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9 IN THE UNITED STATES DISTRICT COURT  
 10 EASTERN DISTRICT OF CALIFORNIA

11  
12 David Shayne Heine, California Veal Tech, Inc.  
 a California corporation,

13 Plaintiffs,

14 v.

15 Tim Vilsack in His Official Capacity as United  
 16 States Secretary of Agriculture, United States  
 Department of Agriculture, United States  
 17 Department of Agriculture Food Safety and  
 Inspections Service, Yudhbir Sharma, DVM,  
 18 USDA Employee Known Only as "Dr. Pannu,"  
 USDA Employee Known only as "Ken," USDA  
 19 Employee Known only as "Dr. Redding,"  
 USDA Employee Known Only as "Dr.  
 20 Henley," Dr. Amy Lieder, Penny Patrali and  
 DOES 1-100 inclusive,

21 Defendants.

Case No. 1:12-cv-01992-AWI-SMS

**STIPULATION AND ORDER FOR  
DISMISSAL OF ACTION**

22  
23 The parties to this action, by and through their undersigned attorneys of record, hereby  
24 stipulate and agree as follows:

25 **RECITALS**

26 A. Plaintiff David Shayne Heine ("Heine") is owner of a sole-proprietorship business  
 27 entity alternately called "Shayne's Custom Calves" and "Cal Veal" and through these entities he  
 28 purchases unwanted calves from dairies in California and transports said calves to federally-

1 inspected meat slaughter and processing facilities in California. The calves are to be slaughtered and  
2 processed to provide food for human consumption.

3 B. The Food Safety and Inspection Service (“FSIS”) is the agency of the United States  
4 Department of Agriculture (“USDA”) charged with the responsibility of enforcing the requirements  
5 of the Federal Meat Inspection Act. Pursuant to this authority, FSIS administers the food safety  
6 inspection programs at federally-inspected slaughter and processing facilities which slaughter and  
7 process veal calves in the United States, including the State of California. As part of this inspection  
8 program, FSIS inspection program personnel conduct in-plant screening tests of meat samples at  
9 such facilities when they suspect an animal presented for slaughter may have violative levels of  
10 antimicrobial drug residues.

11 C. A dispute has arisen between Heine and USDA regarding the application of FSIS’s  
12 meat inspection regulations to calves delivered by Heine to federally-inspected meat processing  
13 facilities. Plaintiff Heine contends that FSIS, through its employees, has treated calves delivered by  
14 Heine to federally-inspected slaughter and processing facilities differently than calves delivered for  
15 slaughter and processing by other persons. Defendants deny that contention and deny that Plaintiffs  
16 are entitled to any relief under the claims alleged in the Third Amended Complaint filed in this  
17 action. In order to clarify the federal regulatory requirements for the slaughter and processing of  
18 veal calves at federally-inspected facilities at issue in this litigation, resolve this action, and avoid the  
19 expense and uncertainty of further litigation without any admission of fault or liability, the parties  
20 stipulate as follows:

21 **STIPULATION**

22 1. The parties stipulate and agree that the slaughter and processing of veal calves  
23 intended for human consumption is regulated by the Federal Meat Inspection Act (21 U.S.C. §§601  
24 *et seq.*, as amended) and the regulations promulgated by FSIS pursuant to the authority of the FMIA,  
25 *i.e.*, Title 9 of the Code of Federal Regulations, Sections 300-end, including without limitation 9  
26 CFR Sections 310.21, 309.13 and 309.16. A true and correct copy of the current version of 9 CFR §  
27 310.21 (“Carcasses suspected of containing sulfa and antibiotic residues; sampling frequency;  
28 disposition of affected carcasses and parts”) is attached to this Stipulation as Exhibit A and

1 incorporated herein by reference. A true and correct copy of the current version of 9 CFR § 309.13  
2 (“Disposition of condemned livestock”) is attached to this Stipulation as Exhibit B and incorporated  
3 herein. A true and correct copy of the current version of 9 C.F.R. § 309.16 (“Livestock suspected of  
4 having biological residues”) is attached as Exhibit C and incorporated herein. FSIS inspection  
5 program personnel have an obligation to conduct inspection activities in accordance with the FSIS  
6 regulations.

7       2.       FSIS Directive 10,800.1, Rev. 1, provides instructions to FSIS inspection program  
8 personnel (IPP) on selecting animals and performing chemical residue sample collection and testing  
9 procedures, including veal calves. Directives are instructions written to FSIS employees to  
10 implement FSIS policies and procedures under the authority of the FMIA. Directives remain in  
11 effect for an indefinite period of time and are primarily administrative in nature. Directives may be  
12 revised without notice and are not subject to notice and comment rulemaking. A true and correct  
13 copy of FSIS Directive 10,800.1, Rev. 1 (“Residue Sampling, Testing and Other Verification  
14 Procedures under the National Residue Program for Meat and Poultry Products”), which is currently  
15 in effect, is attached to this Stipulation as Exhibit D and incorporated herein by reference. FSIS  
16 inspection program personnel have a responsibility to follow the procedures contained in this  
17 directive until revised.

18       3.       Nothing in this Stipulation and Order creates any obligations or responsibilities that  
19 do not already exist under current law.

20       4.       The parties stipulate and agree that the above-captioned action should be dismissed  
21 without prejudice as to all parties and causes of action, each party to bear its own attorneys’ fees and  
22 costs.

23 Dated: May 27, 2015

BENJAMIN B. WAGNER  
United States Attorney

25 By: /s/ Benjamin E. Hall  
26 BENJAMIN E. HALL  
27 Assistant United States Attorney

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Dated: May 27, 2015

/s/ Scott C. Safian  
SCOTT C. SAFIAN  
Director, Enforcement and Litigation Division  
Office of Investigation, Enforcement and Audit  
Food Safety and Inspection Service

Dated: May 26, 2015

THE ZUMWALT LAW FIRM, APC.

By: /s/ Graham S. Lopez  
GRAHAM S. LOPEZ  
Attorneys for Plaintiffs

Dated: May 26, 2015

/s/ David Shayne Heine  
DAVID SHAYNE HEINE  
Plaintiff

**ORDER**

IT IS SO ORDERED. This action is hereby DISMISSED without prejudice, and the case shall be administratively closed.

IT IS SO ORDERED.

Dated: May 28, 2015

  
\_\_\_\_\_  
SENIOR DISTRICT JUDGE

# Exhibit A



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\*\*\* This document is current through the May 14, 2015 \*\*\*  
\*\*\* issue of the Federal Register \*\*\*

TITLE 9 -- ANIMALS AND ANIMAL PRODUCTS  
CHAPTER III -- FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE  
SUBCHAPTER A -- AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POUL-  
TRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION  
PART 310 -- POST-MORTEM INSPECTION

**Go to the CFR Archive Directory**

*9 CFR 310.21*

§ 310.21 Carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected carcasses and parts.

- (a) Calf carcasses from animals suspected of containing biological residues under § 309.16(d) of this subchapter shall, on post-mortem inspection, be handled in accordance with the provisions of this section.
- (b) For purposes of this section, the following definitions shall apply:
  - (1) Calf. A calf up to 3 weeks of age or up to 150 pounds.
  - (2) Certified calf. A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.
  - (3) Healthy carcass. A carcass that an inspector determines shows no lesions of disease or signs of disease treatment at post-mortem inspection
  - (4) Producer. The owner of the calf at the time of its birth.
  - (5) Sick calf carcass. A calf carcass that an inspector on post-mortem inspection determines has either signs of disease treatment or lesions of disease or was from an animal identified as sick on ante-mortem.
  - (6) Sign of treatment. Sign of treatment of a disease is indicated by leakage around jugular veins, subcutaneous, intramuscular or intraperitoneal injection lesions, or discoloration from particles or oral treatment in any part of the digestive tract.
  - (7) Veterinary medical officer. An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(c) Selection of carcasses for testing. The inspector shall perform a swab bioassay test =n1 on:

=n1 The procedures for performing the swab bioassay test are set forth in one of two self-instructional guides: "Performing the CAST" or "Fast Antimicrobial Screen Test." These guides are available for review in the office of the

FSIS Docket Clerk, Room 4352 South, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

- (1) Any carcass from a calf tagged as "U.S. Suspect" at the time of ante-mortem inspection, except that calves whose carcasses are condemned for pathology shall not be tested for drug residues.
- (2) Any carcass which he/she finds has either lesions of disease which is not condemned because of these lesions or a sign of treatment of disease at the time of post-mortem inspection,
- (3) Any carcass of a calf from a producer whose calf or calves have previously been condemned for residues as prescribed in paragraph (e) of this section, and
- (4) Carcasses from healthy-appearing certified and noncertified calves, as determined by the veterinary medical officer during ante-mortem inspection, will be selected for testing as set forth below:

Testing level	Sampling Rate (percent of estimated day's slaughter)	
	Certified	Noncertified
A	100	100
B	50	50
C	20	30
(Start) D	5	10
E	2	5
F	1	2

(d) Testing of carcasses:

- (1) The inspector shall test all carcasses as prescribed in paragraph (c) of this section.
- (2) Upon initiation of this program at an establishment, the inspector shall begin the testing rate for carcasses from healthy-appearing certified and noncertified calves at Level D as prescribed in paragraph (c)(4) of this section. The inspector shall increase the testing rate to the next higher level the following business day when three carcasses in 100 or less consecutively tested show a positive test result for a drug residue. The inspector shall decrease it to the next lower level when no more than two calves show a positive test result for a drug residue in either 500 calves consecutively tested or all calves tested over a 60 working day period.
- (3) Test results shall be determined by the veterinary medical officer.
- (4) The establishment may designate one or more of its employees to aid the inspector in performing the swab bioassay test under the supervision of the veterinary medical officer who shall interpret the results, maintain animal identification with the test unit, and ensure integrity of the testing program.
- (5) All carcasses and parts thereof from calves selected for testing shall be retained until all test results are complete.
- (6) The veterinary medical officer shall condemn all carcasses and parts thereof for which there are positive test results and release for human consumption all carcasses and parts thereof for which there are negative test results.
- (7) If there is a positive test result, subsequent calves from the producer of the calf shall be tested in accordance with paragraph (e) of this section. These test results will not be included in computations to determine an establishment's compliance record.
- (8) The veterinary medical officer may reduce inspection line rates when, in his/her judgment, the prescribed testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for extensive testing.

(e) Calves from producers with a previous residue condemnation. The inspector shall perform a swab bioassay test on all carcasses of all calves in the group. The veterinary medical officer shall determine the test results and shall condemn any carcass and parts thereof for which there is a positive test result and pass for human consumption any such carcass and parts thereof for which there is a negative test result. All subsequent calves from the same producer which

has previously sold or delivered to official establishments any carcass that was condemned because of drug residues must be tested according to this paragraph until five consecutive animals test completely free of animal drug residues.

(f) If the owner or operator of an official establishment disagrees with the veterinary medical officer's disposition of carcasses and parts thereof, the owner or operator may appeal as provided in section 306.5 of this chapter.

**HISTORY:** [50 *FR* 32164, Aug. 9, 1985, as amended at 52 *FR* 2104, Jan. 20, 1987; 55 *FR* 7475, March 2, 1990; 60 *FR* 66482, 66483, Dec. 22, 1995, as confirmed at 61 *FR* 4849, Feb. 9, 1996]

**AUTHORITY:** AUTHORITY NOTE APPLICABLE TO ENTIRE PART:  
21 *U.S.C.* 601-695; 7 *CFR* 2.18, 2.53.

**NOTES:** NOTES APPLICABLE TO ENTIRE TITLE:

**EDITORIAL NOTE:** Other regulations issued by the Department of Agriculture appear in title 7, title 36, chapter II, and title 41, chapter 4.

**NOTES APPLICABLE TO ENTIRE CHAPTER:**

[PUBLISHER'S NOTE: For Chapter III Policy Statements, see: 62 *FR* 55996, Oct. 28, 1997; 64 *FR* 2803, Jan. 19, 1999.]

**NOTES APPLICABLE TO ENTIRE PART:**

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 310 Notice of Complying with Food Safety Standards, see: 62 *FR* 63254, Nov. 28, 1997.]

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 310 Changes to Salmonella verification sampling program, see: 78 *FR* 53017, Aug. 28, 2013; 79 *FR* 32436, June 5, 2014.]



# Exhibit B



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TITLE 9 -- ANIMALS AND ANIMAL PRODUCTS  
CHAPTER III -- FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE  
SUBCHAPTER A -- AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POUL-  
TRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION  
PART 309 -- ANTE-MORTEM INSPECTION

**Go to the CFR Archive Directory**

*9 CFR 309.13*

§ 309.13 Disposition of condemned livestock.

(a) Except as otherwise provided in this part, livestock identified as U.S. Condemned shall be killed by the official establishment, if not already dead. Such animals shall not be taken into the official establishment to be slaughtered or dressed; nor shall they be conveyed into any department of the establishment used for edible products; but they shall be disposed of in the manner provided for condemned carcasses in part 314 of this subchapter. The official U.S. Condemned tag shall not be removed from, but shall remain on the carcass until it goes into the tank, or is otherwise disposed of as prescribed in part 314 of this subchapter, at which time such tag may be removed by a Program employee only. The number of such tag shall be reported to the veterinary medical officer by the inspector who affixed it, and also by the inspector who supervised the tanking of the carcass.

(b) Any livestock condemned on account of ketosis, swine erysipelas, vesicular diseases, grass tetany, transport tetany, parturient paresis, anasarca, anaplasmosis, leptospirosis, listeriosis, or inflammatory condition including pneumonia, enteritis, and peritonitis may be set apart and held for treatment under supervision of a Program employee or official designated by the area supervisor. Veal calves that are unable to rise from a recumbent position and walk because they are tired or cold may also be set apart and held as provided in this paragraph. The U.S. Condemned identification tag will be removed by a Program employee following treatment under such supervision if the animal is found to be free from any such disease.

(c) Livestock previously affected with listeriosis, including those released for slaughter after treatment under paragraph (b) of this section, shall be identified as U.S. Suspect.

(d) When livestock under the provisions of this section is to be released for a purpose other than slaughter, the operator of the official establishment or the owner of the livestock shall first obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction.

**HISTORY:** [35 FR 15563, Oct. 3, 1970; 72 FR 38700, 38729, July 13, 2007]

**AUTHORITY:** AUTHORITY NOTE APPLICABLE TO ENTIRE PART:  
*21 U.S.C. 601-695; 7 CFR 2.18, 2.53.*

**NOTES:** [EFFECTIVE DATE NOTE: 72 *FR* 38700, 38729, July 13, 2007, amended paragraph (b), effective Oct. 1, 2007.]

**NOTES APPLICABLE TO ENTIRE TITLE:**

**EDITORIAL NOTE:** Other regulations issued by the Department of Agriculture appear in title 7, title 36, chapter II, and title 41, chapter 4.

**NOTES APPLICABLE TO ENTIRE CHAPTER:**

[PUBLISHER'S NOTE: For Chapter III Policy Statements, see: 62 *FR* 55996, Oct. 28, 1997; 64 *FR* 2803, Jan. 19, 1999.]

# Exhibit C



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TITLE 9 -- ANIMALS AND ANIMAL PRODUCTS  
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TRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION  
PART 309 -- ANTE-MORTEM INSPECTION

**Go to the CFR Archive Directory**

*9 CFR 309.16*

§ 309.16 Livestock suspected of having biological residues.

(a) Except as provided by paragraph (d) of this section, livestock suspected of having been treated with or exposed to any substance that may impart a biological residue which would make the edible tissues unfit for human food or otherwise adulterated shall be handled in compliance with the provisions of this paragraph. They shall be identified at official establishments as "U.S. Condemned." These livestock may be held under the custody of a Program employee, or other official designated by the Administrator, until metabolic processes have reduced the residue sufficiently to make the tissues fit for human food and otherwise not adulterated. When the required time has elapsed, the livestock, if returned for slaughter, must be re-examined on ante-mortem inspection. To aid in determining the amount of residue present in the tissues, officials of the Program may permit the slaughter of any such livestock for the purpose of collecting tissues for analysis for the residue. Such analysis may include the use of implant screening procedures designed to detect the presence of antimicrobial residues in any species of livestock.

(b) All carcasses and edible organs and other parts thereof, in which are found any biological residues which render such articles adulterated, shall be marked as "U.S. Condemned" and disposed of in accordance with § 314.1 or § 314.3 of this chapter.

(c) [Reserved]

(d) Calves shall not be presented for ante-mortem inspection in an official establishment except under the provisions of this paragraph.

(1) Definitions. For purposes of this paragraph, the following definitions shall apply:

(i) Calf. A calf up to 3 weeks of age or up to 150 pounds.

(ii) Certified calf. A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.

(iii) Healthy calf. A calf that an inspector determines shows no visual signs of disease or treatment of disease at ante-mortem inspection.

(iv) Producer. The owner of the calf at the time of its birth.

(v) Sick calf. A calf that an inspector on ante-mortem inspection determines has either signs of treatment or signs of disease.

(vi) Veterinary medical officer. An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(2) General requirements. (i) The identity of the producer of each calf presented for ante-mortem inspection shall be made available by the official establishment to the inspection prior to the animal being presented for ante-mortem inspection.

(ii) The inspector shall segregate the calves presented for ante-mortem inspection at the establishment and identify each calf as one of the following: (a) Certified, (B) noncertified, or (C) previous residue condemnation.

(3) Certified group. (i) For a calf to be considered certified, the producer and all other subsequent custodians of the calf must certify in writing that while the calf was in his or her custody, the calf was not treated with animal drugs or was treated with one or more drugs in accordance with FDA approved label directions and was withheld from slaughter for the period(s) of time specified by those label directions. All prior certifications must be presented with the animal at the time of slaughter. The certifications shall contain a list of the calves with accompanying identification numbers, as required by paragraph (d)(3)(ii) of this section, followed by the following language:

I hereby certify that, while in my custody, from to (time period of custody), the above-listed calf or calves have not been treated with drugs, or have been treated with one or more drugs in accordance with FDA approved label directions and have been withheld from slaughter for the period(s) of time specified by those label directions. I certify that, to the best of my knowledge and belief, all information contained herein is true, that the information may be relied upon at the official establishment, and that I understand that any willful falsification of this certification is a felony and may result in a fine of up to \$ 250,000 for an individual or up to \$ 500,000 for an organization, or imprisonment for not more than 5 years, or both (21 U.S.C. 677, 18 U.S.C. 1001 and 3571).

Executed on

(date of certification)

(signature of certifier)

(typed or printed name and address of certifier)

(business of certifier)

(ii) Each calf must be identified by use of backtag, eartag, or other type of secure identification which displays a number which shall be recorded on all written certifications.

(iii) The inspector shall have segregated for veterinary medical officer examination any certified calf which he or she determines to show any sign of disease or which is not identified individually. Such animal will be tagged as "U.S. Suspect" and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(c) and (d).

(iv) The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(c) and (d).

(4) Noncertified group. On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as "U.S. Suspect" and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(c). The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(c).

(5) Calves from producers with previous residue condemnation. On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as "U.S. Suspect" and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(e). The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(e).

(e) The name of each and all person(s) who sold or consigned each swine to the establishment shall be made available by the establishment to any Program employee or other authorized employee of the United States Department of Agriculture upon that employee's request and presentation of his or her official credentials. Swine identification, by

means approved by the Animal and Plant Health Inspection Service, USDA, under part 71 of this title, must be maintained throughout post-mortem inspection, in accordance with § 310.23(a) of this subchapter.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0053)

**HISTORY:** [36 FR 24928, Dec. 24, 1971, as amended at 44 FR 45606, Aug. 3, 1979; 44 FR 59499, Oct. 16, 1979; 47 FR 746, Jan. 7, 1982; 47 FR 41336, Sept. 20, 1982; 50 FR 32164, Aug. 9, 1985; 50 FR 53127, Dec. 30, 1985; 52 FR 2104, Jan. 20, 1987; 53 FR 40387, Oct. 14, 1988; 55 FR 7474, Mar. 2, 1990]

**AUTHORITY:** AUTHORITY NOTE APPLICABLE TO ENTIRE PART:  
21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

**NOTES:** NOTES APPLICABLE TO ENTIRE TITLE:

EDITORIAL NOTE: Other regulations issued by the Department of Agriculture appear in title 7, title 36, chapter II, and title 41, chapter 4.

NOTES APPLICABLE TO ENTIRE CHAPTER:

[PUBLISHER'S NOTE: For Chapter III Policy Statements, see: 62 FR 55996, Oct. 28, 1997; 64 FR 2803, Jan. 19, 1999.]

# Exhibit D



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

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# FSIS DIRECTIVE

10,800.1  
Rev. 1

3/3/14

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

### CHAPTER ONE – GENERAL

#### I. PURPOSE

A. This directive provides instructions to inspection program personnel (IPP), including Public Health Veterinarians (PHVs) and Consumer Safety Inspectors (CSIs), on selecting animals and performing chemical residue sample collection and testing procedures in accordance with the National Residue Program (NRP) for meat, and poultry products. This directive addresses the role of IPP in the collection of animal identification (ID) and producer information, in conducting in-plant residue screening tests, and in completing residue sampling tasks using the Public Health Information System (PHIS).

B. This directive advises IPP about their responsibilities, as part of the NRP, to verify that the establishment is controlling residues in its food safety system. It also advises them on actions to take when a residue violation is suspected or identified through sampling, when a residue repeat violator is identified, and when an establishment fails to collect animal ID information or to maintain animal ID identifiable with the carcass pending FSIS residue test results.

#### KEY POINTS:

- *IPP select carcasses for NRP scheduled (directed) sampling from all animals that pass antemortem inspection, regardless of post-mortem disposition.*
- *Establishments that do not have an effective residue control program in place in their Hazard Analysis and Critical Control Point (HACCP) system when slaughtering cull dairy cows and bob veal calves are targeted for in-plant testing for chemical residues at an increased rate.*
- *FSIS condemns an entire carcass and its parts when there is no Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) established tolerance or action level for the identified chemical residue in muscle, whether the chemical residue is found in muscle, organ, or other tissue.*
- *IPP will take action in an establishment that receives animals from a producer who has been determined to have more than one (1) FSIS laboratory-confirmed residue violation within a twelve (12) month period.*
- *The Kidney Inhibition Swab (KIST™) test has replaced the Fast Antimicrobial Screen Test (FAST) in all slaughter establishments*

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- *FSIS laboratories now use multi-residue screening methods on tissue samples submitted from positive KIS™ tests.*
- *The sample size for muscle tissue collected for directed livestock and poultry residue samples submitted to FSIS Laboratories has increased from one (1) pound to two (2) pounds.*
- *FSIS requires livestock slaughter establishments to hold or control livestock carcasses and parts selected for FSIS directed residue testing and not to allow them to enter commerce until the FSIS laboratory reports negative or non-violative test results.*

## **II. SIGNIFICANT CHANGES**

FSIS is reissuing this directive to incorporate instructions from FSIS notices and other FSIS directives related to residue verification and to provide instructions for completing residue verification tasks using PHIS. It also provides clarification on actions that IPP are to take when an establishment fails to provide information on the violator upon reporting of a violative residue.

## **III. CANCELLATIONS**

FSIS Directive 10,800.1, Procedures For Residue Sampling, Testing, And Other Responsibilities For The National Residue Program, dated 7/12/07  
 FSIS Directive 10,220.2, Use of CAST and FAST Screening Tests for Bob Veal Calves, dated 4/9/96  
 FSIS Directive 10,220.3, Using the FAST Antimicrobial Screen Test (FAST) to Detect Antimicrobial Drug Residues in Swine and Cattle, dated 8/23/06  
 FSIS Notice 54-13, Inspection Responsibilities When a Chemical Residue Does not Have an Established Tolerance, dated 8/14/13  
 FSIS Notice 52-13, Level of In-Plant Targeted Testing For Chemical Residues in Cull Dairy Cows and Bob Veal, dated 8/12/13  
 FSIS Notice 73-13, Instructions for Carcass Selection for the National Residue Program Scheduled Samples, dated 11/4/13

## **IV. BACKGROUND**

A. The United States has a complex 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, FDA, and EPA. FSIS works with EPA and FDA to implement the NRP. The primary responsibility of FSIS in the NRP 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 417.2, establishments are 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. A food safety hazard is any biological, chemical, or physical hazard that may cause a food to be unsafe for human consumption. The possible sources from which chemical food safety hazards may arise include chemical contamination, drug residues, and pesticides. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5(a)(1).

C. IPP conduct an in-plant screening test when they suspect an animal presented for slaughter may have violative levels of antimicrobial drug residues. IPP may determine the need for this testing based on herd history, antemortem or post-mortem examination findings, and information posted on the FSIS Residue Repeat Violator List for Use by FSIS Inspection Program Personnel. IPP also use in-plant screening tests to monitor producers and suppliers who have marketed animals with violative levels of antimicrobial residues to determine whether noncompliance has been addressed and corrected and to verify the performance of an establishment's HACCP system in preventing or eliminating chemical residue hazards. In addition, IPP use the in-plant screening test to determine whether further confirmatory testing of tissue samples for antimicrobial drug residues by FSIS laboratory is needed. This testing is necessary in slaughter classes with a higher incidence of violative chemical residues.

D. In July 2012, FSIS announced in a Federal Register Notice (Docket No. FSIS-2012-0012) the restructuring of the NRP and the process used for scheduling of chemical compounds for residue testing. To complement this new approach to sampling and sample scheduling, FSIS has implemented several multi-residue methods (MRMs) for analyzing meat and poultry product samples for animal drug residues, pesticides, and environmental contaminants in its inspector-generated testing program. The MRMs are more efficient than the previous platform and enables FSIS laboratories to analyze each sample for more chemical compounds than was previously possible.

E. On December 10, 2012, FSIS issued a Federal Register Notice, Not Applying the Mark of Inspection Pending Certain Test Results (Docket No. FSIS-2005-0044), announcing that it was changing its procedures. FSIS will withhold its determination on whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. The policy and procedures announced in this Federal Register became effective February 8, 2013.

F. IPP are to refer to Attachment One for information on FSIS program areas' roles and responsibilities under the NRP.

## **CHAPTER TWO - SAMPLING PROJECTS UNDER THE NRP**

### **I. SCHEDULED (DIRECTED) SAMPLING PROGRAMS**

A. Sample requests for NRP scheduled residue testing will appear as directed tasks on the establishment task list in PHIS. The sampling task provides information on when to collect the sample (collection window) and which slaughter production class to sample. IPP are to follow the instructions provided in Attachment Two and in FSIS PHIS 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 Chapter Four.

B. FSIS periodically conducts exploratory residue sampling projects. These projects may focus on residue testing for a specific slaughter class or a specific chemical compound (e.g., dioxin survey). IPP will receive notification of exploratory residue sampling projects through an FSIS Notice.

### **II. INSPECTOR-GENERATED SAMPLING**

#### **A. In-Plant Screening Test (KIS™ Test)**

Under the direction of the PHV, IPP are to conduct a KIS™ test on any carcass that, based on herd history or antemortem or post-mortem inspection findings, may contain a violative drug residue. IPP are to follow the instructions provided in Chapter Three for circumstances warranting a KIS™ test and Chapter Four for performing KIS™ tests and documenting the task in PHIS.

## B. Inspector-Generated Tissue Samples

IPP are to collect and submit tissue samples for inspector-generated residue testing in response to a positive KIS™ test and in situations where a PHV has reason to believe that a carcass or its parts may contain violative levels of one or more chemical residues, even if the KIS™ test is negative. IPP are to refer to Chapter Four for instructions on performing inspector-generated tissue sample collection and documenting the task in PHIS.

## III. IMPORT SAMPLING

Import inspection personnel are to sample imported meat or poultry when PHIS assigns a laboratory Type of Inspection (TOI). Import inspection personnel are to refer to FSIS PHIS Directive 9900.6 for instructions on the sampling of imported products for residues.

## IV. NATIONAL SECURITY AND OTHER SPECIAL SAMPLING

In cases involving national security, threat conditions may dictate additional sampling and verification procedures. The FSIS District Office (DO), Office of Field Operations (OFO) Headquarters, the Policy Development Staff (PDS) of the Office of Policy and Program Development (OPPD), or the Office of Public Health Science (OPHS) will contact IPP with specific instructions in the event of an emergency. The DO, OFO Headquarters, PDS, or OPHS will instruct IPP regarding other special sampling situations on an as-needed basis (See FSIS Directive 5420.2).

## CHAPTER THREE - CIRCUMSTANCES WARRANTING INSPECTOR-GENERATED SAMPLING

### I. PATHOLOGIES AND CONDITIONS WARRANTING CARCASS RETENTION AND SAMPLING

A. At slaughter, IPP are to look for indications of violative chemical use or exposure and collect tissue samples for residue analysis as part of verification of the food safety system. Depending on the slaughter class involved, there are pathologies that, if found, may also indicate residue testing is appropriate.

B. The PHV is to perform a KIS™ test on any carcass suspected of containing violative levels of chemical residues and on any carcass exhibiting signs of systemic conditions (e.g., septicemia, peritonitis, pyemia). The PHV is to use professional judgment when selecting carcasses for chemical or drug residue testing based on evidence of acute or subacute disease conditions, pathological lesions, production practices, herd history, environmental exposure, and threats to homeland security. The PHV is to test animals for chemical residues when they are identified as U.S. Suspect for chemical residues during antemortem inspection and when post-mortem findings may indicate antimicrobial treatment, violative chemical use or exposure, even if the carcass and its parts have been condemned.

C. The following list contains descriptions of pathologies and conditions that may warrant testing of carcasses for chemical residues. Residue testing may be appropriate when these conditions are observed. If these conditions exist, IPP are to retain carcasses for PHV inspection and disposition. Whenever needed, PHVs are to refer to the FSIS Entry Training for the Public Health Veterinarian modules for information on performing antemortem and post-mortem disposition determinations.

**NOTE:** PHVs may utilize the Entry Training for the Public Health Veterinarian modules on Post-Mortem Inspection and Multi-Species Dispositions for correlating with CSIs on pathology and regulatory requirements for addressing each condition.

1. Mastitis – Antemortem: Signs of mastitis can vary based on the severity and duration of infection and may exhibit varying degrees of clinical signs, from pus-like or discolored

discharge from the teats, redness and swelling of the udder, to no visible change in the udder. Post-mortem: Carcasses with inflammatory ventral edema in the perineal area or ventral hemorrhages and yellow serous exudates.

2. Metritis – Post-mortem: Acute inflammation, including enlargement of the uterine body; distension of the uterus with a fetid brown, red brown, or black fluid; thinning of the uterine wall and lack of evidence of normal uterine involution (e.g., no lines of contracture in the myometrium).
3. Peritonitis and surgery – Antemortem: Findings of surgical devices (e.g., suture, toggles, fistula devices) are only significant if they are associated with active peritoneal or subcutaneous inflammation. Post-mortem: Localized or diffused active peritoneal inflammation with fibrinous exudate or fetid ascitic fluid or with ventral abdominal cellulites secondary to percutaneous abomasal surgery.
4. Injection Sites – Antemortem and post-mortem: Carcasses with lesions associated with injections. Injection sites may be found in a variety of locations including the neck, shoulder, thorax, axilla, ventral abdomen (along the subcutaneous abdominal vein), flank, hindquarter, pelvic area (perirectal), and tail. Look for signs of cellulitis that is away from pressure points (e.g., tuber ischii, hip joint, stifle joint). These are typically found in the semimembranosus and semitendinosus muscle.

**NOTE:** IPP are not to submit tissue excised from an injection site for residue testing. IPP are to collect tissues from an area away from the injection site.

5. Pneumonia – Antemortem or Post-mortem: Acute, sub-acute, and chronic active pneumonias and pleuritis, resulting from reticulo-peritonitis complex, or embolic pneumonia.
6. Pleuritis – Post-mortem: Inflammation of the pleura lining in the thoracic cavity and lungs.
7. Pericarditis – Post-mortem: fibrinous or fibrinosuppurative inflammation of the pericardium of the heart.
8. Endocarditis – Post-mortem: Inflammation of the endocardium of the heart and acute pulmonary, renal, or other embolic lesions.
9. Septicemia, pyemia or generalized disease – Antemortem and post-mortem: Animals exhibiting any of the following conditions: depression, an elevated or subnormal body temperature, hyperemic skin, congested mucous membranes, dehydration, or poor body condition, in association with an injury or inflammatory condition, such as abscesses, arthritis, pneumonia, mastitis, metritis, or diamond skin.

**NOTE:** Animals exhibiting any clinical or post-mortem signs of septicemia or toxemia are to be tested for residue.

10. Injury or inflammatory conditions – Ante-mortem and post-mortem: Carcasses found with conditions not resulting in condemnation such as arthritis, pneumonia, mastitis, metritis, nephritis, cystitis, or diamond skin.
11. Acute cellulitis or other acute inflammation - Post-mortem: Fibrinous or fibrinosuppurative exudate in any location on the carcass or viscera.
12. Beta-agonist use: Antemortem: Animals exhibiting clinical signs of excessive or unusually heavy muscle development or hyperexcitability. Post-mortem: Heavy muscle development or a "dark cutter." Beta-agonist drugs, such as clenbuterol and ractopamine, may be administered to show animals to give them a competitive advantage.

13. Signs of Treatment – Antemortem and post-mortem: Signs of treatment, as indicated by leakage around jugular veins, subcutaneously, intramuscularly, or intraperitoneally, or clinical signs indicative of treatment by mouth, such as discoloration from particles found in any part of the digestive tract. These are important signs when examining veal calves for testing.

**NOTE:** Dairy cows may present for slaughter with fetlock or ankle bands. These bands indicate that the animal has previously received treatment for a medical condition. When observed, IPP are to correlate with the PHV on when to retain these carcasses for KIS™ testing.

## II. INCREASED SAMPLING FREQUENCY

A. IPP are to refer to the FSIS Residue Repeat Violator List to determine whether a producer is listed as a repeat violator.

B. The PHV is to direct the IPP to increase the frequency of KIS™ testing when the PHV is notified through supervisory channels or otherwise determines that an establishment:

1. Has a supplier that has had more than one (1) FSIS laboratory-confirmed chemical residue violation in the previous 12 months;
2. Receives livestock from a supplier that is on the Residue Repeat Violator List;
3. Does not have a residue control program designed to control residue violations; or
4. Slaughters dairy cows or bob veal calves and does not supply the producer's name and address or some other type of credible certification that demonstrates the supplier is not on the Residue Repeat Violator List (See Chapter Five, I.E., Note, for examples of types of credible certification).

C. The PHV is to review the establishment's chemical residue control program and follow the instructions outlined in Chapter Five on verifying an establishment's control of chemical residues.

D. The PHV is to discuss the findings with the establishment at the weekly meeting and document the meeting in a Memorandum of Interview (MOI). The PHV is to provide the link to the Residue Repeat Violator List to the establishment. This list is accessible on the FSIS Web site using the following link:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>

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

1. Test a minimum of two (2) animals each time the establishment receives animals, 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, up to 100% testing of the lot, 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 producers listed on the FSIS Residue Repeat Violator List;
4. Continue increased testing rate on all dairy cows and bob veal as long as the establishment lacks an effective control program; and

5. Use the increased testing rate for dairy cows and bob veal from any unknown source, even if the animals appear to be normal, as well as on animals with pathologies listed in Section I of this chapter. For bob veal, this increased testing rate is in addition to the rate described in 9 CFR 310.21 (see Section III of this chapter).

F. The PHV is to refer to Chapter Five for instructions on determining compliance and actions to take in situations of multiple laboratory-confirmed chemical residue violations.

### III. KIS™ TESTING OF BOB VEAL CALVES

A. Bob veal calf carcasses for KIS™ testing are to be selected from apparently healthy calves, as determined by the IPP or PHV, during antemortem inspection. A **bob veal** is an immature calf generally considered to be up to 3 weeks of age, or up to 150 pounds with a non-functional rumen (9 CFR 310.21(b)(1)).

**NOTE:** Certified groups (calves) described in 9 CFR 310.21 no longer exist.

B. 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 1.

**Table 1: Testing of Healthy-Appearing Bob Veal Calves (9 CFR 310.21)**

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

C. Upon initiation of the slaughtering of bob veal calves at the establishment, the IPP is to begin testing at Level D, as shown in Table 1.

1. The IPP is to **increase** the testing rate to the next higher level, on the following production day, when three (3) carcasses in out of 100 or less fewer tested consecutively tested have a violation for drug residue confirmed by an FSIS laboratory.
2. The IPP is to **decrease** the testing rate to the next lower level when no more than two (2) bob veal calves have a violation for drug residues confirmed by an FSIS laboratory in out of 500 bob veal calves consecutively tested, or for 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.

D. The PHV is to retain all carcasses and parts from the bob veal calves selected for KIS™ testing until all test results are completed. The PHV may reduce inspection line speeds when, in his or her judgment, the required testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for intensified testing.

E. When a KIS™ test is positive, the PHV is 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 Chapter Four.

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

#### **IV. TESTING FOR NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)**

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

1. Down/disabled livestock;
2. Any active inflammatory conditions, including mastitis, metritis, pneumonia, and peritonitis;
3. Injection sites showing marked local inflammation or necrosis; and
4. Arthritis, chronic traumatic injuries or lameness.

B. If the use of NSAIDs is suspected in any livestock, the PHV is to direct IPP to collect tissue samples for KIS™ testing and submission to the FSIS laboratory for NSAID testing, using the instruction provided in Chapter Four. The PHV is to retain the carcass and its parts pending the receipt of test results.

**NOTE:** The KIS™ test does not detect NSAIDs. Regardless of KIS™ test results, IPP are to collect and submit samples to the laboratory for analysis for NSAIDs whenever the PHV suspects NSAID use.

#### **V. TESTING FOR BETA-AGONISTS**

A. IPP are to collect tissue samples for beta-agonist testing (e.g., ractopamine [Paylean®], 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, hyperexcitability or a “dark cutter;” 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.

**NOTE:** The term “dark cutter” refers to muscle tissue that fails to turn the typical cherry red color when the cut surface is exposed to air and remains dark in color (ranging from dark red to almost black) during processing. Dark cutting beef is most often associated with pre-slaughter stress and has been linked to the misuse of growth promotants.

B. When the PHV suspect beta-agonist use, IPP are 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 Chapter Four. 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. The PHV is to retain the carcass and its parts pending the receipt of test results.

**NOTE:** The KIS™ test does not detect beta-agonist drugs. Regardless of KIS™ test results, IPP are to collect and submit samples to the FSIS laboratory for beta-agonist testing whenever the PHV suspects beta-agonist use.



## VI. TESTING OF SHOW ANIMALS

**NOTE:** For the purposes of this directive, a “lot” of show animals (cattle, hogs, sheep, goats) is defined as all animals presented for inspection each day from a single fair or livestock show that are otherwise healthy and have an equal chance of being selected for testing.

A. IPP are to perform KIS™ testing whenever an establishment presents show animals, including steers, heifers, market hogs, mature sheep, and lambs for slaughter, using the instruction provided in Chapter Four, and as follows:

1. When show animals appear otherwise healthy, the PHV is to select animals at random from the entire lot of show animals for testing at the following frequency:

**Table 2: Number of Show Animals to Choose for KIS™ Testing per Lot Size**

Number of Livestock Animals Per Lot	Number of Animals Tested
1-10	1
11-50	2
51-100	3
100+	4

2. When show animals appear unhealthy or are suspected of having antibiotic residues (e.g., injection sites, evidence of a disease process), IPP are to tag the animals as “U.S. Suspect” and perform a KIS™ test. IPP are to follow the instructions provided in Chapter Four on actions to take based on the KIS™ test results.

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

B. IPP are to refer to Chapter Four for instructions on tissue sample collection and submission for inspector-generated residue tests.

1. For beta-agonists testing of show animals, submit samples to the Western Laboratory (WL) and select the “CG\_SHOW\_WL” task from the drop-down menu in the Sample Management window of PHIS.
2. For antibiotics and sulfonamides testing of show animals, 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.

## VII. TESTING ANIMALS AT A HERD LEVEL

A. IPP are to select animals within a livestock herd for targeted residue testing whenever they suspect that animals within a herd have been treated with a veterinary drug at levels that may exceed tolerances or if they suspect that a herd may have been exposed to an environmental contaminant (e.g., heavy metals, pesticides) at levels of public health concern. IPP are to refer to Table 3 for guidance in determining the number of animals to test based on herd size.

**Table 3: Number of Herd Animals to Select for KIS™ Testing By Herd Size**

Number of Livestock Animals Per Lot	Number of Animals Tested
1-10	1

11-50	2
51-100	3
100+	4

1. If IPP suspect an antimicrobial drug, they are to perform a KIS™ test. If the test is positive, IPP are to submit the appropriate tissue samples to the FSIS Midwestern Laboratory for confirmation.
2. If IPP suspect a chemical exposure other than to an antibiotic, they are to collect tissue samples and submit them to the appropriate FSIS laboratory for testing.

B. IPP are to retain carcasses selected for residue testing pending results reporting from the FSIS laboratory.

C. IPP are to inform the establishment that in the event the laboratory detects a residue at a violative level, FSIS may request a recall of the carcasses from the entire herd.

### VIII. LIVESTOCK USED FOR RESEARCH

A. Livestock used for research are not eligible for slaughter unless the livestock meet the criteria listed in 9 CFR 309.17. The operator of the establishment, the sponsor of the investigation, or investigator 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; USDA Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS); the EPA; and FSIS.

B. Written approval by FSIS is required prior to the time of slaughter, as defined in 9 CFR 309.17 (a)(2). The sponsor of the investigation or the investigator is to contact the Policy Development Staff (PDS) of the Office of Policy and Program Development (OPPD), using the contact information provided in Section IX.F of this Chapter and provide a written copy of the approval letter from the appropriate approving Agency.

C. Based on the requirements of the approving Agency (e.g., FDA), the investigator, sponsor, or establishment is to supply PDS 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 approval letter at least ten days prior to the slaughter date.

D. PDS is to review the information for completeness and accuracy to determine whether the livestock were treated and then withheld from treatment according to the approval letter. PDS also reviews this information to verify that the total number of approved livestock is not exceeded and maintains a record of the actual numbers of experimental and control animals.

E. 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.

F. Upon receipt of the written approval from PDS, the PHV is to provide antemortem and postmortem 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 402-344-5008 or e-mail to [residue@fsis.usda.gov](mailto:residue@fsis.usda.gov).

G. Upon receipt of the completed slaughter information, PDS will send a slaughter report to the approving agency.

## CHAPTER FOUR – IPP RESPONSIBILITIES FOR COLLECTING SAMPLES

### I. GENERAL INFORMATION

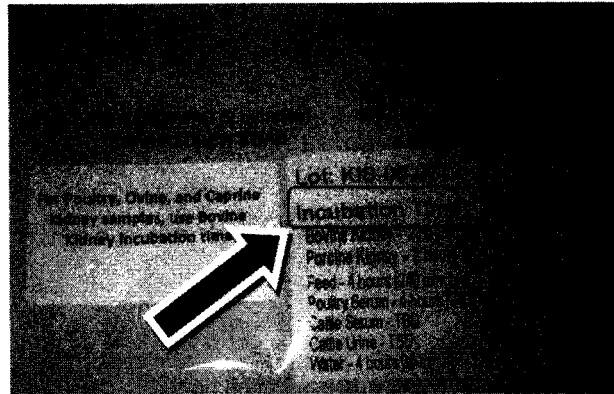
- A. Only IPP are authorized to collect tissue samples for FSIS residue sampling programs. Under the direction of a PHV, IPP are to collect kidney, liver, and muscle tissues from animals whenever there is reason to suspect that a violative level of chemical residue is present or when PHIS assigns a directed residue sampling task to the establishment's task list.
- B. IPP are to ensure sample integrity when collecting, preparing, and packaging samples for chemical residue testing.
- C. For KIS™ test and any other inspector-generated sampling, IPP are to retain the carcass and its parts, unless otherwise subject to condemnation, pending test results. If the KIS™ test is positive, IPP are to continue to retain the carcass and parts (if not already condemned) and submit kidney, liver, and muscle tissues for further analysis to the appropriate FSIS laboratory. IPP are to document the retain tag number in PHIS for any inspector-generated sample submitted.
- D. For directed residue sampling of livestock, IPP are to verify that the establishment holds or controls livestock carcasses selected for testing pending the test results. For directed 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.
- E. IPP are to follow the instructions provided in Attachment Two and FSIS PHIS Directive 13,000.2 for accepting, scheduling, and completing the residue sampling task using PHIS.

### II. ORDERING SAMPLING SUPPLIES FOR RESIDUE TESTING

- A. IPP are to use only sampling supplies provided by FSIS laboratories when conducting residue testing.
- B. IPP are to submit requests for KIS™ test supplies to the Midwestern Laboratory via Outlook (SamplingSupplies-MidwesternLab@fsis.usda.gov). The following KIS™ test supplies are available from the FSIS Midwestern Laboratory:
1. Digital Dry Block Heater (tests up to 20 units);
  2. KIS™ Tests (in packets of 25 tests);
  3. Negative Controls (four (4) tablets - approximately one (1) month, as each reconstituted tablet is good for five (5) days when stored at proper temperatures);
  4. 15 ml Tube of De-ionized or Distilled Water (or equivalent);
  5. Timer;
  6. Transfer Pipettes (in packs of 25 – approximately one month) or equivalent device for delivering 1 ml of water; and
  7. Test Tube Rack (or equivalent device, to hold KIS™ tests).

**NOTE:** Upon receipt of KIS™ test supplies, IPP are to check the label on the KIS™ test package for the correct test incubation time based on the slaughter class and sample source (see Figure 1). IPP should note that incubation times may vary between different lots.

**Figure 1. Image of a KIS™ test swab package with incubation time label**



C. For directed residue samples, IPP can request sampling supply through PHIS by right-clicking on the scheduled residue sampling task on the Task Calendar and select "Order Supplies". A screen will open and display the project code and the FSIS Laboratory that will fill the sample supply request. IPP should include any additional information regarding their request in the "Comments" box provided and then click "submit request" to place their order.

D. For directed and inspector-generated tissue sample (not KIS™ test supplies), IPP may also submit requests for sampling supply to any of the three FSIS Laboratories via Outlook, using one of the following e-mail addresses:

Eastern Laboratory ([SamplingSupplies-EasternLab@fsis.usda.gov](mailto:SamplingSupplies-EasternLab@fsis.usda.gov)),  
Midwestern Laboratory ([SamplingSupplies-MidwesternLab@fsis.usda.gov](mailto:SamplingSupplies-MidwesternLab@fsis.usda.gov)), or  
Western Laboratory ([SamplingSupplies-WesternLab@fsis.usda.gov](mailto:SamplingSupplies-WesternLab@fsis.usda.gov))

IPP are to include the following information in their e-mail request for supplies:

1. The sampling project code;
2. The establishment number and establishment name;
3. The IPP's name and contact phone number; and
4. The specific supplies needed.

**NOTE:** In order to ensure delivery of the requested sampling supplies, the establishment's physical street address (no P.O. Box number) must be entered in PHIS in the "Laboratory Sample Supplies Address" field, under the "General" tab in the Establishment Profile. FSIS laboratories use this address information to ship sampling supplies. Omission or inaccurate entry of this information may result in unnecessary delays in the receipt of sampling supplies. FSIS PHIS Directive 5300.1 provides instruction on how to enter establishment address information into PHIS.

### **III. COLLECTING ANIMAL IDENTIFICATION AND SUPPLIER INFORMATION**

A. IPP are to obtain all man-made animal identification (ID) from the establishment for animals selected for KIS™ testing and for all directed and inspector-generated tissue samples submitted to FSIS laboratories for chemical residue testing. IPP are to document all alphanumeric information from all types of ID tags that are present on the animal selected for sampling. 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, and
6. Any special ID used on cattle imported from Mexico and presented for slaughter.

**NOTE:** IPP are to record any tattoo numbers present on swine selected for chemical residue testing if there is no other type of animal ID information available for the selected animal.

B. IPP are to request from the establishment the producer information for those animals that are KIS™ test positive and for all directed and inspector-generated tissue samples submitted to FSIS laboratories for residue testing (including samples for special residue sampling projects, such as the Dioxin Survey). However, if this 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 into PHIS 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.

C. If producer information on a violative result is later determined, IPP are to submit the information to the Policy Development Staff (PDS) by e-mail to [residue@fsis.usda.gov](mailto:residue@fsis.usda.gov), by fax to 1-402-344-5008, 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. (See Chapter Five, I.E.)

D. IPP are to maintain the animal ID information identifiable with the carcass and hold all collected identification tags until KIS™ test results report as negative. If the KIS™ test results are positive or if samples are submitted for other analyses, IPP are to document all animal ID information in the appropriate data fields in the Sample Collection – Sample Management page in PHIS.

E. For carcasses selected for chemical residue testing that are also subject to blood sample collection for the USDA APHIS brucellosis or tuberculosis 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.

#### **IV. CONDUCTING IN-PLANT SCREENING TESTS (KIS™ TESTS)**

A. Under the direction of the PHV, IPP are to conduct a KIS™ test on any livestock carcass where there is reason to believe the carcass may contain a violative drug residue, based on herd or flock history or ante mortem or post-mortem inspection findings. Although the KIS™ test cannot detect non-antimicrobial drugs, such as NSAIDs (e.g., flunixin, phenylbutazone), IPP are to conduct a KIS™ test when they suspect a violative level of either an antimicrobial drug (e.g., penicillin) or other compound.

**NOTE:** IPP at livestock slaughter establishments that have historically recorded less than one (1) in-plant screening test per week, on average, may not receive KIS™ test supplies. In this situation, IPP are to submit one (1) pound each of kidney, liver, and muscle tissue to the FSIS Laboratory for analysis as an inspector-generated sample, using the instructions provided in Section V of this Chapter.

B. IPP are to refer to Chapter Three for descriptions of pathological conditions and situations that may warrant retention and testing of carcasses. IPP are to retain the carcass while performing the KIS™ test. IPP are to record pathology findings in the appropriate manner in the PHIS.

C. The Inspector-in-Charge (IIC) is to ensure that IPP designated to conduct the KIS™ test, including IPP that are new hires and those who have changed assignments and not previously received training in KIS™ testing, receive training on how to perform the test. The IIC can request training materials from the Office of Outreach, Employee Education and Training (OOEET), Center For Learning (CFL) by sending an e-mail to [CEDL@fsis.usda.gov](mailto:CEDL@fsis.usda.gov).

1. Training materials available include the "Performing the KIS™ Test" CD-ROM and the KIS™ Test Instructions booklet. The KIS™ Test Instructions booklet is available as a related document to this Directive and is also available at the FSIS website using the following link:  
[http://www.fsis.usda.gov/wps/wcm/connect/0a89eec9-ea8c-4ac0-9435-a5e7f108a42b/KIS\\_Booklet\\_0710\\_2.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/0a89eec9-ea8c-4ac0-9435-a5e7f108a42b/KIS_Booklet_0710_2.pdf?MOD=AJPERES)
2. The designated IPP are to review the training materials. Upon completing the review, the IPP are to log onto AgLearn and affirm completion of the KIS™ test training.

D. IPP assigned to livestock slaughter establishments are to record the results of KIS™ tests in the Daily Disposition Record page in the Animal Disposition Reporting (ADR) function in PHIS. IPP are to refer to Attachment Two for instructions on recording KIS™ test results in PHIS.

E. IPP are to refer to Table 4 for information on actions to take based on KIS™ test results.

**TABLE 4. Further Action By IPP Based on KIS™ Test Results**

<b>What is the KIS™ Test Result?</b>	<b>Does the PHV suspect a non-antimicrobial chemical residue may be present in the carcass?</b>	<b>What further action is the IPP to take?</b>
Positive	No	Submit one (1) lb. each of muscle, kidney, and liver tissue to the PHIS-assigned FSIS Laboratory.
	Yes	Submit one (1) lb. each of muscle, kidney, and liver tissue to the PHIS-assigned FSIS Laboratory and provide a brief description of the clinical and pathological findings that prompted the suspicions.
Negative	Yes	
	No	Release the carcass and its parts to the establishment.

F. If the PHV submits tissue samples for pathology and residue testing on the same carcass, the IPP are to reference the pathology form number in the "Remarks" section of the Sample Collection Data tab in the Sample Collection - ADR Sample Management window in PHIS.

G. In circumstances where a carcass and its parts have been condemned based on post-mortem findings, IPP are still to collect and submit liver, kidney, and muscle tissue samples for inspector-generated residue testing and document the carcass as "Condemned" in the Sample Collection – ADR Sample Management window in PHIS. IPP do not need to retain a condemned carcass and its parts pending residue test results.

H. IPP are to package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section VII of this Chapter.

#### I. Documenting KIS™ Test Results Using Digital Photography

1. In cases where there is no PHV available on site, and IPP have doubt as to the KIS™ test result, IPP with FSIS-authorized digital cameras are to take digital photographs of the KIS™ test result. IPP are to capture a close-up image of the KIS™ test result that provides a clear image of the test result and includes information (i.e., retain tag number) that identifies the sample to the corresponding sampled carcass. IPP are to upload the digital image to their government-issued computer and send it electronically via e-mail to the PHV for review and final determination of the test results.
2. The District Office (DO) is to ensure that IPP with FSIS-authorized digital cameras have received training on how to take digital photographs, upload the images to their government-issued computer, and send them electronically via e-mail to the PHV. IPP are not to use personal cameras or other non-FSIS issued electronic devices to take or transmit digital photographs.
3. In situations where digital cameras are not available, when there are problems with Internet connectivity, or if poor digital image quality makes it impossible for the PHV to determine the KIS™ test result, the assigned PHV is to travel to the establishment where the KIS™ test was performed and verify the test results in person. The Agency expects these situations will be rare.
4. IPP are not to use an FSIS-issued digital camera to document conditions within an establishment or collect other types of photographic evidence without prior approval from the DO.

#### V. CONDUCTING INSPECTOR-GENERATED RESIDUE SAMPLING OTHER THAN THE KIS™ TEST

A. In addition to circumstances when a KIS™ test result is positive, IPP are to collect and submit tissue samples for inspector-generated residue testing when an animal presented for slaughter may have violative levels of drug residues based on herd or flock history, information from the RVIS residue violator list, or antemortem or post-mortem examination findings. IPP are to refer to Chapter Three for instruction on circumstances that warrant inspector-generated sampling.

B. IPP are to create inspector-generated residue sampling tasks through the Daily Disposition page of the Animal Disposition Reporting function of PHIS. IPP are to refer to Attachment Two for instructions on how to schedule and complete inspector-generated sampling tasks in PHIS.

C. IPP are to retain the carcass and its parts pending residue test result reporting. IPP are to enter the retain tag number into PHIS and indicate that the carcass and parts are "Retained" in order to elevate the sample analysis priority.

D. For inspector-generated residue testing, IPP are to collect and submit the following tissues for analysis:

1. Livestock (except sheep and goats): one (1) pound each of muscle, kidney, and liver tissues.
2. Sheep and goats: one (1) pound of muscle tissue, one (1) pound of liver tissue and both kidneys.

3. Poultry: one (1) pound of muscle tissue and the kidneys and livers collected from six (6) poultry carcasses.

E. IPP are to package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section VII of this chapter.

## **VI. CONDUCTING DIRECTED RESIDUE SAMPLING TASKS**

A. IPP receive notification of directed residue testing as a task added to the establishment's task list in PHIS. IPP are to follow the instructions provided in Attachment Two for accepting, scheduling, and completing directed residue sampling tasks using PHIS.

B. IPP are to notify establishment management when scheduling a directed residue sample. IPP are to provide enough time for the establishment to hold the sampled carcass.

C. To collect a directed residue sample, IPP are to:

1. Select from all animals that have passed antemortem inspection on the day designated for scheduled sampling for the livestock class indicated on the sample request;
2. Randomly select carcasses at the kill floor stage, regardless of post-mortem disposition. IPP are not to select animals condemned on antemortem because these animals are not permitted into the slaughter facility;
3. Collect and submit the following tissues for analysis from the carcass selected for directed sampling:
  - a. Livestock (except sheep and goats): two (2) pounds of muscle tissue and one (1) pound each of kidney and liver tissues.
  - b. Sheep and goats: two (2) pounds of muscle tissue, one (1) pound of liver tissue and both kidneys.
  - c. Poultry: two (2) pounds of muscle tissue and the kidneys and livers collected from six (6) poultry carcasses.
4. Package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section VII of this chapter.
  - a. For samples that are collected and shipped on the same day, IPP are to submit tissue as fresh, refrigerated samples (not frozen) on gel coolant packs.
  - b. For samples that cannot be shipped on the same day as collected, IPP are to freeze the samples overnight and ship them on the next available shipping day.

D. If the same carcass that is randomly selected for directed residue testing also warrants sample submission because of a KIS™ test result, IPP are to perform both sampling tasks for that carcass and cross-reference the samples in PHIS. IPP are to divide available tissue, when necessary, to submit with both forms when the tissue is limited (e.g., one bob veal kidney or one-half bob veal liver with each form).

1. For the scheduled sample that is also KIS™ test positive, IPP are to cross reference the samples by entering into the remarks box, under the Sample Collection Data tab, "KIS™ test positive" and also enter the retain tag number in this box.



2. For the KIS™ test positive sample submission, IPP are to cross reference the samples by entering in the remarks box, "Also submitted for a scheduled sample on form # (provide form #)".
3. IPP are to ensure that they enter the retain tag number into the data field on both sample forms.

E. IPP are to inform the establishment that livestock carcasses selected for directed residue testing are to be held or controlled until the FSIS laboratory reports the results. IPP are to continue to recommend that an establishment hold any poultry carcass selected for residue testing pending the test results.

**NOTE:** Only the sampled livestock or poultry carcass and its parts are typically held or controlled by the establishment, because for chemical residues, lots are typically determined on a single carcass basis during the slaughter operation, unless there is evidence of flock or herd application of the treatment.

F. When an establishment decides to voluntarily condemn a carcass from a healthy-appearing animal that has been selected for directed residue testing, IPP are to indicate in PHIS that the establishment elected to destroy the carcass. IPP are to indicate that the carcass was "Passed and discarded by establishment" in the Sample Collection Data tab in the Sample Collection - Sample Management window in PHIS.

## **VII. SAMPLE PACKAGING AND SHIPPING**

A. IPP are to use only the shipping materials provided by the laboratory and refer to FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other Applications, for complete instructions on the proper use of sample seals.

1. FSIS Form 7355-2A/2B (FSIS Laboratory Sample Container Seal) comes as a set of seals on a strip, one (1) large seal (7355-2A) for the outer shipping box, one (1) medium-sized strip (7355-2B) for the plastic bag containing the primary container and the form, and several small seals, all bar-coded identically to cross-reference each other.
2. IPP are to use one (1) sample seal set (FSIS Form 7355-2A/2B) for each sample. IPP are to refer to FSIS Directive 7355.1 for instruction on the use of sample seal sets when shipping multiple samples, each with its own sample submission form, in one (1) shipping container.

B. At least one (1) day prior to packing and shipping the sample, IPP are to pre-chill the shipping container in a refrigerator or freezer and place the gel coolant packs in the freezer.

C. Upon collection of the tissue samples, IPP are to:

1. Place each type of tissue collected in a separate sample bag. Do not commingle them even if they are from the same carcass. Expel excess air from the bag prior to closure. Close the bag using the zipper lock closure. If a zipper lock bag is not available, close the top of the bag by twisting the top of the bag and securing it with several loops of rubber band. Then fold the twisted end over and secured again with several loops of rubber band. Place each bagged tissue specimen in a second bag with a label identifying the tissue.
2. Using one (1) FSIS Form 7355-2A/2B, Laboratory Sample Container Seal set, apply one (1) small barcode label to each double-bagged tissue specimen. Repeat steps 1 and 2 for each tissue sample collected.
3. Affix one (1) small bar-coded sample label from FSIS Form 7355-2A/2B sample seal set to the completed and signed printed sample form. Affix the bar-coded label in the space provided at the top center of the form.

4. If the sample will be shipped on the same day as the collection day, place the bagged tissue specimen in a secure refrigerator and allow a sufficient amount of time for chilling, if time permits, prior to packing the sample in the shipping container. If the sample cannot be shipped on the same day as the collection, place the bagged tissue specimens in a secure freezer and keep frozen until the sample can be shipped overnight on the next available shipping day.

D. On the day of sample shipping, IPP are to

1. Retrieve the frozen gel coolant packs from the freezer and the pre-chilled shipping container.
2. Retrieve the tissue specimens from the refrigerator, if shipping overnight on the same day as sample collection, or from the freezer, if shipping one or more days after sample collection, on the next available shipping day.
3. Place the cardboard separator and absorbent pad on the bottom of the shipping container and place the frozen gel coolant pack on top of the corrugated cardboard pad.
4. Place all bagged tissue specimens into a large zipper lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the zipper lock bag. Place the sealed sample bag containing the frozen tissue samples in the shipping container on top of the frozen gel coolant pack. When needed, place a second frozen gel coolant pack on top of the frozen tissue sample, to ensure that the sample arrives at the laboratory at an acceptable temperature.
5. Review the information on the pre-printed carrier shipping airbill (i.e., FedEx airbill) provided with the sampling supplies and select the airbill with the laboratory name and address that corresponds to the FSIS laboratory name and address printed on the FSIS sample form to ensure delivery of the sample to the correct FSIS laboratory. Enter the return address information on the airbill.
6. Place the completed, signed and dated sample form in the plastic sleeve provided. Place the completed sample form and any unused sample seals in the shipping container.
7. Insert the foam plug and press down to minimize the space between the sample and foam plug. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container.

**NOTE:** Do not tape or wrap the samples or use any newspaper or similar material as packing material. Use of such materials may result in a sample discard by the laboratory.

8. Complete the information on the large bar-coded seal from the same FSIS Form 7355-2A/2B sample seal set, sign the seal, and affix the signed, large bar code seal across the seam of the closed sample box flap.
  - a. For shipping containers with self-sticking closures, apply the large bar-coded seal to the closed inner flap of the box parallel to the edge of the closed flap. Then, close the outer flap over the seal and engage the self-sticking closures to secure the top.
  - b. For shipping containers without self-sticking closures, apply the seal across the closed outer flaps. Then secure the outside flaps with clear packaging tape.
9. Affix the carrier shipping airbill on the shipping container and remove any old stamp receipts and carrier shipping bar codes from the container.
10. Ensure that the samples collected remain under FSIS control prior to pickup by the contract carrier.

E. Special instructions for packing and shipping residue samples for Florfenicol analysis.

F. IPP who are seeking to submit tissue samples for Florfenicol analysis are to contact the FSIS Eastern Laboratory for specific instruction on how to pack and ship the sample, using the following Outlook address: [FSIS - Laboratory Inquiry - Eastern Lab \(LaboratoryInquiryEasternLab@fsis.usda.gov\)](mailto:FSIS - Laboratory Inquiry - Eastern Lab (LaboratoryInquiryEasternLab@fsis.usda.gov)).

## **VIII. ACCESSING LABORATORY RESIDUE TEST RESULTS**

A. IPP are to periodically check PHIS for the status of residue test results. Test results are reported in PHIS upon completion of the sample analysis. IPP can access test results in PHIS through the Laboratory Sample data field on the Inspector Home page.

B. Sample discard: If the FSIS Laboratory discards a sample submitted for residue testing, the IPP are to take appropriate action, based on the reason for sample discard.

1. The IPP are to review the reason for sample discard as indicated in PHIS and make the necessary adjustments in how the samples are collected, sealed, and shipped to ensure that the laboratory does not discard future samples because of improper handling or packaging.
2. If the discarded sample was an inspector-generated residue sample, and there are any tissues from the original submission available, IPP are to send replacement tissue samples from the same carcass. IPP are to complete the task in PHIS as an inspector-generated sample, enter all necessary information in the data fields in the Sample Collection window using the instructions provided in [Attachment Two, FSIS PHIS Directive 13000.2](#) and the PHIS User Guide. The IPP is to note in the "Remarks" field that the sample submitted is "REPLACEMENT TISSUES" and reference the sample form number from the original submission.
3. If the discarded sample was an inspector-generated residue sample, and there is only muscle tissue available from the original submission, the IPP are to submit replacement muscle tissue samples from the same carcass and follow the instructions in Section VIII.B.2 of this chapter for completing the task in PHIS. FSIS will use the results from the laboratory testing on the muscle tissue to determine whether there is a residue violation and the disposition of the carcass.

C. IPP are to provide a printed copy of the test results from PHIS to establishment management. IPP are to inform the establishment that it can receive sample results by e-mail if it provides an e-mail address to the IIC, who will enter it into the establishment profile information in PHIS. IPP are to advise establishments to add [LIMSDirect@fsis.usda.gov](mailto:LIMSDirect@fsis.usda.gov) to its e-mail address book to ensure that the e-mails are not blocked. IPP are to provide a printed copy of sample results to the establishment regardless of whether it receives results via e-mail.

## **IX. IPP ACTIONS UPON REPORTING OF TEST RESULTS**

A. IPP are to check PHIS and review the test results for any residue samples submitted (directed or inspector-generated). The PHV is to make a final disposition on the carcass and parts and take any necessary regulatory enforcement actions based on the results.

1. For residue test results reported as "Not Detected" or "Detected - non-violative," the PHV is to:
  - a. Inform the establishment that the test result is "in compliance," and
  - b. Release the carcass and its parts.
2. For residue test results where the identified compound does not have an established tolerance for muscle, such as those test results reported as "Detected but not Quantified, Violation" or those

having a quantified violation for some part (such as organ tissue or fat) without a quantified muscle result, the PHV is to:

- a. Condemn the carcass and all parts, and
  - b. Notify the establishment of the results and the final disposition of the carcass and parts.
3. For a residue test result reported as "Detected –violative," the PHV is to ensure that appropriate disposition is made for the carcass and parts as follows:
- a. Violation in muscle or in muscle and parts – condemn carcass and parts.
  - b. Violation in parts but no violation in muscle – condemn parts, pass carcass.
4. IPP are to notify the establishment of each new violation, any developing trends, and final disposition of any carcass and its parts at the weekly meeting and document the meeting in an MOI.

B. IPP are to seek guidance through their supervisory chain of command for any questions regarding residue test results or action to take based on test results. IPP may also submit questions through AskFSIS using the instructions provided in Chapter Six.

## **CHAPTER FIVE – COMPLIANCE AND ENFORCEMENT ACTIONS**

### **I. IPP Responsibilities**

A. IPP are to verify that an establishment reassesses its HACCP plan whenever any changes occur that could affect the hazard analysis or HACCP plan (9 CFR 417.4(a)(3) for chemical hazards (i.e., residues) and as part of the corrective action when an unforeseen hazard has occurred (9 CFR 417.3(b)(4)) for a chemical hazard (i.e. residues) in its slaughter process. Changes that may affect the hazard analysis or alter the HACCP plan may include changes in livestock suppliers or any new source of livestock for slaughter, such as show animals, cull dairy cows, veal calves, and cattle imported from Mexico for immediate slaughter. Under HACCP, these types of animals represent a different source of livestock that potentially have a higher incidence of drug residue violations and the potential for use of expensive human-use medications or illegal or exotic compounds.

**NOTE:** IPP are to refer to FSIS Directive 9700.1 for specific instructions for performing verification procedures in establishments that import cattle from Mexico for immediate slaughter.

B. Veal Calves with Suspected Implants: PHVs are to condemn any pre-ruminant calf presented for slaughter that has an implant or evidence of implant use.

**NOTE:** PHVs do not need to collect or submit tissue samples when there is an implant present.

1. During antemortem inspection of pre-ruminant calves whose meat will be labeled as "veal," IPP are to determine whether the animal has an implant. Signs that an implant has been used include:
  - a. Palpable implant (linear, firm swelling under the skin of the ear);
  - b. Missing ears;
  - c. Ears with incisions, indicating recent surgery;
  - d. Mutilated ears;

- e. Atrophied testicles; or
- f. Unusually heavy muscle development.

When IPP observe signs on antemortem inspection of a pre-ruminant calf that an implant exists, they are to retain the animal and 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 tagged "U.S. Suspect."

- 2. 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.

**NOTE:** If an implant is present, IPP will feel a linear, firm swelling under the skin when palpating the ear, brisket, and 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.

- a. If necessary, 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.
  - b. IPP are to retain the carcasses of "U.S. Suspect" pre-ruminant calves exhibiting signs of an implant for post-mortem inspection by the PHV to determine compliance.
  - c. The PHV is to examine the rumen of the retained carcass to determine its functionality.
- 3. Following completion of the examination, the PHV is to:
    - a. Pass the carcass for human food if the animal has a functioning rumen, and the carcass is not subject to condemnation under 9 CFR 311 because of the presence of an implant, or
    - b. 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.

**NOTE:** If the carcass is missing an ear, the PHV is unable to determine whether an implant was present and, therefore, cannot pass the carcass because there is no basis to find that the carcass is not adulterated.

- 4. If the PHV determines that a calf had an implant and a non-functioning rumen, he or she is to verify that the establishment takes the appropriate corrective actions under 9 CFR 417.3(a) or 417.3(b).
- 5. If the establishment fails to take appropriate corrective action, the PHV is to document a noncompliance record (NR) and take the appropriate enforcement action as set out in FSIS PHIS Directive 5000.1.

C. IPP are to verify that the establishment collects and maintains animal ID until the completion of post-mortem inspection, in accordance with 9 CFR 310.2. IPP are to document noncompliance when an establishment fails to comply with FSIS regulations for identifying, holding, and sampling of carcasses and parts for drug residues:

- 1. Livestock: 9 CFR 309.16 (suspected of having biological residues), 310.2 (identification of carcass), 310.23 (identification of swine), and 320.1(records required to be kept); and

2. Poultry: 9 CFR 381.74 (suspected of having biological residues), 381.78(b) (separation of poultry suspected of containing biological residues), 381.80(b) (biological residues), and 381.175 (records required to be kept).

D. IPP are to take appropriate action based on test results reported through the FSIS laboratory, as described in Chapter Four, Section IX. If IPP determine that the establishment failed to hold or maintain control of a livestock carcass selected for directed residue testing, they are to immediately contact the DO. The DO may instruct the IPP to write 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 set out in 9 CFR 417.5(c).

E. When the FSIS laboratory reports a violative residue result, IPP are to review the establishment's residue control program.

1. If an establishment includes a chemical residue control program in its food safety system but fails to follow its program as written, and FSIS detects a chemical residue at a violative level, IPP are to document an NR using:
  - a. 9 CFR 417.5(a)(1), if the establishment has a prerequisite program that it failed to follow because the establishment's decisions are not supported;
  - b. 9 CFR 416.15, if the establishment addresses residue control in its Sanitation Standard Operating Procedures (SOP) but has failed to take corrective actions, or the corrective actions are ineffective;
  - c. 9 CFR 417.3(a), if the establishment addresses residue control in its HACCP plan and fails to take corrective actions or corrective actions were ineffective; and
  - d. 9 CFR 318.20, to document the establishment's failure to prevent livestock with violative residue levels from entering slaughter when the violation is associated with a Residue Repeat Violator.
2. If the establishment has not incorporated chemical residue control in its HACCP plan or Sanitation SOP, or in another prerequisite program, IPP are to issue an NR citing 9 CFR 417.3(b).
3. If an establishment has determined in its hazard analysis that chemical residues are not reasonably likely to occur because they have implemented a prerequisite program to reduce or prevent the hazard, and FSIS detects a violative residue through Agency testing, IPP are to verify that the establishment's corrective actions meet all the applicable requirements of 9 CFR 417.3(b) for an unforeseen hazard, including reassessment (9 CFR 417.3(b)(4)) and documentation of its reassessment, even if the establishment made no changes to its HACCP plan as a result of its reassessment.

F. In addition, when the FSIS laboratory reports a violative residue result, IPP are to verify that the establishment has provided information about the violator at the time of sample collection and for the carcass that was reported as violative. If the information was not provided at the time of sample collection, IPP are to request it. IPP are to document a 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), if they address residues in a pre-requisite program; or 416.16, if they address residues in their Sanitation SOP.

**NOTE:** An establishment may demonstrate that it is informing itself of the source of the animals it slaughters by maintaining information identifying the violator, including but not limited to the producer's

name and physical address. However, providing the identification of the producer is not a regulatory requirement. In lieu of producer information, an establishment may obtain a letter or other type of credible certification from the seller or livestock market. The establishment may use this type of documentation to demonstrate that the animals received for slaughter are not from a producer known to have more than one (1) residue violation in the last 12 months on the most recently posted Residue Repeat Violator List. In addition, this documentation may also identify those animals from a producer known to be on the Residue Repeat Violator List.

G. The PHV is to review information on livestock and poultry suppliers used by the establishment and discuss any concerns regarding their suppliers and violative residue findings with the establishment at the weekly meeting. When necessary, the PHV is to raise concerns, through supervisory channels, to the DO. IPP are to document the information discussed in an MOI, as set out in FSIS PHIS Directive 5000.1.

H. The PHV is to discuss with the establishment at the weekly meeting, and document in an MOI, any concerns that the establishment may lack an effective residue control program, or any information that the establishment receives animals for slaughter from a:

1. Producer that has more than one (1) FSIS laboratory-confirmed chemical residue violation in the previous 12 months; or
2. Producer that is under an injunction or issued warning letters by FDA.

The PHV is also to provide the following link to the Residue Repeat Violator List to the establishment:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>

**NOTE:** A firm or person listed on the Residue Repeat Violator List remains eligible to market its livestock for slaughter provided the livestock do not bear or contain violative levels of chemical residues. An official establishment would need to be aware when it receives livestock from a person or firm on the Residue Repeat Violator List in order to be able to design and implement its food safety program to effectively address the potential chemical hazard.

I. When a PHV is notified that the establishment has had more than one (1) FSIS laboratory-confirmed residue violation from animals purchased from a single producer, he or she is to discuss this finding with the establishment and document the discussion in an MOI. The PHV is to refer to the flow chart in Attachment Three for guidance on potential scenarios and actions that he or she can take in situations of multiple laboratory-confirmed chemical residue violations and residue repeat violators.

J. The PHV is to discuss all new noncompliance with the establishment at the weekly meeting and inform the establishment that its failure to prevent this hazard from recurring raises questions about the adequacy of the establishment's HACCP system.

1. If the Agency finds additional residue violations between an establishment and a firm or person listed on the Residue Repeat Violator List, IPP are to issue an NR for each occurrence, as described in Section I.D, of this chapter. IPP are to link the NRs in accordance with FSIS PHIS Directive 5000.1, Chapter IV, to document that there is a trend occurring.
2. The IPP are to include in the NR a description of any developing trend of noncompliance, the number of the previous NRs with the same cause, and a description of how the noncompliance derived from the same cause.
3. With multiple or recurring noncompliances, the IPP are to assess whether the establishment's HACCP system is inadequate under 9 CFR 417.6. The IPP are to keep their supervisor apprised of the situation.

K. If the IPP determine that the HACCP system is inadequate, and that enforcement action is warranted, the IPP are to contact the DO to discuss whether to issue a Notice of Intended Enforcement (NOIE), citing 9 CFR 417.6 and whether to schedule the establishment for a Food Safety Assessment (FSA).

## II. DISTRICT OFFICE RESPONSIBILITIES

A. When OPPD advises a DO of an establishment that has had more than one (1) FSIS laboratory-confirmed residue violation from the same source, the DO is to notify the IIC at the establishment and the Frontline Supervisor (FLS).

B. If IPP inform the DO that an establishment did not hold or maintain control of product that was tested by FSIS, the DO is to take appropriate administrative action under the Rules of Practice (9 CFR Part 500):

1. Issue an NOIE because the HACCP system is inadequate as specified in 9 CFR 417.6 as a result of multiple or recurring noncompliances (9 CFR 500.4(a)); or
2. Take a withholding action or impose a suspension without providing the establishment prior notification if FSIS residue test results report as violative because establishment produced and shipped adulterated product (9 CFR 500.3(a)(1)).

C. If the DO is aware of any other establishments in the District that purchase animals from a producer that is on the Residue Repeat Violator List, it is to make the IICs at these establishments and their FLSs aware that the producer is a repeat source for animals with violative chemical residues.

D. If the DO believes criminal, civil, or administrative enforcement action may be warranted, it is to contact Office of Investigation, Enforcement and Audit (OIEA), Compliance Investigation Division (CID), Regional Director (RD), following the procedures outlined in FSIS Directive 8010.5, Case Referral and Disposition. OIEA, CID, RA, in consultation with headquarters, is to consider whether additional enforcement actions or sanctions are necessary.

## III. DOCUMENTING VERIFICATION RESULTS IN PHIS

A. IPP are to document the results of their verification procedures in PHIS, including findings of regulatory compliance and noncompliance. IPP are to refer to FSIS PHIS Directive 5000.1, Chapter V, FSIS PHIS Directive 13.000.1, and the PHIS User Guide for instructions on how to use PHIS to document inspection results.

B. If a noncompliance exists, IPP are to document these findings in an NR using the instructions provided in FSIS PHIS Directive 5000.1, Chapter V., Section II..

## CHAPTER SIX

### I. DATA ANALYSIS

A. The Data Analysis and Integration Staff (DAIS) within the Office of Data Integration and Food Protection (ODIFP) and the Science Staff within the Office of Public Health Science (OPHS) 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.

B. ODIFP and OPHS will share these analyses with the Office of Policy and Program Development (OPPD) and the Office of Field Operations (OFO).



## II. QUESTIONS

Refer technical questions to OPHS, policy questions to PDS and all sampling questions to RIMS through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Directive 10,800.1  
Question Field: Enter your question with as much detail as possible.  
Product Field: Select **General Inspection Policy** from the drop-down menu.  
Category Field: If your question is about residue sampling, select **Sampling-General** from the drop-down menu. For all other residue questions, select **Residue** from the drop-down menu.  
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.



Assistant Administrator  
Office of Policy and Program Development

## ATTACHMENT ONE: PROGRAM AREA RESPONSIBILITIES AND DUTIES

### A. Office of Public Health Science (OPHS)

OPHS leads the development and implementation of the NRP by providing scientific guidance in the planning, testing, and analyzing of data for the program. OPHS also provides support to the Office of Policy and Program Development (OPPD), the Office of Field Operations (OFO), and other FSIS program areas in response to questions and requests regarding the NRP. OPHS manages two key roles for the NRP:

#### 1. Science Staff:

- a. Receives, evaluates, and provides residue-related information and scientific support to OFO and OPPD other program areas regarding procedures and training for chemical residue control activities;
- b. Coordinates the Surveillance Advisory Team (SAT) that annually reviews chemical residue prevalence and intelligence information, including exposure assessments, from EPA, FDA, and the Centers for Disease Control and Prevention (CDC ) to develop the NRP including exposure assessments;
- c. Coordinates the Interagency Residue Control Group (IRCG) monthly meetings with FDA. These interagency meetings are the means for FSIS, FDA, EPA, CDC, USDA Agriculture Research Service (ARS), and USDA Agricultural Marketing Service (AMS), together with other Federal partners (such as the APHIS) as needed, to discuss emerging chemical residue exposure issues, and follows up on detected findings in domestic or imported meat, poultry, and egg products;
- d. Coordinates activities that may arise for the NRP violative samples and the dissemination of residue-related information among FSIS, FDA, and EPA in accordance with the existing Memorandum of Understanding (MOU);
- e. Compiles, analyzes, and evaluates chemical residue data collected under the NRP;
- f. Annually publishes the U.S. National Residue Sampling Plan ("Blue Book");
- g. Annually publishes the chemical residue data in the U.S. National Residue Program Data ("Red Book");
- h. Designs and coordinates sampling programs under the NRP, including other exploratory residue sampling programs, such as the dioxin survey, together with other Federal partners; and
- i. Provides updates, as requested by OFO, on chemical residue results reported in PHIS, inclusive of carcass or part disposition.

**NOTE:** The U.S. National Residue Sampling Program Plans (Blue Book) and the U.S. National Residue Program Data (Red Book) can be accessed at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>

#### 2. FSIS Field Service Laboratories:

- a. Conduct laboratory tests and provide the results of those tests in accordance with Agency objectives and guidelines; and
- b. Assess and update modifications to laboratory methodologies in support of scheduled, inspector-generated, and other chemical residue-related sampling.

**B. Office of Field Operations (OFO)**

**1. Recall Management & Technical Analysis Staff (RMTAS)**

- a. Provides data analysis and oversight to the NRP for OFO Headquarters and the Districts;
- b. Participates as the OFO representative in the monthly FSIS NRP meetings, IRCG, SAT, and other residue-related activities, such as the Dioxin Survey Committee;
- c. Provides the conduit for follow-up information requested from the Districts or from the IPP for other programs areas outside OFO (e.g., OPPD, OPHS, ODIFP, FDA CVM); and
- d. Assists the Districts by working with OOEEET in the design and delivery of residue-related training to the IPP and PHVs.

**2. District Office (DO)/District Veterinary Medical Specialist (DVMS):**

- a. Receives notification of chemical residue violations and violators' information from FSIS Laboratories and the Policy Development Staff (PDS) through the Residue Violation Information System (RVIS);
- b. Coordinates chemical residue-related activities, disseminates chemical residue information to field personnel on an "as needed" basis and operates in conjunction with OPHS and PDS when special sampling situations arise. Cooperates with residue violation investigations that may involve FSIS, FDA, and EPA;
- c. Cooperates with and aids RMTAS and PDS in trace-back activities that may require contacting auction houses, brokers, establishments, or PHVs in order to obtain information that FSIS needs for residue management efforts;
- d. Works with RMTAS to ensure that OFO staff and IPP complete the appropriate training necessary to carry out NRP responsibilities;
- e. Verifies, through RVIS and FDA notifications of firms under indictment or those that have received warning letters, the degree and level of application of various chemical residue-related activities conducted at the in-plant level by interpreting and analyzing operational reports, data, and other information to effect corrective actions in situations where the program failed;
- f. May receive information from RMTAS, PDS, OPHS, or OFO headquarters relating to field chemical residue violations that require increased in-testing by the PHV;
- g. Oversees the implementation and training needs for KIS™ testing in selected establishments;
- h. Informs OFO leadership of actions taken in response to repeat violators, so that repeat violators that are shipping to different Districts can be identified; and

- i. Provides oversight and follow-up on corrective actions needed, based on residue data analysis provided by the RMTAS.

3. Public Health Veterinarian / Inspector-in-Charge (PHV/IIC)

- a. Identifies animals at antemortem inspection as suspect for chemical residue testing;

**NOTE:** PHVs are to handle animals for slaughter with known violative chemical residue levels in accordance with 9 CFR 309.16, 310.21, and 311.39 when and where applicable.

- b. Retains and tests carcasses suspected to have pathological conditions described in Chapter Three, Section I. If the in-plant screening test is positive or the PHV suspects the use of a non-steroidal drug (NSAID), the PHV is to submit tissue samples to the appropriate FSIS laboratory and continue to retain the carcass and parts;
- c. Evaluates and understands how the establishment addresses chemical residue control in its HACCP system;

**NOTE:** The Federal Register Notice: Residue Control in a HACCP Environment can be accessed at:

<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-043N.pdf>.

- d. Ensures that the proper equipment and supplies are available for the collection of samples and performance of KIS™ tests and that adequate control of sampling supplies, heating blocks, and other equipment is maintained;
- e. Verifies that IPP have been trained in the post-mortem identification of carcasses or products suspected of violative chemical residues;
- f. Verifies that all necessary ID are collected and maintained as required in Chapter Four, Section III;
- g. Verifies that IPP have been trained in chemical residue sampling and testing procedures;

**NOTE:** PHVs can access the "Residue Detection Program" training module for PHVs at:

[http://www.fsis.usda.gov/PDF/PHVk-Residue\\_Detection\\_Program.pdf](http://www.fsis.usda.gov/PDF/PHVk-Residue_Detection_Program.pdf)

- h. Conducts, or directs an IPP to conduct, KIS™ tests when the misuse of antimicrobials is suspected;
- i. Enters, or directs an IPP to enter, all information for directed and inspector-generated chemical residues samples into PHIS using the instruction provided in FSIS PHIS Directive 13000.2, including the carcass owner's information and all animal ID to enable traceback to the farm of origin;
- j. Selects animals randomly and samples carcasses or parts for testing from all animals passing antemortem inspection under the NRP scheduled sampling plans;
- k. Ensures proper handling, labeling, processing, sealing, and shipping of the samples by IPP to avoid discard of any samples and to maintain sample security as instructed in FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and other Applications;

- l. Tracks the status of the sample and determines disposition of carcass/parts from the information provided in LIMS-Direct;
  - m. Performs increased testing of animals that the establishment receives from a same supplier when a repeat chemical residues violation is identified;
  - n. Documents, or directs an IPP to document, noncompliance using the instructions provided in Chapter Four; and
  - o. Informs DO and DVMS of actions taken in response to more than one (1) FSIS laboratory-confirmed chemical residue violations from animals purchased from a repeat violator.
4. Inspection Program Personnel (IPP)/Consumer Safety Inspector (CSI)
- a. Identifies animals for directed chemical residue sampling during antemortem inspection;
  - b. Identifies animals for inspector-generated sampling during post-mortem inspection;

**NOTE:** Training modules for IPP can be accessed at:

[http://www.fsis.usda.gov/FSIS Employees/Slaughter Inspection Training/index.asp](http://www.fsis.usda.gov/FSIS_Employees/Slaughter_Inspection_Training/index.asp)

- c. Retains carcass from suspect animals;
  - d. Collects tissue samples for KIS™ testing and for submission to FSIS laboratories (directed and inspector-generated samples);
  - e. Conducts KIS™ residue screening tests when assigned and when the misuse of antimicrobials is suspected;
  - f. Schedules and completes directed chemical residue sampling tasks in PHIS using the instructions provided in FSIS PHIS Directive 13000.2;
  - g. Prepares, packages, and ships samples to the laboratory to avoid discard of any samples and maintains sample security as instructed in FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and other Applications;
  - h. Tracks the status of the sample analysis and determines carcass and parts disposition by reviewing LIMS-Direct; and
  - i. Documents noncompliance using the instructions provided in this Directive and FSIS PHIS Directive 5000.1.
5. Frontline Supervisor (FLS)/Multi In-Plant Performance System Assignment:
- a. Evaluates and assesses in-plant residue control performance of PHV and IPP;
  - b. Evaluates the uniformity between PHVs under his or her supervision in the use of professional judgment in targeting any carcass for inspector-generated testing for chemical residues;
  - c. Evaluates and assesses in-plant staffing needs, sets priorities to ensure that an adequate chemical residues control system is in place, and provides feedback to the PHV;

- d. Maintains current information on the NRP and informs IPP of any program changes in a timely manner;
- e. Operates in conjunction with the DO to ensure uniform and consistent implementation of the NRP;
- f. Verifies that PHVs advise establishments they may receive automatic notification via e-mail when results are posted on PHIS;
- g. Verifies that relief PHVs make dispositions based on test results and provide results to the establishment when the latter elects to hold carcasses;
- h. Ensures that relief PHVs receive needed information to assure sampling of veal calves continues at the proper level; and
- i. Evaluates the performance of field personnel to ensure uniform and consistent implementation of the NRP (i.e., IPP submit proper tissues, do not commingle tissues, send tissues to the appropriate laboratory);
- j. Ensures that proper animal ID is maintained to allow traceback to producers for residue violative animals.

#### C. Office of Policy and Program Development (OPPD)

- 1. Coordinates activities related to any policy-related 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. Uses RVIS to manage violation cases. Case management includes communication through the OFO headquarters with FSIS field personnel and DOs, FDA Districts, State officials, and the owners and establishment officials responsible for violations;
- 3. Reviews requests for slaughter of livestock used in research: if the request meets the guidelines of the approval letter from FDA, APHIS VS, EPA or FSIS, provides written approval for slaughter and notification to OFO, the investigator, the sponsor, and the establishment;
- 4. Evaluates and interprets existing policy and develops new policy and guidance documents based on trend analysis of AskFSIS questions; and
- 5. When requested by OFO (headquarters or Districts), provides policy guidance to IPP and PHVs on chemical residue sampling and related issues.

#### D. Office of Data Integration and Food Protection (ODIFP)

##### The Data Analysis and Integration Staff (DAIS):

- a. Retrieves residue data from FSIS residue sampling projects for analysis by OFO RMTAS;
- b. Creates various chemical residue tables on monthly and quarterly basis for FSIS program areas; and
- c. Creates the monthly and quarterly chemical residue tables for the OFO RMTAS and DOs under the established criteria and format.

E. Office of Investigation, Enforcement and Audit (OIEA)

1. The Compliance and Investigations Division (CID)

Conducts surveillance, investigations, and other compliance activities that protect the public from unsafe products to ensure that regulated industry and industry officials comply with FSIS food safety adulteration, and other statutory and regulatory requirements.

2. The Enforcement and Litigation Division (ELD)

- a. Provides enforcement, litigation, and related expertise and services to OIEA and the agency.
- b. Conducts evaluation and analysis of case evidence and recommendations from OFO, CID, and other offices to initiate criminal, civil or formal administrative enforcement action in appropriate cases.

## ATTACHMENT TWO: COMPLETING RESIDUE SAMPLING TASKS IN PHIS

A. This attachment to FSIS Directive 10,800.1 provides instructions to inspection program personnel (IPP) on how to:

1. Properly submit directed residue lab samples,
2. Enter KIS™ test results, and
3. Submit an inspector-generated tissue sample for confirmatory residue testing in PHIS.

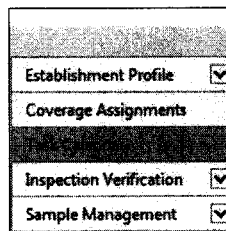
**NOTE:** These instructions are consistent with, and are a supplement to, the sample submission sections found in FSIS PHIS Directive 13,000.2. Detailed instructions on scheduling and submitting lab samples are also available at InsideFSIS on the "Find PHIS Information" page.

### B. KEY POINTS

1. IPP are to use the task list and task calendar when scheduling or collecting a directed sample and not the **Sample Management** navigation menu tab.
2. After collecting the directed sample, IPP are to click on the **Submit to Lab** button prior to printing the form.
3. IPP are to use the **Animal Disposition** navigation menu tab for entry of KIS™ test results (both negative and positive) and for sample submission in response to positive KIS™ test results.

### C. To schedule and submit a directed lab sample for residue testing, IPP are to:

1. Go to **Task Calendar** on the left navigation menu.




2. Go to Establishment Task List.
3. Select the correct assignment from the Assignments dropdown list.
4. Select the correct establishment from the Select Establishment dropdown list.
5. Select **Lab Sampling** from the Filter tasks by dropdown list.
6. Click **Add** to schedule a sample on the task calendar as soon as possible.
7. After the **Collection and Parcel Pickup** dates default to the current date, change the collection date and Parcel Pickup date, if needed. Make certain the window shows available lab capacity (number <100 and a green box). Click the **Save** button.



8. After scheduling the sample, collect the sample.
9. After collecting the sample, right click on the task on the calendar and select **Document**. The Sample Collection popup window will open.
10. Enter all information on the **Sample Collection Data** tab. The Remarks box can be left blank. Click **Save and Continue**. The **Additional Info** tab is now displayed for completion of the questionnaire.

11. After answering each question, scroll to the bottom and click **Save** before advancing to the next question. A green check indicates that the answer was saved. Answer all questions. **IMPORTANT:** Review all information on the form for accuracy. Changes **cannot** be made after submission.
12. Click **Submit to Lab** button to transmit the information. A message stating that the sample collection data has been submitted to the lab will appear. If the **Submit to Lab** button is not clicked, the sample will be discarded.
13. Click **Print Form** at the top right of the window. Affix the sample seal label in the designated space at the top center of the printed form. **Sign and date** the printed form. Then, place this form in the shipping container with the sample.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE		Form ID:100176868
<b>SAMPLE ANALYSIS REQUEST FORM</b>		
-- For Lab Use Only --	Place Sample Seal Label Here	 100176868
<b>COLLECTION INFORMATION</b>		
1. SAMPLE FORM ID:	100176868	7. ESTABLISHMENT ID:
2. PROJECT CODE:	MT60	8. ESTABLISHMENT NAME:

SIGNATURE:		TITLE:		DATE:	
<b>FOR LABORATORY USE ONLY</b>					
Date Received	Analyst Code	Receipt Temperature	Not-Analyzed Code	Not-Analyzed Explain	
PAGE 1 OF 2					
FSIS FORM 8000 - 18 (07/24/11)					

- Close the PHIS sample collection window by clicking on "X" in the upper right corner. After the task has been scheduled and submitted, the # **scheduled** and **Done** columns of the **Establishment Task List** will both increase by one (1).

**D. To enter negative KIS™ screening test results in PHIS, IPP are to:**

- Go to **Animal Disposition** on the left navigation menu.
- Go to **Establishment Reporting** to open the Establishment Reporting page.

**Establishment Reporting**

Establishment\*:

Date\*:

Shift\*:

Type\*:

- Enter the Establishment, correct date, shift, and type of product in the dropdowns. Either add a new disposition by clicking **Add Disposition Record** or edit a disposition already in the system. Click on **Edit** pencil icon for the disposition that will be edited. The **Daily Disposition Record Detail** page will open. Click on the **Add Lab Sample Collection** link. The **Sample Management-ADR Sample Collection** page will open.

Sample Management -ADR Sample Collection	
Establishment Profile	
Coverage Assignments	
Task Calendar	
Inspection Verification	
Sample Management	
Animal Disposition	
Establishment Reporting	
Weight Reporting	
Frequency	
No Kill Period	
View Report	
Generate a Sample	
Establishment*:	
Project Code*:	KIS
KIS Test	
Test Date*:	07/25/2012
Slaughter Sub-Class*:	Other
Tag #:	NBA011045678

4. Select **KIS** from the Project Code dropdown, and then wait for the KIS™ Test box to open.
5. The day's date and tag number of the selected record will be displayed by default.
6. Enter the residue case number, if there is a case number.
7. In the Reason Code dropdown, select the correct reason for sampling.
8. In the Result dropdown, select **Negative**.

Reason Code*:	Arthritis
N5 Zone*:	20 to 26 mm
Result*:	<div style="border: 1px solid black; padding: 2px;">           Select One            Select One            Positive  <b>Negative</b>            Indeterminate         </div>
Comments:	

9. Enter any other requested information.
10. Do not complete the **Analyses and Select Sample** dropdown for a negative test.

Generate a Sample	
Establishment*:	
Project Code*:	KIS
KIS Test	
Test Date*:	07/23/2012
Slaughter Sub Class*:	Other
Tag #:	NBA011045678
Case Number:	
Reason Code*:	Pneumonia
Result*:	Negative
Comments:	
Analyses:	<input type="checkbox"/> Antibiotics (Kidney, Liver, Muscle) <input type="checkbox"/> Sulfonamides (Liver, Muscle) <input type="checkbox"/> Fluoroquinolones (Liver, Muscle)
Select Sample:	Select One

11. Click the **Save** button. The **Sample Management-ADR Sample Collection** page will open. The top of the page will show, "Your negative sample result has been recorded for reporting purposes. The results will not be sent to a lab." Exit the window to enter results for another sub-class.

**E. To enter positive KIS™ screening residue test results and submit an inspector-generated residue sample in PHIS, IPP are to:**

1. Go to the **Animal Disposition** navigation menu tab.
2. Go to **Establishment Reporting** and start at the **Class Summary List**. Click on the **Edit** pencil to open the **Class Summary Information** page.

3. Click on the type of Sub-Class. The **Sub-Class Summary** page will open.

4. Either add a new disposition or edit a disposition already in the system. Click on the **Edit** pencil icon for the disposition that will be edited. The **Daily Disposition Detail Record** page will open.

5. Click on the **Add Lab Sample Collection** link. The **Sample Management-ADR Sample Collection** page will open.

idar Verification <input checked="" type="checkbox"/> Management <input checked="" type="checkbox"/> Position <input type="checkbox"/> Reporting Method	Generate a Sample Establishment*: <input type="text"/> Project Code*: KIS
	KIS Test Test Date*: 07/19/2012 Slaughter Sub-Class*: Steer Tag #: 477019254607 Case Number: <input type="text"/> Reason Code*: Pyemia/Septicemia Result*: Positive Comments: <input type="text"/>
	Analyses*: <input checked="" type="checkbox"/> Antibiotics (Kidney, Liver, Muscle) <input checked="" type="checkbox"/> Sulfonamides (Liver, Muscle) <input checked="" type="checkbox"/> Flunixin (Liver, Muscle)
	Select Sample*: Animal-Cattle-Steer

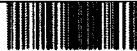
6. Select **KIS**. The day's date and tag number of the selected record will be displayed by default.
7. Enter the requested information and select "positive" from the Result dropdown.
8. When the additional fields **Analyses** and **Select Sample** are presented, check the boxes for the appropriate analyses and sample.
9. Click the **Save and Continue** button. The **Sample Management-Sample Collection** page will appear. Because the sample was positive, schedule sample collection.
10. Click on the **Schedule Sample** link and the **Schedule Lab Sample Task** (yellow box in previous section) pop-up window opens.
11. After the **Collection** and **Parcel Pickup** dates default to the current date, change the collection date and Parcel Pickup date, if needed. Make certain the window shows available lab capacity (number <100 and a green box). Click the **Save** button.
12. Complete the required Collection Information and be certain the Seal # is entered correctly.

Herd/Flock Owner*:	Joe Farmer		
Address*:	1313 Mockingbird Ln		
City*:	Cheeseville	State*:	WI
		ZIP*:	53233

13. Complete Animal Information fields with red asterisks. The address defaults to the establishment address. Update the address to the herd/owner's address. However, if the owner's address is not known at the time of sample collection, submit with the establishment's address because residues in tissues degrade over time.

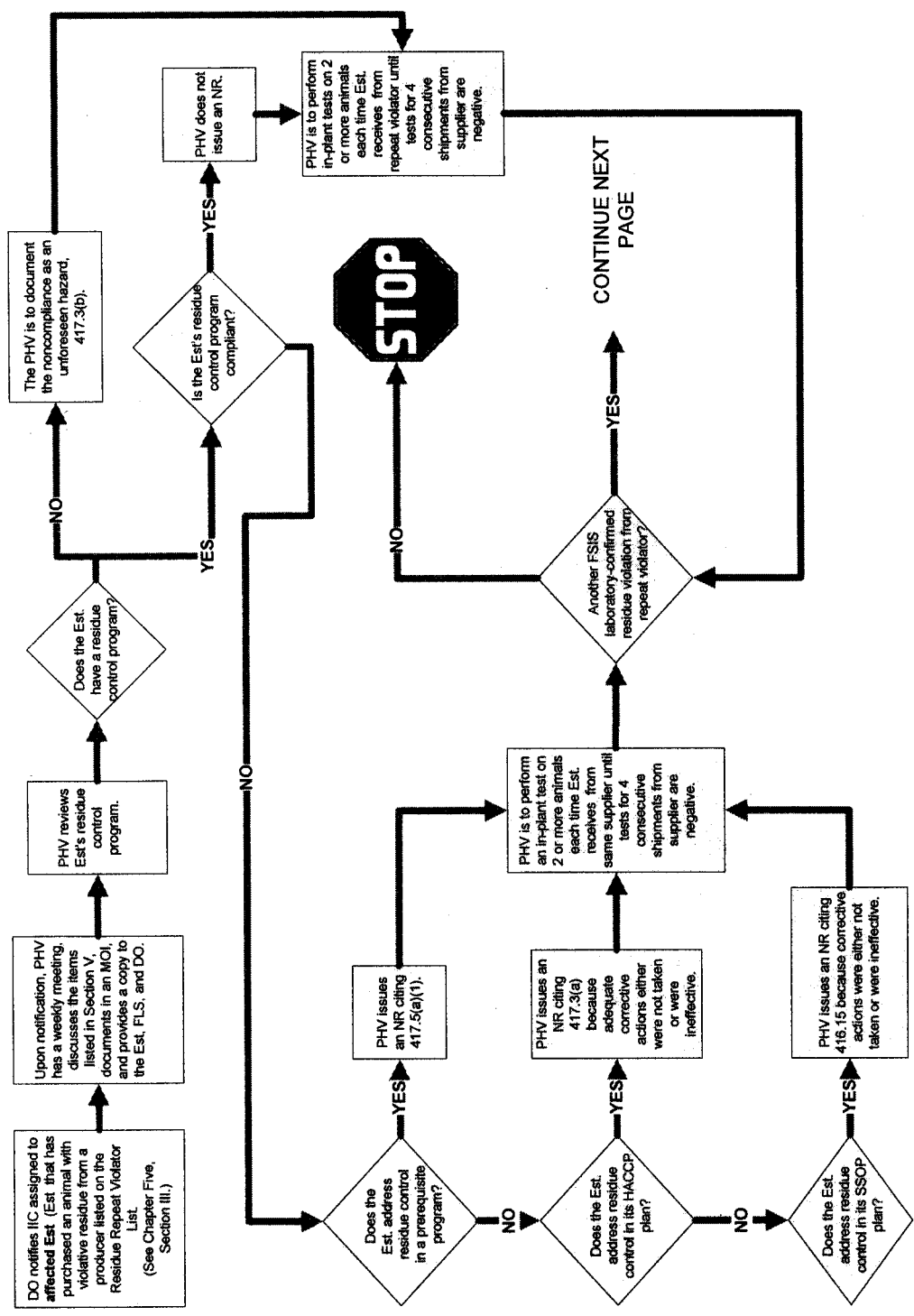
**NOTE:** If producer information on violative results is determined later, it should be sent to Residue@fsis.usda.gov, faxed to 402-344-5008, or provided by phone to 800-233-3935.

14. Click **Submit to Lab** button. A message will display to open the **Additional Info** tab and complete the questionnaire.
15. Click on each individual question in the questionnaire, provide an answer, and then click **Save** before proceeding to the next question. When a green check icon is displayed, the answer was successfully saved.
16. Answer all questions. If there is no tag number, enter "no tag."
17. Review all information on the form for accuracy. Changes **cannot** be made after submission.
18. Click the **Submit to Lab** button when all questions are answered.

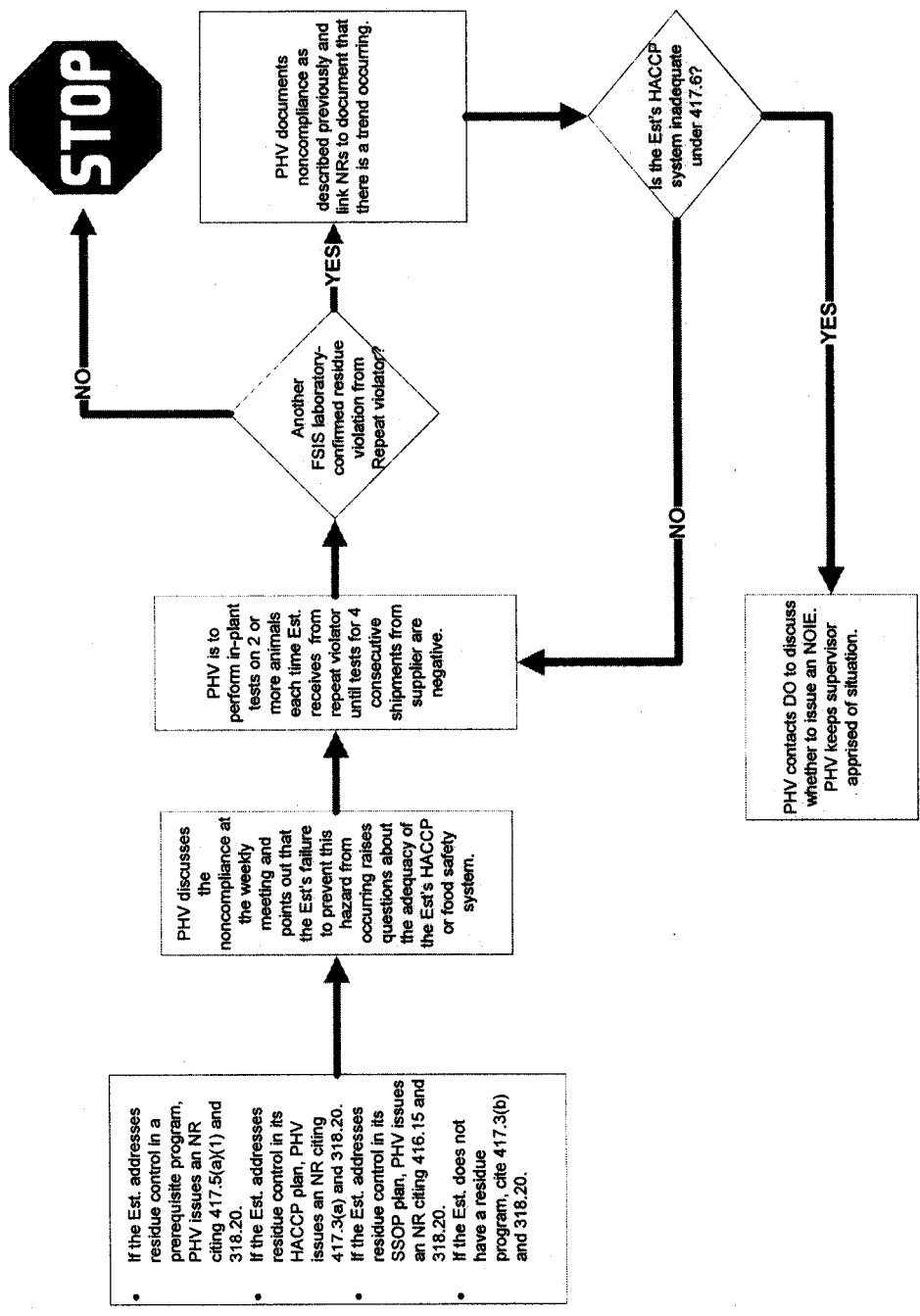
-- For Lab Use Only --	Place Sample Seal Label Here	 100207895
<b>COLLECTION INFORMATION</b>		
1. SAMPLE FORM ID: 100207895	7. ESTABLISHMENT ID: M.....	
2. PROJECT CODE: KIS	8. ESTABLISHMENT NAME: # Beef Packing	
3. SAMPLE SOURCE: Animal-Cattle-Steer	9. COLLECTION DATE: 07/23/2012	
4. ANALYSIS: Antibiotics (Kidney, Liver, Muscle), Flunixin (Liver, Muscle), Sulfonamides (Liver, Muscle)	10. SHIPMENT DATE: 07/23/2012	
	11. COLLECTOR NAME: Carlos Gomez	

19. Print a copy of the lab form, place the sample seal label in the designated area, **sign and date** the form, and submit with the sample tissues to the lab. Exit the system.

**Attachment Three - Regulatory Action against Establishments that have Residue Violations from Repeat Violators**



Attachment Three - Regulatory Action against Establishments that have Residue Violations from Repeat Violator



- If the Est. addresses residue control in a prerequisite program, PHV issues an NR citing 417.5(a)(1) and 318.20.
- If the Est. addresses residue control in its HACCP plan, PHV issues an NR citing 417.3(a) and 318.20.
- If the Est. addresses residue control in its SSOP plan, PHV issues an NR citing 416.15 and 318.20.
- If the Est. does not have a residue program, cite 417.3(b) and 318.20.

CONTINUED FROM PREVIOUS PAGE



**RELATED DOCUMENTS:**

1. **Animal Identification: Examples of Official Ear Tags**
2. **KIS™ Test Sampling Instruction Booklet**

**RELATED LINKS:**

Recording Positive and Negative In-plant Residue Test Results and Sample Information for submission to the Laboratory (on FSIS intranet site under PHIS resources)

Scheduling and Submitting a Directed Lab Sample (on FSIS intranet site under PHIS resources)