in response to an unforeseen hazard per 9 CFR 417.3(b).

3. If IPP determine that the establishment has failed to address the chemical residues in its hazard analysis at animal receiving or that the establishment has failed to provide ongoing support that the hazards are controlled, IPP are to document an NR and cite 9 CFR 417.5(a)(1) and 417.2(a).

D. Supporting Documentation (9 CFR 417.5(a)(1)): IPP are to determine whether the establishment considers residue test results from FSIS testing and whether these results continue to support its hazard analysis decision.

E. Validation (9 CFR 417.4): IPP are to determine if the establishment has met the regulatory requirements for validation to support its control of residues in its HACCP system. IPP are to follow instruction in FSIS Directive 5000.6 Step 4 and Step 6.

1. IPP are to determine the type of documentation the establishment uses to support its control of residues in its HACCP system.

2. If the establishment implements its own residue testing as a prerequisite program or CCP, IPP are to evaluate the program and determine if the establishment implements its testing program and takes action on any violative test result in a manner that supports its hazard analysis decision. There is no requirement that a slaughter establishment conduct its own residue testing; however, an establishment may implement a testing program to support its hazard analysis

NOTE: The purpose of validation is to demonstrate that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product while the purpose of ongoing verification is to support that the HACCP system is functioning as intended on an ongoing basis. Because the control of residues in the live animal occurs at pre-harvest, there are no known controls that can be implemented within the slaughter process, following animal receiving, to prevent residues. A slaughter establishment will typically use scientific support, such as historical FSIS testing data, and best practices guidance for its validation. In-plant validation data would include documentation that the establishment is following its residue control program to ensure chemical residues are not a hazard in the animals it receives for slaughter and to continually support that the hazard is prevented from becoming reasonably likely to occur (RLTO).

F. Reassessment (9 CFR 417.4(a)(3)(i)): IPP are to determine whether the establishment reassesses its HACCP plan annually and in response to each violative residue test result through FSIS testing or other testing, and that the establishment taking appropriate corrective actions in response to violative residue test results, including:

1. The establishment confirms the producer's history by reviewing the Residue Repeat Violator List to determine if animals it has received came from a supplier with one or more FSIS Lab confirmed violations within the past 12 months;

2. The establishment purchases animals from producers that have a history of providing residue-free animals and employs an effective residue prevention program, including verifying the receipt and accuracy of relevant documentation;

3. The establishment ensures that animals received for slaughter are adequately identified to allow for traceback to the producer or farm of origin in the event of a residue violation.

V. LIVESTOCK USED FOR RESEARCH

A. To be eligible for slaughter, livestock used for research are to meet the criteria listed in 9 CFR 309.17. The operator of the establishment, the sponsor of the investigation or research, or the investigator or researcher is required to submit data or summary evaluations of data that demonstrates the use of the research product will not result in adulterated products from the research animals. The agencies responsible for granting approval for the use of livestock for research include the FDA, EPA and APHIS.

B. At the request of the manufacturer, researcher, or investigator, the reporting of the date and location of the slaughter can be waived by FDA provided the investigational animals are maintained under investigational condition and under the supervision of the manufactures/investigator for the investigation drug withdrawal period. In these situations, IPP will not be notified when these animals are sent for slaughter.

C. If the investigator does not request a waiver from the requirements to report the date and place of slaughter, the investigator or sponsor is to supply FSIS with the slaughter date, the establishment name, establishment's physical address, the number and type of experimental livestock, and the number and type of control animals, with reference to the FDA approval letter at least ten days prior to the slaughter date.

D. If the slaughter request meets the guidelines of the approval letter (from FDA, APHIS VS, EPA, or FSIS), PDS issues written approval, as defined in 9 CFR 309.17, and sends a copy to the District Manager (DM), the Inspector-in-Charge (IIC), the Investigator, the sponsor, and the establishment.

E. Upon receipt of the written approval from PDS, the PHV is to provide ante-mortem and post-mortem coverage for these animals, noting any abnormal or adverse findings. Following slaughter, the PHV is to complete pages 2 and 3 of the written approval letter and fax the completed pages to the attention of the Residue Staff, PDS, at fax number 844-876-9475, or e-mail to residue@usda.gov.

VI. VERIFYING SLAUGHTER ELIGIBILITY OF VEAL CALVES WITH SUSPECTED IMPLANTS

A. During ante-mortem inspection of pre-ruminant calves whose meat will be labeled as "veal," IPP are to determine whether the animal has an implant.

B. When an implant is present, IPP will feel a linear, firm swelling under the skin when palpating the ear, brisket, or tail head. The implant may feel like "beads on a string." The individual pellets that make up the implant are approximately 3 mm in size and about 2 mm apart. Signs that an implant has been used may include:

1. Palpable implant (linear, firm swelling under the skin of the ear, brisket or tail);
2. Missing ears;
3. Ears with incisions, indicating recent surgery;
4. Mutilated ears;
5. Atrophied testicles; or
6. Unusually heavy muscle development.

C. When IPP observe signs on ante-mortem inspection of an implanted pre-ruminant calf, they are to retain the animal and the PHV is to tag it as "U.S. Suspect." IPP are to correlate with the PHV to determine when the entire lot (i.e., all calves) from the same producer should be held for PHV disposition.

D. During post-mortem verification activities in pre-ruminant calves, IPP are to palpate the ears, brisket, and tail head of the "U.S. Suspect" carcasses for implants. IPP are to consult with their supervisor to determine whether adjustments in the slaughter line speed may be necessary to complete the inspection procedure.

1. IPP are to be aware that if necessary (e.g., when the ear has an identification device, such as a metal tag or tattoo), establishment personnel may remove ears before hide removal, place them in a plastic bag, and attach the bag to the carcass. The establishment may also remove the ears when skinning the head and present them for inspection in a manner acceptable to the PHV;

2. IPP are to retain the carcasses of pre-ruminant calves exhibiting signs of an implant for post-mortem inspection by the PHV to determine compliance; and

3. The PHV is to examine the rumen of the retained carcass to determine its functionality.

E. Following completion of the post-mortem exam, the PHV is to:

1. Condemn the carcass if the rumen was not functioning (pre-ruminant), and the animal had an implant, missing ears, ears with incisions that indicate recent surgery, or ears mutilated to the extent that the PHV is unable to determine whether an implant was present; or

2. Pass the carcass for human food if the animal has a functioning rumen and does not meet any of the criteria for condemnation described in Section VI.B.

F. If the PHV determines that a calf had an implant and a non-functioning rumen, IPP are to document an NR under 9 CFR 417.5(a)(1) and verify that the establishment takes the appropriate corrective actions under 9 CFR 417.3(a) or 417.3(b).

G. If the establishment fails to take appropriate corrective action, the PHV is to document a NR and take the appropriate enforcement action as set out in FSIS Directive 5000.1.

VII. VERIFYING TEST AND HOLD (or Control)

A. For surveillance residue testing of livestock, IPP are to verify that the establishment holds or controls livestock carcasses selected for testing pending the test results. For surveillance residue testing of poultry, IPP are to continue to recommend that establishments hold the specific poultry carcasses selected for residue testing pending the test results.

B. IPP are to take regulatory control action to prevent adulterated product from entering commerce when it becomes apparent that the establishment failed to hold or control a carcass and its parts that was subjected to surveillance residue testing and the test result was violative.

C. If an establishment does not hold or maintain control of product tested by FSIS for residue testing, IPP are to document an NR because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as required in 9 CFR 417.5(c). In this situation, IPP are to immediately contact the District Office (DO).

D. If IPP determine that the establishment failed to hold or maintain control of a livestock carcass selected for surveillance residue testing prior to the reporting of residue test results, they are to correlate with their supervisory chain of command for further guidance.

CHAPTER FIVE – DATA ANALYSIS

The Office of Planning, Analysis, and Risk Management (OPARM) will review residue sample collection and analysis rates and residue sampling results to determine whether trends exist nationally, by district, and by circuit, or other factors, if identified. OPARM will share these analyses with the Office of Public Health Science (OPHS), Office of Policy and Program Development (OPPD), and the Office of Field Operations (OFO).

CHAPTER SIX – QUESTIONS

Refer questions regarding this directive to your immediate supervisor or to the OPPD through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Residue as the Inquiry Type.

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

Assistant Administrator
Office of Policy and Program Development