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

FSIS DIRECTIVE

5400.5 | 11-21-97

INSPECTION SYSTEM ACTIVITIES

I. PURPOSE

FSIS is modernizing its approach to inspection to rely less on after-the-fact detection of problems and more on verifying the effectiveness of establishment processes and process controls. The Agency established the basic regulatory framework for this approach when it issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule (July 1996), which amended the regulations to require official establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

A modernized approach to inspection requires changes in the performance-based inspection system (PBIS) and the activities FSIS has conducted under that system--in particular, the tasks in the Inspection System Guide (ISG). Therefore, for establishments that are subject to the HACCP system regulations, FSIS is replacing the ISG and portions of the PBIS directives with this directive and its attachments. Inspection program personnel are to follow the instructions in this directive in every establishment that is subject to the HACCP system regulations.

II. [RESERVED]

III. REASON FOR ISSUANCE

FSIS is issuing this directive to provide procedures, forms, and instructions that are appropriate for use in a modernized inspection system.

In an official establishment, inspection program personnel are to follow the instructions in this directive (along with its attachments) if the establishment is subject to the HACCP system regulations.

The HACCP system regulations apply in official establishments as of the following dates:

> January 26, 1998, in an establishment with 500 or more employees ("large establishment");
>
> January 25, 1999, in an establishment with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than $2.5 million) ("smaller establishment"); and
>
> January 25, 2000, in an establishment with fewer than 10 employees or annual sales of less than $2.5 million ("very small establishment").

In FSIS Directive 5000.1, “Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations,” the Agency is providing instructions to inspection program personnel for enforcing the HACCP system regulations (9 CFR part 417), the regulations on Sanitation Standard Operating Procedures (SOP's) (9 CFR part 416), the E. coli process control verification requirements (in establishments that slaughter cattle, swine, chickens, or turkeys) (9 CFR 310.25(a) and 381.94(a)), and the pathogen reduction performance standards for Salmonella (in establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey) (9 CFR 310.25(b) and 381.94(b)).

The Agency also is limiting the application of the following FSIS directives to establishments that are not subject to the HACCP system regulations: 5400.1 and 5400.2 (Inspection System Guide and updating procedures); 8800.1 (PBIS implementation); 8800.3 (updating establishment/shift monitoring plans); 8810.1 (Plant Profile instructions); 6350.1 (trimming, vacuuming, and other carcass interventions); 6540.1 (antimicrobial use of TSP); 7310.4 (foreign particle contamination); 8820.1 (corrective action system); 8821.1 (boneless meat reinspection); 8830.1 (progressive enforcement action); and 11,100.3 (Sanitation SOP requirements).

IV. REFERENCES

Regulations: 9 CFR chapter III.
Directives: FSIS Directives 5000.1,"Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations" and FSIS Directive 8800.2, "Performance-Based Inspection System: Overview of Policies and Implementing Procedures."

V. ABBREVIATIONS AND FORMS

ADP-- automated data processing
CO-- an FSIS compliance officer
CS-- an FSIS circuit supervisor
DO-- the appropriate Field Operations district office
IIC-- the inspector in charge
IMDD--Inspection Methods Development Division
ISP-- inspection system procedure(s), as compiled in the ISP Guide
NDG-- Noncompliance Determination Guide
NR-- Noncompliance Record
PBIS--the performance-based inspection system (see FSIS Directive 8800.2)
PS-- Procedure Schedule
RDAD--Regulations Development and Analysis Division, Office of Policy, Program Development and Evaluation

Attachment 1:
FSIS Form 5400-1 -- Plant Profile(HACCP)
Instructions for Completion

Attachment 2:
FSIS Form 5400-2 -- Procedure Schedule
FSIS Form 5400-3 -- Procedure Schedule (unscheduled)
FSIS Form 5400-3B -- Schedule Summary Sheet
Example of Form 5400-2
Example of Form 5400-3

Attachment 3:
FSIS Form 5400-4 -- Noncompliance Record
FSIS Form 5400-4a -- Noncompliance Record Continuation

Attachment 4:
FSIS Form 5400-5 -- Establishment/Shift Inspection Procedure Worksheet HACCP Est./Shift

Attachment 5:
Noncompliance Determination Guide

Attachment 6:
Inspection Systems Procedures

VI. OVERVIEW

A. PBIS

Two components of PBIS will guide inspection program activities. These components are designed for use in determining whether an establishment is complying with regulatory requirements--in particular, in making determinations about compliance with the HACCP system regulations (HACCP plan requirements and the adequacy of HACCP plans in operation), the regulations on Sanitation Standard Operating Procedures (SOP's), and other consumer protection requirements.

The first PBIS component is the ISP Guide, which includes all the in-plant "Procedures," grouped into the following "Activities": Sanitation SOP's (01);(02--Reserved); HACCP Systems (03); Economic/Wholesomeness (04); Sampling (05); Other Requirements (06);(07--Reserved); and Emergency Elements (08). The hierarchical categories in the ISP Guide are Activities, Elements, and Procedures; the most specific category is Procedures (comparable to Tasks in the ISG). Scheduling will be determined by frequency at the Procedure level.

The second PBIS component is the automated system that schedules work and incorporates the findings from conducting the procedures. The design of the automated system has several factors. These include the Activity-Element-Procedure structure, priority assignment parameters, frequency assignments, and time functions. (The automated system uses the current priority model, frequency rules, and time assignment parameters, where applicable.)

In operation, the automated system generates schedules for in-plant procedures and creates reports based on data entered into the ADP system. These data include documentation on procedures performed by inspection program personnel and information from inspection program personnel on establishment failure to comply with regulatory requirements and noncompliance trend indicators (PS's, FSIS Form 5400-2, and NR's and NR's Continuation Sheet, FSIS Form 5400-4 and FSIS Form 5400-4a, respectively). FSIS uses the reports in evaluating establishment noncompliance (including trends) and to support supervisory and management decision making. (FSIS also provides a summary report to establishment management.)

B. Enforcement Policy

The distribution of adulterated or misbranded product is prohibited, and compliance with FSIS regulations is required. It is the responsibility of establishment management to prevent contamination and adulteration and, when it nevertheless occurs, to take actions that bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the problem. Actions that do not accomplish both are inadequate. FSIS will take further action based on recurring or repeated noncompliance with regulatory requirements.

VII. ISP GUIDE

A. General

FSIS is issuing the ISP Guide to provide the in-plant procedures that the Agency currently views as appropriate in enforcing regulatory requirements and administering the inspection mandates. The ISP Guide lists the applicable regulatory requirements and FSIS directives. (To provide consistency in conducting the procedure for pre-operational sanitation in slaughter operations, Appendix A to FSIS Directive 5000.1 sets out the instructions for random selection of units within an establishment.)

B. Updating the ISP Guide

The Agency expects that as FSIS modernizes its system of food safety regulation, changes in these procedures will be necessary. In particular, the Agency's comprehensive regulatory review includes reconsideration of FSIS directives and procedures. As the Agency amends its regulations, it will modify related directives and procedures as appropriate. Implementation of ISP changes will accord with bargaining unit contractual requirements.

RDAD and IMDD are responsible for managing and coordinating development of ISP changes, which generally will occur in conjunction with rulemaking proceedings or other Agency policy issuances. Resolution of differences and clearance of draft ISP changes will be part of the regular policy review process for FSIS issuances.

RDAD will work with the Labor Management Relations staff to facilitate bargaining unit consideration of draft changes. RDAD will work with AISD on production, distribution, and integration of approved changes.

Agency personnel who believe changes are needed should make their suggestions, through regular supervisory channels, to their Deputy Administrators. Deputy Administrators should forward their recommendations to RDAD.

VIII. PLANT PROFILES

FSIS uses FSIS Form 5400-1 to collect information needed to implement and maintain PBIS and to update CORE files (Common On-line Reference for Establishments). See Attachment 1 for the instructions for completing this form.

IX. INSPECTION PROCEDURE WORKSHEETS

A. General

FSIS Form 5400-5 is the mechanism for updating the ADP component of PBIS. (The ADP system specifies ISP codes for each procedure.) FSIS Form 5400-2 is generated by the automated system in the DO.

Using FSIS Form 5400-5 the inspection program personnel develop, and then maintain, an establishment/shift procedure plan that reflects the current operations for one shift in a particular official establishment. Development and maintenance of establishment/shift procedure plans involves worksheet completion, review, and revision (when necessary to identify clearly the establishment and shift and/or applicable ISP codes).

B. Developing Establishment/Shift Procedure Plans

Whenever FSIS issues a grant of inspection, inspection program personnel are to obtain a blank FSIS Form 5400-5 from the DO and complete it as follows:

- enter the establishment number and shift at the top of the form;
- using the ISP Guide, review each procedure listed on the form and if it applies to the establishment's operations for that shift, place an "X" in the space provided.

Inspection program personnel are to complete a separate FSIS Form 5400-5 for each shift and submit the completed form(s) to the DO.

C. Maintaining Establishment/Shift Procedure Plans

1. Deleting procedures. If an establishment has discontinued the operation(s) for which a particular procedure is performed, enter a "K" next to the "Not Performed" space on FSIS Form 5400-2 unless the establishment expects to resume the operation(s) within 4 weeks.

2. Adding procedures. If there was an error in completing FSIS Form 5400-5 or an establishment has expanded its operations (new process or product) and, as a result, the FSIS Form 5400-2 does not include procedure(s) for all establishment operation(s):

- identify procedure(s) to be added (using the ISP Guide) on the FSIS Form 5400-5,
- notify the DO (electronically or by mail), and
- retain a copy of the FSIS Form 5400-5 until confirmation of the change is received.

3. Annual review. Inspection program personnel are to review the preprinted FSIS Form 5400-5 for each establishment at least annually and upon rotation to assure that there is a plan for every shift and that the plan accurately reflects the operations that the establishment currently conducts during that shift. Inspection program personnel, at least annually, or upon rotation, are to:

- o draw a line through code for any procedure that does not apply to establishment operations during that shift,
- o place an "X" in the space provided for each procedure that applies to establishment operations during that shift but is not premarked, and
- o submit completed form(s) to the DO.

X. CONDUCTING INSPECTION SYSTEM PROCEDURES

A. Multiple Establishment Duties

1. Inspection program personnel who are responsible for conducting in-plant activities in more than one establishment are to determine the order of establishment visits:

- o based on information about establishment hours of operation and compliance/noncompliance history,
- o to randomize the timing of inspection visits, and
- o when necessary, to respond to emergency situations.

2. To summarize the inspection sites for a work week, FSIS will issue an FSIS Form 5400-3B as a cover sheet for the weekly set of FSIS Forms 5400-2 when inspection program personnel are responsible for conducting in-plant activities in more than one establishment.

B. Procedure Priorities and Substitutions

1. Inspection program personnel are to review the FSIS Form 5400-2 for the establishment(s) in which they conduct in-plant activities.

2. The procedures with the highest priority number on the FSIS Form 5400-2 are the procedures with the greatest food safety significance.

3. Inspection program personnel may use professional judgment in substituting unscheduled procedures for ones specified on the FSIS Form 5400-2:

- o consistent with the Agency's food safety priorities, and

- o for the purpose of achieving FSIS's regulatory objectives.

4. Whenever inspection program personnel perform an unscheduled procedure, they are to list the ISP code on the FSIS 5400-3.

C. Performing Procedures

Inspection program personnel are to:

- o perform procedures as specified in the ISP Guide,
- o respond to identified and suspected instances of insanitary conditions, other types of adulteration, and misbranding,
- o document their findings of noncompliance with regulatory requirements,
- o advise establishment management when they find noncompliance with regulatory requirements, and
- o perform other functions, as appropriate (for example, filing directives, reviewing labels, and removing official devices).

D. Documenting Procedure Performance

1. Completing FSIS Form 5400-2 (Sample in Attachment 2)

a. The form will be utilized for documenting performance of scheduled procedures. The inspection result for a procedure will either be performed, not performed, or a noncompliance trend indicator will be circled. Only one inspection result should be entered on the schedule for each procedure.

b. The results of the procedure will either indicate compliance or noncompliance with the regulations. If the results of the procedure indicate compliance, circle the word “performed.” If the results of the procedure indicate noncompliance, circle the most appropriate trend indicator.

c. All sampling procedures where FSIS inspection personnel select, process, and mail samples to the laboratory will be recorded as performed. The word “performed” should be circled on the form.

d. If the procedure is not performed, circle “not performed” on the form.

e. If the procedure is not applicable to the establishment, enter the letter "K" next to the "not performed" on the form unless the establishment expects to resume the operation(s) within 4 weeks.

f. If a procedure needs to be added, the procedure(s) to be added should be identified to the DO electronically or by mail.

g. Any questions about completing form should be directed to the PIC at the DO.

2. Completing FSIS Form 5400-3 (Sample in Attachment 2)

a. The form will be utilized for documenting performance of unscheduled procedures. The establishment number/shift and the date visited should be completed on the top of the form. The inspection result for a procedure will either be performed, not performed, or a noncompliance trend indicator will be entered. Only one inspection result should be entered on the schedule for each procedure.

b. The results of the procedure will either indicate compliance or noncompliance with the regulations. The procedure code of the procedure that is performed should be recorded and the letter of the appropriate inspection result documented in the "result code" space provided on the form. The result codes are listed at the bottom of the form. For example, if the results of the procedure indicate compliance, document the result code for the appropriate trend indicator.

c. Remember, there is no trend indicator for noncompliance with the Basic inspection procedures. Document the procedure code and leave the results code space blank. The procedure code will indicate to the DO that there is noncompliance with the Basic requirements.

d. All sampling procedures where FSIS inspection personnel select, process, and mail samples to the laboratory will be recorded as performed.

e. Any questions about completing the form should be directed to the PIC at the DO.

XI. NONCOMPLIANCE RECORDS

A. General

A Noncompliance Record and Noncompliance Record Continuation Sheet, FSIS Form 5400-4 and FSIS Form 4a, respectively, serves as FSIS's official record of noncompliance with one or more regulatory requirements. (As stated on the FSIS Form 5400-4 and 4a: "This document

serves as written notification of your failure to comply with regulatory requirement(s), which could result in additional regulatory and administrative action.")

Each time performance of a procedure results in finding(s) of noncompliance with regulatory requirement(s), inspection program personnel are to complete an FSIS Form 5400-4 and, if necessary 4a, as specified in Paragraph XI.B. and using the Noncompliance Determination Guide. Inspection program personnel are to file FSIS Form 5400-4 and 4a as security items in a government office.

(For instructions on the use of FSIS Form 5400-4a when more than one inspector performs sanitation-related ISP procedures, see Appendix B to FSIS Directive 5000.1.)

1. Inspection program personnel are to provide establishment management with a copy of the FSIS Form 5400-4 and, if necessary 4a, (as soon as possible and, in any event, by the end of the tour of duty) and an opportunity to respond.

2. Until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an FSIS Form 5400-4, the form is "open." Inspection program personnel are to review the file of "open" FSIS Form 5400-4's daily.

3. When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an FSIS 5400-4, inspection program personnel are to file the form as “closed.”

4. The IIC and appropriate inspection program personnel are to meet with establishment management weekly to discuss noncompliance findings (if any) and action(s) taken by the establishment to bring itself into compliance.

B. Completing the Form

The numbered blocks on the FSIS Form 5400-4 and 4a are to be completed as follows:

1 Date--Enter the date noncompliance occurred.

2 Record No.--Number the FSIS Form 5400-4 completed in a given establishment sequentially, by year (i.e., 1-97, 2-97, 3-97, etc., regardless of who completes the form or the shift).

3 Est. No.--Enter as a 5-digit number followed by a red meat or poultry designator and the shift number (e.g., 00345 M/2).

4 To (Name & Title)--Enter the name of the responsible establishment individual. When documenting noncompliance with the HACCP system regulations, always use the name of the official who signed the HACCP plan. When documenting noncompliance with the Sanitation SOP regulations, always use the name of the official who signed the Sanitation SOP's.

5 Personnel Notified--Enter the name of the establishment management person who was notified of the noncompliance.

6 Relevant Regulation(s)--Cite the provision(s) of the regulations with which the establishment failed to comply (e.g., § 416.14 when an establishment fails to revise its Sanitation SOP's as necessary to keep them effective and current; § 417.2(c)(1) when a HACCP plan does not list food safety hazards identified in the establishment's hazard analysis).

7 Relevant Section/Page of Establishment Procedure/Plan--Identify the relevant section or page of an establishment document when noncompliance involves failure to comply with a requirement to follow written establishment procedures (e.g., in response to a deviation from a critical limit, an establishment failed to follow the corrective action procedure(s) specified in its HACCP plan (§§ 417.2(c)(5) and 417.3(a)); an establishment failed to conduct one or more pre-operational Sanitation SOP's before the start of operations (§ 416.13(a)). If there is no applicable requirement, enter "NA".

8 Noncompliance Classification Indicators--Mark the indicator that best describes the noncompliance. (These are the same trend indicators as appear on the FSIS Form 5400-2 and -3.)

9 ISP Code--Enter the code of the procedure performed.

10 Description of Noncompliance--Describe the failure to comply with regulatory requirement(s) as fully as possible in the space provided. Include the exact location in the establishment where the noncompliance finding was made. Avoid subjective judgment terms (e.g., "dirty" or "poor"). Use the FSIS Form 5400-4a if additional space is needed to complete the description of the noncompliance.

11 Signature of Inspection Program Employee--Sign after completing blocks 1 through 10.

12 Plant Management Response--Provide establishment management with an opportunity to respond to the FSIS Form 5400-4, either verbally or in writing. Block 12 (immediate action(s)) is for action the establishment is taking to correct the noncompliance that resulted in issuance of the form, including appropriate product disposition. Block 13 (further planned action(s)) is for action the establishment plans to take to bring itself into compliance with regulatory requirements. This includes measures to prevent recurrence.

13 Signature of Plant Management and Date--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the FSIS Form 5400-4.

14 Verification Signature of Inspection Program Employee and Date--Sign after establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of the FSIS Form 5400-4 and, if necessary 4a.

/s/ Margaret O'K. Glavin

Deputy Administrator
Office of Policy, Program Development
and Evaluation

FSIS Directive 5400.5
Attachment 1

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
PLANT PROFILE (*HACCP*)

INSTRUCTIONS: All pages of this form MUST be completed. All BLOCKS must be completed or N/A indicated when not applicable.

PLANT NAME, AND PHYSICAL LOCATION ADDRESS

MAILING ADDRESS (*If different)*

ZIP CODE

PLANT TELEPHONE NO. (*Include Area Code)* ( )

FAX NO. (*Include Area Code)* ( )

INSPECTION SYSTEM
☐ SIS ☐ NELS ☐ NTIS

INSPECTION AUTHORITY
☐ Federal ☐ State ☐ T/A

DISTRICT NAME/NO.

CIRCUIT NAME/NO.

ESTABLISHMENT NO. (*Meat)*

ESTABLISHMENT NO. (*Poultry)*

APPROVED OPERATING HOURS

SHIFT 1					SHIFT 2			
SLAUGHTER		PROCESSING			SLAUGHTER		PROCESSING	
START	FINISH	START	FINISH	DAY	START	FINISH	START	FINISH
				SUNDAY				
				MONDAY				
				TUESDAY				
				WEDNESDAY				
				THURSDAY				
				FRIDAY				
				SATURDAY				

PLANT TYPE *Check applicable box(es)*
☐ Slaughter/Processing Combination ☐ Pure Processing ☐ Pure Slaughter ☐ Custom Exempt Operation ☐ Retail Exempt Operation

TOTAL PRODUCTION AREA SQ. FT. *(One total for all areas)*

ENTER THE NUMBER OF INSPECTION PROGRAM PERSONNEL WITH PBIS RESPONSIBILITIES ➜	SHIFT 1	SHIFT 2

Plant Management Names *(If more space is needed, use reverse)*

POSITION	SHIFT 1	SHIFT 2
President/General Manager		
Production Supervisor		
Foreman and Department		
Foreman and Department		
Foreman and Department		
Check if appropriate: ☐ HACCP/QC Manager ☐ HACCP/QC Technician ☐ Additional Foreman		

FEDERAL, STATE, LOCAL REQUIREMENTS *(Certificates, Letters, Permits, Etc.)*

ITEM	CERTIFICATE DUE DATE	CURRENT CERTIFICATE ON FILE		
		YES (✓)	DATE	N/A (✓)
Potable Water Source ☐ Municipal				
Potable Water Source ☐ Wells				
Shipping Inedible Material *(If applicable)*				
Ice Potability *(Outside supplied)*				
Other *(Specify):*				
Sewage *Check Date* ➜				
Backflow *Check Date* ➜				

List Government Office Facilities and Services *(Location, security file, restroom/locker, laundry facilities, Electronic coded entry, etc.)*

SPECIAL TELEPHONE CODES *(Include Area Codes)*

FSIS DESIGNATED PARKING SLOT: *(If yes, give location and/or slot number)* ☐ Yes ☐ No

PRODUCT AND OPERATIONS PROFILE *(HACCP)*

PRODUCT PROCESS ACTIVITIES AT THIS PLANT (Place an "X" in all appropriate blocks)

- ☐ Boning/Grinding
- ☐ Boneless Meat Reinspection
- ☐ Breaking/Cutting
- ☐ Chipping/Dicing
- ☐ Crackling/Skin popping
- ☐ Denaturing/Tanking
- ☐ Freezing
- ☐ Ice glazing parts
- ☐ Labeling/Packaging only
- ☐ Raw meat/poultry patties (without extenders)
- ☐ Poultry cut-up (RTC)
- ☐ Portion control
- ☐ Rendering/refining (edible animal fats, margarine, lard)
- ☐ Rendering (inedible)
- ☐ Basting
- ☐ Exports
- ☐ Tenderizing (mechanical other than massaging)
- ☐ Batter/breading
- ☐ Veal and Calf Skinning
- ☐ Freeze drying
- ☐ Injecting
- ☐ Marinating
- ☐ Meat and/or poultry patties (with extenders and other ingredients)
- ☐ Pumping
- ☐ Tenderizing (with solutions, massaging)
- ☐ Filtered lard
- ☐ Fresh sausage
- ☐ Margarine
- ☐ Assembly of products only
- ☐ Casings
- ☐ Slicing
- ☐ Smoking for appearance and flavor only (no formulation)
- ☐ Acidified products
- ☐ Curing
- ☐ Pizza
- ☐ Dough covered/ wrapped product
- ☐ Mechanical deboning
- ☐ Pizza topping
- ☐ Canned (perishable)
- ☐ Corn dogs
- ☐ Cured beef or pork (corned beef)
- ☐ Cured sausage
- ☐ Cured, water added pork products
- ☐ Fried chicken
- ☐ Cooked meat/poultry without formulation (open kettle, charbroil, braise)
- ☐ Sandwiches (meat brought from outside plant)
- ☐ Canning (thermally processed /shelf stable)
- ☐ Cooked and/or smoked sausages
- ☐ Dinners/entrees
- ☐ Dry/Semi-dried sausage
- ☐ Imports
- ☐ Meat/poultry pies
- ☐ Certification (freezing, heating, drying)
- ☐ Jerky * Cooked meat/poultry
- ☐ Formulation (frying, barbequing, etc.)
- ☐ Rolls/loaves/ luncheon meats
- ☐ Jellied products
- ☐ Cooked and/or smoked pork products
- ☐ Soups/salads/gravy
- ☐ Cooked patties (all)
- ☐ Cooked meats (roast beef, corned beef)
- ☐ Partially defatted (species) fatty tissues

PLEASE ADD ANY PRODUCTS/PROCESSES NOT GIVEN ABOVE

PARTIAL QUALITY CONTROL PROGRAMS/PROCEDURES

LIST BY NAME ALL PARTIAL QUALITY CONTROL PROGRAM(S) AND PROCEDURE(S) *(If more space is needed, use a separate sheet)*

LIST PLANT'S SPECIAL RULES *(i.e., hair nets, loose items in shirt coat pockets) (If more space is needed, use reverse)*

FSIS Directive 5400.5
Attachment 1

DATA FOR THE COMMON ON-LINE REFERENCE FOR ESTABLISHMENTS *(HACCP)*	EST. NO *(Meat)*	EST. NO. *(POULTRY)*	EST. NO. *(Equine)*	EST. NO. *(OTHER)*

Instructions: Place an "X" in the blocks appropriate for each plant. Make your decisions based on your knowledge of authorized activities for each plant and your observations of activities conducted at each plant.

	MEAT	POULTRY	EQUINE	OTHER
SLAUGHTER DATA	□ Cattle □ Calves □ Sheep □ Swine □ Reindeer (v) □ Buffalo (v)	□ Young Chick □ Mature chick □ Turkeys □ Geese □ Ducks □ Guineas □ Rabbit (v) □ Ratite (v) □ Quail (v)	□ Equine	
PROCESSING DATA	□ Raw product - Ground □ Raw - Not Ground □ Thermally Processed/Commercially Sterile □ Not Heat Treated - Shelf Stable □ Heat Treated - Shelf Stable □ Fully Cooked - Not Shelf Stable □ Heat Treated But Not Fully Cooked - Not Shelf Stable □ Product With Secondary Inhibitors - Not Shelf Stable			

* ID SERVICE CODE TABLE
N = No ID Service
1 = Plant handling unwrapped meat
2 = Plant that can handle wrapped or boned meat products only
3 = Combination of 1 and 5
4 = Combination of 2 and 5
5 = Approved identification services

OTHER DATA	MEAT	POULTRY	EQUINE	OTHER
ID Service *(enter code)* * Food Inspection Service Certification Service Voluntary Poultry Inspection Voluntary Equine Processing Animal Food Inspection Voluntary Processing	□ _____ □ □	□ _____ □ □	□ _____ □ □	□ _____ □ □
	□ Beef □ Veal □ Lamb □ Goat □ Pork □ Buffalo □ Reindeer	□ Poultry □ Rabbit □ Ratites □ Quail		

PLANT INFORMATION *(The entries below pertain to the plan as a whole.)*

EXEMPTED ACTIVITIES		OTHER INDICATORS		
□ Custom Slaughter □ Custom Processing □ Retail □ Buddhist □ Other *(specify):* _____	□ Confuscian □ Islamic □ Kosher	□ Other FDA □ HQ Point □ Tissues/Organs for Research/ Pharmaceuticals	□ Inedible Fats □ Inedible Fat Shipper □ Railsiding □ Unborn Fetal Blood	□ Inedible Blood □ Edible Blood □ High Pathology □ High Antibiotic Residue

PAGES 1, 2 AND 3 MUST BE COMPLETED, BEFORE SIGNING.

SIGNATURE OF FSIS INSPECTOR-IN-CHARGE PREPARING FORM | DATE

FSIS Directive 5400.5
Attachment 1

FSIS Form 5400-1, Plant Profile

General Instructions

FSIS Form 5400-1, Plant Profile, should be completed as each establishment becomes subject to the HACCP provisions of the Pathogen Reduction/HACCP regulation (see Directive 5400.5, III).
All pages of the form are to be maintained as a set.
The form is to be completed in duplicate by the inspector-in-charge.
The original copy of the form is filed in the government office where it is accessible to all inspection program personnel. If available, the previous plant profile (FSIS Form 8810-1) should be attached to the new original. The copy of the revised plant profile (FSIS Form 5400-1) should be mailed to the district office.
All sections must be completed or an "NA" placed in the space provided.
Any additional information should be recorded on a separate sheet, referenced in the appropriate space on the form, and the sheet attached to the form.

Plant Profile
Note: The numbers in these instructions correspond to the circled numbers on the Form.

1. Plant Name and physical location.
Enter the plant name and location. Give a brief description of the location , e.g., street address, zip code, local geographic location, route number or highway, etc.

2. If the mailing address is different from the location or street address include mailing address.

3. Enter the plant phone number, including area code.

4. Enter the plant FAX number, including area code.

5. Inspection Activities
Mark any applicable space.

6. Inspection Authority.
Mark the appropriate box .

7. District Name/No.
Identify the district by name or abbreviation and enter the numerical designation for that district.

8. Circuit Name/No.
Identify the circuit by name and number, e.g. Portland/09, etc.
Circuit names and numbers are found in the MPI Directory.

9. Establishment Number.
Enter the establishment number in PBIS format, e.g. 00038--P or 00038--M. If the establishment produces both meat and poultry enter both numbers.

10. Approved Operating Hours.
Enter the hours of operation approved by the district manager. If slaughter and processing have different hours enter in the appropriate space. If the plant has more than one shift use the space for second shift. Use military time when entering hours of operation.

11. Plant type.
Mark all boxes that are appropriate to the plant's operations.

12. Total Production Area(s) Sq. Ft.
Enter the total plant production area in this space. Enter the area in square feet. This information can be found on blueprints. Enter only the square footage for area where inspection program responsibilities exist.

13. Enter the number of inspection program personnel with PBIS responsibilities.

14. Plant Management Names.
Enter the name(s) of individuals in plant management and their titles. Write in the appropriate titles if they differ from those on the form. The names listed should be those with which inspection program personnel interact with on a routine basis regarding regulatory requirements. The HACCP/QC spaces should be marked if they are applicable.

15. Federal, State, or Local Requirements.
Required certificates, permits, letters, etc. can vary across the country. Determine if the item is required in the establishment. If so, check the file and determine the date listed on the current record. Record this date. Based on the requirement for renewal, enter the due date in pencil. If additional certificates or permits are on file, enter these on the back of the form.

16. List Government office, facilities, and services.
Enter information in this space that will assist inspection program personnel entering the establishment in locating facilities such as rest rooms, locker rooms, security files, etc.

17. Special telephone codes.
Enter the codes necessary to operate the telephone and reach various departments within the establishment. Enter the number for the circuit supervisor and the district office. Do not enter credit card numbers. Also, indicate location of FSIS dedicated line for a computer hook up.

18. FSIS Designated parking spot. Mark the appropriate space and indicate the slot number if applicable.

Page Two

19. Products and Operations.
Mark all spaces of applicable products and operations conducted in the establishment. Add any products not listed.

20. Partial Quality Control Programs or Procedures (PQCP).
List each QC program or procedure by name.

21. Plants Special Rules.
List any special rules in place in the plant that effect inspection program personnel in their regulatory capacity. Required hair nets, special foot dips, prohibition on loose items in pockets, etc. If additional room is needed use the reverse side of the form.

Page Three

22. Establishment Number.
Enter all appropriate establishment numbers in five digit PBIS format.

23. Slaughter Data
Place a mark in the boxes beside those species slaughtered at the establishment.

24. Process Data
Place a mark in all applicable boxes. These eight processes are representative of the HACCP process designations (417.2 (b)(1)). Slaughter is covered under 24.

25. Other Data
Place a mark in all applicable spaces. Enter the identification service (ID) code from the table above the space.

26. Voluntary Processing
Place a mark in the spaces beside those species processed at the establishment.

27. Exempted Activities
Place a mark in the applicable spaces.

28. Other Indicators
Place a mark in the applicable spaces.

29. Signature and Date
After completing the form, the inspector-in-charge will sign and date the form.

FSIS Directive 5400.5
Attachment 2
Procedure Schedule

Establishment/Shift: 00038 M/1 Page ID: 19 Scheduled Date: 01/27/98
Operating Hours: 0630-1500 Visited Date:

Sanitation /Procedure Verification 01A02 Determ Est has met reg req'ments for devlpment and maintenance of sanitation SOP Pri: 8 Pg: 1-2 Rate:	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
Sanitation/Operational Sanitation 01C01 Verify Est SSOP recds ensur monit effect op; corr action init'd to prev contm Pri: 8 Pg: 1-4 Rate: 260	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
HACCP/Raw Ground 03B01 Rev HACCP sys inclu rcds; obs cndts; ck 2 or more proc steps include Pri: 8 Pg: 3-1 Rate: 52	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
HACCP/Raw Not Ground 03C02 Ver HACCP rcds ensure effective mult CCPs limits, corr act, ver at proc steps Pri: 8 Pg: 3-6 Rate:156	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
Economic/Wholesomeness/Products 04A03 verify rcds; conduct hands-on to deter MSS/MSP/PDBFT/PDPFT/etc meets reg stnd Pri: 7 Pg: 4-3 Rate: 52	a) Performed b) Not Performed g) Economic h) Misbranding i) Protocol
Sampling/Residue 05C01 Rndm select sample(s) for residue/diag determination Pri: 5 Pg: 5-3 Rate: 13	a) Performed b) Not Performed
Other Inspection Requirements/Facilities and Equipment Standard 06D01 Verify rcds; conduct hands-on to deter random fac/equip meets requirements Pri: 5 Pg: 6-2 Rate: 13	a) Performed b) Not Performed j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-2 (9/97) 10/01/97

FSIS Directive 5400.5
Attachment 2

Procedure Schedule

Establishment/Shift: 00038 M/1 Page ID: 19 Scheduled Date: 01/27/98
Operating Hours: 0630-1500 Visited Date:

Sanitation /Procedure Verification 01A02 Determ Est has met reg req'ments for devlpment and maintenance of sanitation SOP Pri: 8 Pg: 1-2 Rate:	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
Sanitation/Operational Sanitation 01C01 Verify Est SSOP recds ensur monit effect op; corr action init'd to prev contm Pri: 8 Pg: 1-4 Rate: 260	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
HACCP/Raw Ground 03B01 Rev HACCP sys inclu rcds; obs cndts; ck 2 or more proc steps include Pri: 8 Pg: 3-1 Rate: 52	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
HACCP/Raw Not Ground 03C02 Ver HACCP rcds ensure effective mult CCPs limits, corr act, ver at proc steps Pri: 8 Pg: 3-6 Rate: 156	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
Economic/Wholesomeness/Products 04A03 verify rcds; conduct hands-on to deter MSS/MSP/PDBFT/PDPFT/etc meets reg stnd Pri: 7 Pg: 4-3 Rate: 52	a) Performed b) Not Performed g) Economic h) Misbranding i) Protocol
Sampling/Residue 05C01 Rndm select sample(s) for residue/diag determination Pri: 5 Pg: 5-3 Rate: 13	a) Performed b) Not Performed
Other Inspection Requirements/Facilities and Equipment Standard 06D01 Verify rcds; conduct hands-on to deter random fac/equip meets requirements Pri: 5 Pg: 6-2 Rate: 13	a) Performed b) Not Performed j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-2 (9/97) 10/01/97

FSIS Directive 5400.5
Attachment 2

Procedure Schedule

Establishment/Shift: Visited Date:

Procedure	Pri	Page	Procedure Description	Result Code (Enter A thru P as defined below)

a) Performed			Wholesomeness)		(Other Inspection Requirements)
	c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation	c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification	g) Economic h) Misbranding i) Protocol	m) Basic n) Other	j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-3 (9/97)

FSIS Directive 5400.5
Attachment 2

Procedure Schedule

Establishment/Shift: 00038 M/1 Visited Date: 1/27/97

Procedure	Pri	Page	Procedure Description	Result Code (Enter A thru P as defined below)
03A01				a
03A01				a
03J01				c
03J02				a

SAMPLE COPY

Result Codes

a) Performed	Non-Compliance Indicators				
	(SSOP)	(HACCP)	(Economic/ Wholesomeness)	(E-Coli)	(Other Inspection Requirements)
	c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation	c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification	g) Economic h) Misbranding i) Protocol	m) Basic n) Other	j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-3 (9/97)

FSIS Directive 5400.5
Attachment 2

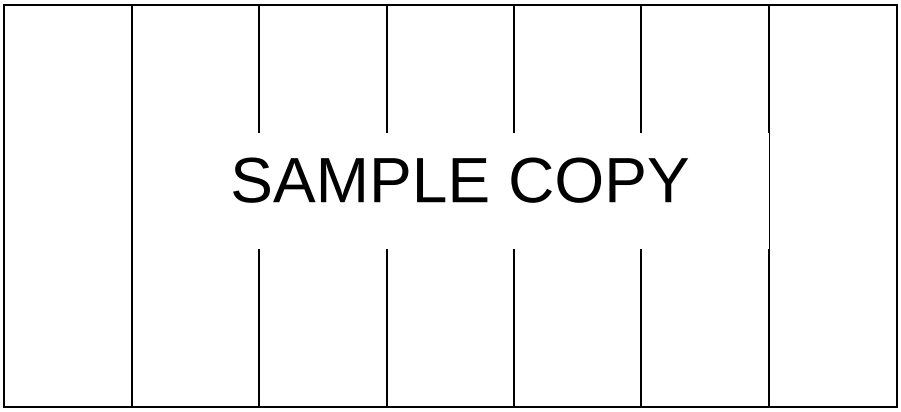
Establishment Schedule Summary

mm/dd/yy Sunday		mm/dd/yy Monday		mm/dd/yy Tuesday		mm/dd/yy Wednesday		mm/dd/yy Thursday		mm/dd/yy Friday		mm/dd/yy Saturday	

SAMPLE COPY

Note: * Indicates a Preoperational Sanitation Procedures. Establishments are listed in Numeric order and Travel Times may vary.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday


SAMPLE COPY

FSIS Directive 5400.5
Attachment 3

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD**	1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.

4. TO (*Name and Title*)

5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN ➜ | HACCP | SOP | OTHER

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS		
	A. ☐ SSOP	☐ Monitoring ☐ Corrective Action ☐ Recordkeeping ☐ Implementation
	B. ☐ HACCP	☐ Monitoring ☐ Corrective Action ☐ Recordkeeping ☐ Plant Verification
C. ☐ Product		☐ Economic ☐ Misbranding ☐ Protocol
D. ☐ Facility		☐ Lighting ☐ Structural ☐ Outside Premises ☐ Product Based
E. ☐ E. COLI		☐ Other

10. DESCRIPTION OF NONCOMPLIANCE:

SAMPLE COPY

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (*immediate action(s)):*

13. Plant Management Response (*further planned action(*s)):

This document serves as written notification that your failure to comply with regulatory requirement(s), which could result in additional regulatory and administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

FSIS FORM 5400-4 (9/97) INSPECTOR COPY

FSIS Directive 5400.5
Attachment 3

NONCOMPLIANCE CLASSIFICATION INDICATORS GUIDE

ACTIVITY	ELEMENT	INDICATOR
Sanitation	Pre-operational Operational	Corrective Action, Records, Monitoring, Implementation
	Procedure Review	Basic—results are reported by procedure
HACCP	Hazard Analysis/Plan/Validation/ Recordkeeping/Reassessment—Basic	Basic—results are reported by procedure
HACCP—Elements B-J	Observation Records Review	Corrective Action; Recordkeeeping; Verification; Monitoring
Microbiological Testing - FSIS	Directed Sampling- e.g., Listeria, Salmonella, E. Coli	Performed
Microbiological Testing - Establishment	E. Coli Written specimen Absence of Testing Recording Test results	Basic-results are reported by procedure
	Sample Collection Sample Analysis Records of Test	Other
Sampling	Salmonella	No Indicator-results reported as performed
	Economic	No Indicator-results reported by procedure
Other Inspection Requirements	Export	Misbranding or No Indicator—results reported by procedure
	Custom Exempt/Retail	No Indicator—results reported by procedure
	Facilities and Equipment Condemned and Inedible Sewage Water Pest and Rodent Control	Lighting Structural Outside Premises Product Based
Economic/Wholesomeness	% Yield/Shrink X% Solution MSS/MSP/PDBFT/PDPFT/etc. Batter/Breading Product Standards CN/Grade Labeling/etc. Net Weight General Labeling Finished Product Standards/AQL/Boneless Meat, etc.	Economic Misbranding Protocol

FSIS Directive 5400.5
Attachment 3

☐ Attachment

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD** **CONTINUATION SHEET**	1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (*Name and Title*)			
5. PERSONNEL NOTIFIED			
6. RELEVANT REGULATION(S)			
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN ➜	| HACCP	| SOP	| OTHER
8. ISP CODE	9. NONCOMPLIANCE INDICATOR		
10. DESCRIPTION OF NONCOMPLIANCE :			

SAMPLE COPY

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	12. DATE

FSIS FORM 5400-4a (9/97) **ORIGINAL - Establishment**

FSIS Directive 5400.5
Attachment 4

ESTABLISHMENT/SHIFT INSPECTION PROCEDURE WORKSHEET
HACCP Est./Shift

Procedures				
01A01 [ ]	04B01 [ ]			
01B01 [ ]	02 [ ]			
02 [ ]	03 [ ]			
	04 [ ]			
01C01 [ ]	04C01 [ ]			
02 [ ]				
03A01 [ ]	05A01 [ ]			
	02 [ ]			
	03 [ ]			
03B01 [ ]	05B01 [ ]			
02 [ ]	02 [ ]			
03C01 [ ]	05C01 [ ]			
02 [ ]				
	06A01 [ ]			
03D01 [ ]				
02 [ ]				
03E01 [ ]				
02 [ ]				
	06D01 [ ]			
03F01 [ ]	02 [ ]			
02 [ ]	03 [ ]			
03G01 [ ]	06E01 [ ]			
02 [ ]				
	06F01 [ ]			
	02 [ ]			
03H01 [ ]				
02 [ ]	06G01 [ ]			
	07A01[ ]			
03I01 [ ]				
02 [ ]				
03J01 [ ]				
02 [ ]				
04A01 [ ]				
02 [ ]				
03 [ ]				
04 [ ]				

FSIS FORM 5400-5 (9/97) USDA-FSIS

FSIS Directive 5400.5
Attachment 4

Noncompliance Determination Guide

The Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule amended FSIS's regulations to require establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur. These regulations are the framework for a modernized approach to inspection. FSIS expects to review and amend its other food safety and consumer protection regulations (including rules to prevent misbranding and economic adulteration) for consistency with this framework and to improve their usefulness to Agency personnel and the public.

The purpose of a HACCP system is to control food safety hazards that are reasonably likely to occur in the food production process. Among other things, an establishment's HACCP plan must include critical limits designed to ensure that performance standards and other process or product requirements in FSIS's regulations are met.

For inspection program activities in establishments that are subject to the HACCP system regulations, FSIS is replacing the Deficiency Classification Guide and the Process Deficiency Record with the Noncompliance Determination Guide (NDG) and the Noncompliance Record (NR). Inspection program personnel are to apply the NDG in all regulatory areas.

Outcomes and Trends

Whenever inspection program personnel perform a procedure in the Inspection System Procedure (ISP) Guide (whether scheduled or unscheduled), they either do or do not find noncompliance with one or more regulatory requirements. When noncompliance with regulatory requirements is not found, the procedure is recorded as "performed" on the Procedure Schedule (PS) (see FSIS Directive 5400.5, Paragraph X.). (No other entry or record is required. FSIS sampling is recorded as "performed" as well.)

FSIS Directive 5400.5
Attachment 5

Inspection program personnel who find noncompliance with one or more regulatory requirements also (1) categorize the noncompliance, by marking the appropriate PS and NR indicator, and (2) using an NR, document and follow-up on their findings. (See FSIS Directive 5400.5, Paragraph XI., for information about the NR.)

The purpose of trend indicators is to improve the Agency's ability to evaluate establishment performance and process control by providing information on trends in noncompliance. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance. Inspection program personnel are to mark the indicator that best describes the noncompliance.

The following summary describes the indicators for various PBIS activities.

Plant Process

For the regulations on Sanitation SOP's (SSOP's), there are four indicators: monitoring, corrective action, recordkeeping, and implementation. The first three indicators correspond to specific requirements in part 416 (see also FSIS Directive 5000.1, Part Three, Paragraph III.B.); inspection program personnel who find that an establishment's noncompliance with requirements for SSOP implementation involves failures in more than one of these areas should use the fourth indicator.

For the regulations on HACCP systems, there are four indicators: monitoring, corrective action, recordkeeping, and verification. Each corresponds to specific requirements in part 417 (see also FSIS Directive 5000.1, Part Two, Paragraph III.B.).

For these regulations and the regulations on E. coli testing and criteria, there also is an indicator for basic noncompliance findings (see below and FSIS Directive 5000.1, Paragraph II. of Parts Two, Three, and Four).

For other product regulations addressed by an 04 Activity or an 06A Export element, there are three indicators: economic, misbranding, and protocol.

> Inspection program personnel who find noncompliance when performing an Other Requirements procedure in an 04 Element prior to the labeling or branding of a product should use the economic indicator. This is the only appropriate indicator when performing an 04C procedure. (Examples: the number of noncomformances found when performing a finished product standards test exceed the regulatory limit; the scale used to determine a product's net weight is found to be inaccurate.)

Inspection program personnel who find noncompliance when performing an Other Requirements procedure in an 04 or 06 Element after product is labeled, branded, or packaged should use the misbranding indicator. This is the appropriate indicator for noncompliance with net weight or standard of identity or composition requirements.

If an establishment that has elected to use an alternative production method or process has on file a protocol which was reviewed by FSIS personnel, inspection program personnel who find economic adulteration or misbranding when performing an Other Requirements procedure in an 04 Element should use the protocol indicator. (Do not use this indicator for deviations from a QC program that is not a regulatory requirement. When a deviation from a plant's QC program is also a failure to met a regulatory requirement, that regulatory failure will be documented using the most appropriate trend indicator. The documentation on the NR's should be as complete as possible.)

For facility regulations, there are four indicators: lighting, structural, outside premises, and product-based. Inspection program personnel who find noncompliance when performing procedures in an 06D, 06E, or 06F Element should select among these indicators based on the root cause of the noncompliance. (For example, noncompliance resulting from a slaughter flooring problem should be classified as structural; noncompliance due to leaking pipes on the loading dock should be classified as outside premises.)

Inspection program personnel who find instances of indirect product contamination potential when performing an ISP procedure for part 416 (SSOP's), may use the fourth facilities trend (product-based) indicator. (For example, inspection program personnel performing an SSOP procedure to verify the cleaning and sanitizing of a hide-puller, find that the equipment is clean and sanitary and will not cause direct product contamination. However, on a nearby wall, there is material which could cause indirect product contamination. This is not an SSOP noncompliance, but would be a facilities noncompliance and recorded using the product-based indicator.

Food Safety Noncompliance

FSIS Directive 5000.1 provides instructions for enforcing the regulations on HACCP systems and SSOP's. It also addresses actions based on noncompliance with the E. coli process control verification requirements and the pathogen reduction performance standards for Salmonella. FSIS Directive 5000.1 divides possible failures to comply with food safety-related regulations into two categories: basic compliance/noncompliance and compliance/noncompliance with other requirements.

Basic Compliance/Noncompliance

Basic compliance checks (ISP procedures 01A01, 03A01, and 05A01) focus on whether an establishment has failed to institute the systems required by FSIS regulations: Either the establishment does not have a required plan or procedures or recordkeeping at all (for example, when an establishment does not have written SSOP's or written procedures for collecting samples for E. coli testing), or what the establishment has clearly does not meet regulatory requirements (for example, when an establishment's SSOP's do not identify which procedures are pre-operational procedures, or when a HACCP plan does not list the critical limits to be met at each critical control point or does not identify the corrective action to be followed in response to a deviation from a critical limit at a critical control point).

Compliance/Noncompliance--Other Requirements

This category includes failure to comply with any requirement not addressed by a basic compliance check. As instructed in FSIS Directive 5000.1, there are situations in which finding noncompliance with these requirements supports an inspection program employee initiating the withholding of inspection (see, in particular, Paragraph III.C. of Parts Two and Three). In other cases, FSIS will use documentation of recurring or repeated noncompliance in determining what further action to take.

In addition, inspection program personnel who, as a result of performing ISP procedure 03B01, 03C01, 03D01, 03E01, 03F01, 03G01, 03H01, 03I01, or 03J01, determine that an establishment has failed to comply with one or more regulatory requirements are to perform the corresponding ISP procedure (03B02, 03C02, 03D02, 03E02, 03F02, 03G02, 03H02, 03I02, or 03J02) for the same lot of product (see FSIS Directive 5000.1).

Other Consumer Protection Noncompliance

For all remaining Activities, Elements, and Procedures, inspection program personnel are to document noncompliance on an NR and, as appropriate, continue to apply a "U.S. Retained/Rejected" tag to misbranded or economically adulterated product. When a "U.S. Retained/Rejected" tag is not used (for example, when a roll of labels stored on a pallet has features that are not of the prominence required by regulation), inspection program personnel are to select the appropriate trend indicator (economic in the preceding example).

When, as a result of performing one of these procedures, inspection program personnel find noncompliance with one or more food safety requirements, they should use the appropriate food safety procedure in documenting the noncompliance.

FSIS Directive 5400.5
Attachment 5

Inspection program personnel who suspect misbranding or economic adulteration are to take action (such as tagging) to control suspect product.