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

FSIS NOTICE	49-07	8/8/07

CONDUCTING FOOD SAFETY ASSESSMENTS RELATED TO THE CONTROL OF *SALMONELLA*

I. PURPOSE

This notice addresses Food Safety Assessments (FSAs) conducted to analyze an establishment's control of *Salmonella*. FSAs generally assess all aspects of an establishment's food safety system (see FSIS Directive 5100.1). This notice provides specified methodologies that Food Safety and Inspection Service (FSIS) personnel are to use when evaluating control of *Salmonella* in poultry slaughter operations. Some strains of *Salmonella* have been particularly associated with human illnesses. Therefore, control of this pathogen is necessary to ensure the safety of poultry. Enforcement, Investigations, and Analysis Officers (EIAOs) are to assess whether poultry slaughter establishments have designed their food safety systems to control, and thereby minimize, the presence of *Salmonella.*

II. BACKGROUND

A. Based on FSIS's experience with establishments that failed one or more *Salmonella* sets and then came into compliance, establishments can effectively control *Salmonella* prevalence when properly addressed in the establishments' food safety system. Establishments can address *Salmonella* in their Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operating Procedures (SOPs), or other prerequisite programs. The decisions establishments make in their hazard analyses, and the supporting documentation for those decisions, will affect how *Salmonella* is addressed in their food safety systems, and whether they do so effectively.

B. Each completed sample set result will be recorded in one of three categories in relation to the standard or baseline guidelines as set out in the Federal Register Notice (71 FR 9772), *Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection*, as follows:

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1. Category 1. 50% or less of the performance standard or baseline guidance (consistent process control);

2. Category 2. From 51% of the performance standard or regulatory guideline to the performance standard or baseline guidance (variable process control); and

3. Category 3. Greater than performance standard or baseline guidance (highly variable process control).

III. CONDUCTING THE FSA

EIAOs are to follow the instructions in FSIS Directive 5100.1, "Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology", when conducting FSAs at poultry slaughter establishments. EIAOs are to pay particular attention to how an establishment that is either in Category 2 or Category 3 is ensuring the control of *Salmonella*. Because an establishment may address the control of *Salmonella* in a number of ways, EIAOs are to perform the assessment in consideration of the following:

A. Establishments that Address the Control of *Salmonella* in Their HACCP Plan

1. If an establishment determines in its hazard analysis that *Salmonella* is a food safety hazard reasonably likely to occur, 9 CFR 417.2 requires that the establishment address *Salmonella* control in its HACCP plans. EIAOs are to seek answers to questions such as:

a. Do the *Salmonella* control measures in the HACCP plans meet all of the requirements contained in 9 CFR 417.2(c)?

b. Are the Critical Control Points (CCPs) capable of preventing, eliminating, or reducing *Salmonella* to the fullest extent possible (e.g., Category 1)?

c. Do the HACCP plans include actions that the establishment will take when the results of a sample set put the establishment in Category 2, reflecting that *Salmonella* control is variable under its process?

d. If the establishment has failed to meet the performance standard, has it reassessed its HACCP plans and hazard analysis, and can the establishment support the decisions that it has made in its reassessment?

e. Is the establishment doing verification testing to demonstrate that its HACCP system is functioning as intended?

f. Does the establishment take any measures to control the condition of birds at the time they are brought to the slaughter plant; that is, does the establishment have an arrangement with its suppliers under which the suppliers work to control the prevalence of *Salmonella* on the birds?

g. Does the establishment take birds off-line for reprocessing? Does it have a CCP at this step?

i. Has the establishment considered the level of contamination from off-line reprocessed birds in the decisions made in its hazard analysis?

ii. Is there documentation to support why the establishment's off-line reprocessing does not need to include a CCP?

h. Does the establishment reprocess birds on-line? If so, does it have the following:

i. a CCP at this step;

ii. a waiver to conduct on-line reprocessing;

iii. monitoring and verification procedures to ensure effectiveness of the on-line reprocessing intervention; and

iv. validation data for the on-line reprocessing intervention (fecal removal, microbial log reduction, and comparability to off-line reprocessing).

B. Establishments that Address *Salmonella* in Their Sanitation SOPs or in a Prerequisite Program

1. EIAOs may find that some establishments determine in their hazard analysis that *Salmonella* is a food safety hazard, but that it is not likely to occur because of measures that the plant includes in its process. The EIAO may see that these establishments have determined that since there are no CCPs in the process that prevents, eliminates, or reduces *Salmonella* (e.g., receiving does not introduce pathogens), the means of minimizing *Salmonella* cannot be feasibly addressed in their HACCP plans. EIAOs may find that these establishments address *Salmonella* by establishing multiple hurdles throughout the process and that *Salmonella* process control is addressed in their hazard analysis and Sanitation SOPs, or other prerequisite programs.

2. EIAOs are to analyze whether the decisions the establishment made in hazard analysis and the procedures it put in place are actually adequate to address *Salmonella*. EIAOs are to seek answers to questions such as:

a. Does the establishment have procedures in place throughout the process that effectively minimize the occurrence of *Salmonella*?

b. Do the Sanitation SOPs or other prerequisite programs contain some level of testing to verify that the measures are effectively preventing or minimizing the occurrence of *Salmonella*?

i. If the establishment tests for *Salmonella,* does it serotype in order to determine whether the *Salmonella* organisms present are associated with public health concerns?

ii. Does the establishment test for any indicator organisms?

c. Does the establishment have supporting documentation to support that the Sanitation SOPs or other prerequisite programs include procedures that make the process capable of producing product that falls into Category 1?

d. If the product has failed to meet the performance standard, (i.e., Category 3), has the establishment reassessed its hazard analysis to determine if the Sanitation SOPs or other prerequisite programs are effective in supporting the decisions made in the hazard analysis necessary to minimize *Salmonella* prevalence?

IV. PREPARING THE FSA REPORT

A. When the EIAO has completed the FSA, he or she is to review the information that he or she gathered about the establishment's food safety system, including the answers to questions in Section III of this notice. The purpose of this review is to assess whether the establishment is maintaining control of its process to the extent necessary to ensure that it is producing safe food.

B. Based on this review, the EIAO is to prepare the final FSA report. The report, as described in FSIS Directive 5100.1, is to include:

1. A brief summary of the establishment's procedures at each step of the HACCP process, including whether there are procedures at each step to control or effectively minimize the occurrence of *Salmonella*, either as part of the HACCP plan or Sanitation SOPs*,* and, if so, what procedures are in place. The purpose of this summary is to provide a description of the food safety system in operation at the time that the FSA was conducted.

2. A description and analysis of any regulatory noncompliances identified at any step, including any relevant history of noncompliance. The EIAO will determine and document whether the noncompliances have an impact on the food safety system's ability to produce safe food, or whether they represent failures to meet regulatory requirements that do not have an impact on food safety.

3. The EIAO is to analyze all of the noncompliances to determine whether, collectively, they provide a reason to conclude that the establishment has not designed its process to control all reasonably foreseeable insanitary conditions, including all hazards likely to occur, and thus to produce safe product. The EIAO should be aware that multiple noncompliances may not provide a basis to conclude that the establishment's process control is inadequate. The EIAO is to have documentation that is adequate to justify the determination he or she makes.

C. Specifically, with respect to *Salmonella*, the EIAO will consider the following factors:

1. What is the establishment's approach *to Salmonella*? Does the establishment address *Salmonella* control in its HACCP plans, Sanitation SOPs, or other prerequisite programs?

NOTE: If the establishment addresses *Salmonella* in its prerequisite programs, the EIAO is to summarize that approach and describe how the establishment determines its ongoing effectiveness.

2. If the controls in place for *Salmonella* are operating as designed, or the establishment is effectively minimizing the occurrence of *Salmonella*, the EIAO can conclude that there is no reason to determine that the food safety system is not properly addressing this pathogen.

V. RECOMMENDING ENFORCEMENT ACTIONS

A. The EIAO may decide that insanitary conditions exist because the food safety system does not include either effective controls or an effective prerequisite program that is preventing *Salmonella* from being reasonably likely to occur.

B. The EIAO is to recommend to the District Office that a Notice of Intended Enforcement (NOIE) be issued when he or she determines, and can support with findings from the FSA, that the establishment is operating under insanitary conditions because there are steps in its hazard analysis, Sanitation SOPs, prerequisite programs, or HACCP plans that:

1. are not properly designed;

2. are not being properly executed; and

3. the establishment is failing to produce safe, unadulterated product.

C. An EIAO is to explain and provide documentation in the NOIE, as set out in 9 CFR 500.4, in what ways the HACCP plan is inadequate; the Sanitation SOPs are not being properly implemented or maintained; or how the establishment has not maintained sanitary conditions.

D. Specifically, with respect to *Salmonella*, for an EIAO to determine that the HACCP plan is inadequate as specified in 9 CFR 417.6, he or she would need to explain how:

1. design features for the control of *Salmonella* are not capable of accomplishing the control of the pathogen. The EIAO should be able to reference a number of related findings and inadequacies in the hazard analysis and HACCP plan and explain how, as a whole, these findings demonstrate that the establishment's food safety system is not capable of controlling the pathogen; or

2. the execution of the measures designed to control *Salmonella* is not succeeding. The EIAO should be able to reference a number of related findings, such as trends of noncompliance in the monitoring, recordkeeping, verification, or corrective actions of the HACCP plan, and explain how the findings demonstrate that the execution of the HACCP plan is not controlling the pathogen.

Refer questions to the Policy Development Division (formerly the Technical Service Center) at 1-800-233-3935.

/s/ Daniel L. Engeljohn for

Assistant Administrator
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