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

FSIS PHIS DIRECTIVE

5100.4 | 4/11/11

PRIORITIZED SCHEDULING OF FOOD SAFETY ASSESSMENTS (FSAs) USING THE PUBLIC HEALTH INFORMATION SYSTEM (PHIS)

I. PURPOSE

A. This directive provides the decision criteria that District Case Specialists (DCSs) are to use in scheduling food safety assessments (FSAs) using the Public Health Information System (PHIS). It includes background information on prioritizing FSAs, instructions on prioritized scheduling of FSAs, an FSA Scheduling Priorities and Criteria Quick Reference Table, and an attachment containing further information on prioritized scheduling of "for cause" FSAs.

B. For the purpose of this directive, the DCS role may include Supervisory Enforcement, Investigations and Analysis Officers (SEIAOs) in districts where they are assigned.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR 300 to end.
Federal Register Notice: Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection (71 FR 9772, 2/27/06)
Federal Register Notice: Salmonella Verification Sampling Program: Response to Comments and New Agency Policies (73 FR 4767, 1/28/08)
The PHIS User Guide is available via the FSIS Intranet on the PHIS page under Resources

V. BACKGROUND

The Agency will place processing and slaughter establishments into a priority level for FSA scheduling using public health decision criteria, in addition to traditional event-based scheduling. Using PHIS, the DCS schedules, assigns, and tracks FSAs for the Enforcement, Investigations, and Analysis Officers (EIAOs) and Public Health Veterinarians (PHVs) trained in the EIAO methodology. The

DCS is to prioritize the scheduling of FSAs based on the criteria outlined in this directive and on the availability of EIAOs. An establishment that meets one or more of the criteria under any of the priority levels in Table 1 will receive a “for cause” FSA. A “for cause” FSA is one that is prompted by a positive sample result, production and shipment of adulterated product, or any other high priority food safety related incident. The Agency will also be scheduling routine FSAs and routine risk-based *Listeria monocytogenes* (RLm) microbiological sampling, which includes completing a comprehensive FSA, at a minimum of once every 4 years.

Table 1: "For Cause" FSA Scheduling Priorities and Criteria Quick Reference

Scheduling Priority	Criteria
1st Priority	FSIS[1] positive *Escherichia coli* (*E. coli*) O157:H7 on ground beef or patties or raw beef components (see FSIS Directive 10,010.1)
	Establishment identified in STEPS as a sole supplier of a positive *E. coli* O157:H7 ground beef or patties or raw beef components (see FSIS Directive 10,010.1)
	Establishment in the STEPS database more than once in the past 120 days identified as a multiple supplier, except if the establishment applied a full lethality treatment to the implicated raw beef product (see FSIS Directive 10,010.1)
	FSIS positive *Listeria monocytogenes* (*Lm*), *Salmonella* or *E. coli* O157:H7 in ready-to-eat (RTE) products or a positive *Lm* food contact surface sample (see FSIS Directive 10,300.1)
	Establishment that produced and shipped adulterated or misbranded product, undergoing a Class I or Class II recall (see FSIS Directive 8080.1)
	Establishment subject of a Part 416 or 417 related enforcement action that is not the result of an FSA
	FSIS positive *Salmonella* in heat treated, not fully cooked, not shelf stable stuffed poultry product
	Human illness linked to FSIS-regulated product (see FSIS Directive 8080.3)[2]
	Establishment with a history of health-related noncompliance records and is in the highest percentile of health-related NR rates
2nd Priority	Establishment in PR HACCP *Salmonella* Category 3 (see Federal Register Notice 73 FR 4767, January 28, 2008)
	Establishment produced product with repetitive *Salmonella* serotypes of public health concern[2] (see Federal Register Notice 73 FR 4767, January 28, 2008)
	Establishment produced product with *Salmonella* PFGE matches[2] (see Federal Register Notice 73 FR 4767, January 28, 2008)
	Documented change in an establishment's production process that may impact public health[2]
	Consumer complaints associated with meat or poultry products as reported through CCMS[2] (see FSIS Directive 5610.1)
3rd Priority	New establishments coming under a permanent grant of inspection[2]
	Repeat residue violators from same supplier source[2] (see FSIS Directive 10,800.1)
	Establishment subject of other enforcement action that is not the result of an FSA (e.g., 9 CFR 500.3(a)(6) or 500.3(b))

[1] FSIS sample results include sample results obtained by other government entities, such as the Agricultural Marketing Service, or a State public health laboratory (see FSIS Directive 10,000.1)
[2] Criteria not automatically scheduled by the ODIFP-DAIG

VI. PRIORITIZED SCHEDULING OF FSAs BY THE DCS

A. General Information

1. The DCS performs several FSA workflow management functions within PHIS, including:

   a. Initiating the FSA by identifying the type of FSA to be scheduled; selecting the establishment where the FSA is to be conducted, using the decision criteria outlined in this directive; and creating FSA and directed FSA sampling task requests;

   b. Assigning the FSA to an EIAO, determining the disposition (approved or rejected) of an FSA request by the EIAO, and monitoring the progress and performance of the FSA; and

   c. Reviewing the documented results of a FSA, providing comments to the EIAO on responses recorded in the FSA tools and routing it back to the EIAO for clarification or re-analysis; concurring with the FSA and routing it back to the EIAO for finalizing.

2. Instructions on how to perform FSA workflow management functions within PHIS can be found in the PHIS User Guide.

3. The DCS is to select the appropriate FSA criteria in the FSA workflow task category when creating an FSA. If the criterion for scheduling the FSA is not listed, the DCS is to select "Other" and include a justification in the free text box provided.

B. "For Cause" FSA Scheduling Information

1. Every week, the Office of Data Integration and Food Protection (ODIFP), Data Analysis and Integration Group (DAIG), will send the DCS in each district a ranked list of eligible establishments that the DCS is to use when scheduling "for cause" FSAs. In addition, the DCS may become aware of other "for cause" FSAs on the priority list by other means (e.g., through notification by an FSIS laboratory of a positive sample result, or the District Manager (DM) may assign FSAs for the DCS to schedule). The DCS is to use the priority levels listed in Table 1 to direct resources when assigning FSAs. The DCS is to notify the ODIFP-DAIG analyst assigned to the district of any "for cause" FSAs to be completed in the district as they are scheduled. Under the direction of the DM, the DCS is to schedule:

   a. FSAs within 30 days of notification by the DAIG;

   b. FSAs with the highest priority level first (see Table 1);

c. Discretionary FSAs as directed by the DM. Discretionary FSAs may include those based on emergency events, or those requested by inspection program personnel (IPP) through supervisory channels. For example, IPP may request an FSA be performed in an establishment that, through its own sampling program, has obtained a positive *E. coli* O157:H7 test result in raw beef product that is either non-intact or intended for non-intact use and has failed to take appropriate corrective action (see FSIS Directive 10,010.1); and

d. FSAs, when informed of, or because of the following developments which are not automatically scheduled by the ODIFP-DAIG:

   i. Human illness linked to FSIS-regulated product from a Federal establishment;

   ii. Repetitive *Salmonella* serotypes of public health concern;

   iii. *Salmonella* Pulse Field Gel Electrophoresis (PFGE) matches;

   iv. Repeat residue violations from the same source;

   v. Consumer complaints associated with the consumption of meat or poultry products as reported through the Consumer Complaint Monitoring System (CCMS);

   vi. Documented change in an establishment's production process that may affect public health (e.g., added process category or significant change in a process that may add, change or enhance food safety hazards, such as the addition of a new HACCP plan or replacement of a CCP with a prerequisite program); and

   vii. A new establishment coming under a permanent grant of inspection.

NOTE: An FSA should be scheduled within 6 months after the issuance of a permanent grant of inspection to new establishments.

2. When an EIAO completes a "for cause" FSA in an establishment that is not subject to 9 CFR Part 430 regulations, FSIS will have met its requirement of scheduling an establishment for an FSA at a minimum of once every 4 years.

3. When a "for cause" FSA is triggered for reasons other than a positive *Lm* result in an establishment subject to 9 CFR Part 430 regulations, an RLm is also to be performed as part of that FSA. This RLm will be substituted for the 4-year

minimum frequency RLm in this establishment. If an FSA had recently been completed in the establishment before the "for cause" trigger, the DM may elect to discuss the need for this additional FSA with the appropriate Executive Associate for Regulatory Operations.

4. When a "for cause" FSA is performed as a result of a positive *Lm* sample, an IVT is to be conducted as part of that FSA. If a 9 CFR Part 500, Notice of Intended Enforcement or Suspension action results from the IVT with FSA, then the DCS is to schedule a follow up IVT before closing out the enforcement action. Following compliant findings with this second IVT, and when the enforcement action is closed out with a Letter of Warning, these two IVTs conducted in the establishment will be considered as meeting the requirement for the 4-year minimum frequency of routine RLm FSA scheduling. If, however, a 9 CFR Part 500, Notice of Intended Enforcement or Suspension action does not result from the initial IVT with FSA, then this single IVT sampling is not a substitute for the 4-year minimum frequency RLm FSA. After 6 months, the ODIFP-DAIG will place the establishment back into the 4-year schedule cycle for a routine RLm FSA.

5. A "for cause" FSA is to be completed within 90 days of receipt of the notification. If the 90 day window cannot be met, the DM is to document the reason in the case file and notify the ODIFP-DAIG.

C. Routine (non-RLm) FSA Scheduling Information

1. Every month, the ODIFP-DAIG will send a 1-month schedule of routine (non-RLm) FSAs to the DCS. The ODIFP-DAIG will send the schedule electronically 6 weeks in advance. The schedule is to include the district number, establishment number, and a prioritized ranking for each establishment.

2. The DCS is to schedule a routine (non-RLm) FSA to be conducted at a minimum of once every 4 years in each official establishment that is not subject to the 9 CFR Part 430 regulations.

3. The DCS is to schedule the routine FSA according to the priority of the risk ranking given (e.g., an establishment ranked as priority 1 is to be scheduled by the DCS before an establishment ranked as priority 2).

D. Routine RLm FSA Scheduling Information

1. Every month, the ODIFP-DAIG will send a 1 month schedule of RLm FSAs to the DCS with a "cc" to the DM. Each establishment that produces post-lethality exposed RTE product will be ranked based on the alternatives it uses, products it produces, and its production volume. The ODIFP-DAIG will send the schedule electronically 8 weeks before the beginning of the month in which the samples are to be collected and will include the district number, establishment name and

number, the establishment size, the week during which the samples are to be collected, and the laboratory assigned to receive and analyze the samples.

2. Upon receipt of the schedule, the DCS has 3 weeks to review the schedule and to determine whether any changes are needed. During this 3 week period, the DCS is to consider issues such as EIAO resources, recent or active FSAs, infrequent production schedules, changes to an establishment's operating status, and processing procedures and submit any needed scheduling changes to the ODIFP-DAIG analyst assigned to the district and the "RLm Sampling Questions" mailbox in Outlook. The ODIFP-DAIG will have 1 week to update the schedule. The final RLm schedule will be distributed by approximately the 1st of the month before the scheduled sampling month.

VII. DATA ANALYSIS

A. At least annually, the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP), will analyze the data collected as a result of completed comprehensive FSAs and any associated sampling. DAIG will analyze the findings of the relevant FSAs to determine whether there are any industry-wide food safety system vulnerabilities. The ODIFP-DAIG will determine whether there are any district specific concerns and, if there are, will promptly notify the Office of Field Operations, Assistant Administrator. DAIG's findings will inform FSIS's development of industry guidance documents, inspection procedures, industry outreach activities, regulations, other policies, and verification sampling programs. These analyses will allow FSIS to focus resources where they are needed.

B. At least annually, DAIG will look for trends in FSA data across process categories in order to identify industry-wide food safety system vulnerabilities. These trends will be identified by analyzing the responses to selected questions in the FSA tool for each HACCP process category. The trends identified in these analyses will be used to inform Agency initiatives, and the analyses will allow FSIS to be more proactive and resource efficient in protecting public health. In addition, DAIG will analyze trends in "for cause" FSA scheduling criteria and will use the findings of the analyses to make adjustments in Agency FSA prioritization guidelines, when needed. DAIG will provide monthly reports to the districts about completed FSAs and outstanding FSAs.

Refer questions regarding this directive to the Risk and Innovations Management Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1

FURTHER INFORMATION ON PRIORITIZED SCHEDULING OF "FOR CAUSE" FSAs

A. FSIS responds to sample results obtained by other government entities, such as the Agricultural Marketing Service or a State public health laboratory (see FSIS Directive 10,000.1).

B. In cases where there is a human illness linked to a FSIS-regulated product from a Federal establishment, the Office of Public Health Science (OPHS) will contact the AA of OFO. The AA or designee will provide the DM information from which he or she may direct the DCS to schedule an EIAO to perform an FSA (see FSIS Directive 8080.3).

C. When an establishment has a history of a high rate of health-related noncompliance records (NR) (e.g., insanitary dressing; violative residues; a history of repetitive noncompliance in the establishment's *Lm* control program, including sanitation issues; or a persistent problem in addressing noncompliances), the Inspector-In-Charge (IIC) and Frontline Supervisor (FLS) may recommend to the DM that an EIAO conduct an FSA.

D. An FSA may be scheduled because of repetitive *Salmonella* serotypes of human health concern found at establishments through FSIS sampling (see the Federal Register Notice at 73 FR 4767, January 28, 2008).

E. For *Salmonella* PFGE matches, PFGE analysis may support an epidemiological link between product samples from a specific supplying establishment and product samples from establishments that receive source material from that establishment (common production source) (see Federal Register Notice 73FR4767, January 28, 2008).

F. When there is a documented change in an establishment's production process that may impact public health (e.g., an added process category or significant change in a process that may add, change or enhance food safety hazards), the IPP may raise concerns through the FLS to the DM, and the DM may direct the DCS to schedule an EIAO to perform an FSA.

EXAMPLE: A district has 2 *E. coli* O157:H7 positive sample results, 1 *Lm* positive sample result, and 1 establishment in *Salmonella* category 3 for PR HACCP sampling to schedule within 30 days. In addition, the DM has asked the DCS to schedule an establishment with a new permanent grant of inspection for an FSA. The district has approximately 200 total establishments to schedule for routine FSAs. The DCS is trying to schedule at least 3 routine FSAs per month to meet the minimum 4-year requirement. The district has 10 EIAOs. The DCS should schedule the 3 positive sampling ("for cause") FSAs first, and the one requested by the DM using 4 of the available EIAOs. The DCS should next schedule the 2nd priority level *Salmonella* Category 3 FSA. The

DCS is to utilize the other 5 available EIAOs to address the routine FSAs for the 4 year minimum requirement. However, if other issues arise that have a higher priority level, these FSAs will be scheduled as the need arises, or as EIAOs become available.