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

FSIS NOTICE

Related document- Highlighted Changes

7/11/19

ACTIONS TO TAKE IN RAW POULTRY ESTABLISHMENTS EXCEEDING *SALMONELLA* PERFORMANCE STANDARDS

I. PURPOSE

This notice reissues instructions for inspection program personnel (IPP) to verify corrective action and reassessment requirements (if applicable) and for Enforcement, Investigations, and Analysis Officers (EIAOs) to perform Public Health Risk Evaluations (PHREs) and Food Safety Assessment (FSA) when appropriate, for those establishments that do not meet a *Salmonella* performance standard for raw chicken or turkey (poultry) carcasses, chicken parts, or not-ready-to-eat (NRTE) comminuted poultry products. The District Office (DO) may elect to schedule the PHRE or FSA before receiving its monthly list of establishments in *Salmonella* Performance Category 3 from the Office of Planning, Analysis and Risk Management (OPARM).

NOTE: At this time, FSIS is not taking actions described in this notice when an establishment exceeds a *Campylobacter* performance standard for raw poultry.

II. BACKGROUND

A. FSIS determines each establishment's category status following procedures announced in the *Federal Register*. These procedures were modified in November 2018 (83 FR 56046). Establishments are now categorized on a weekly basis using a single 52-week moving window approach. More specifically, OPARM will determine each eligible establishment's Performance Category after evaluating routine sampling results from the most recently completed 52-week window, by determining that a minimum number of samples were analyzed, and by calculating the *Salmonella* percent positive. Establishments are assigned to Category 1 when the percent positive for the 52-week window is one-half or less of the product's maximum allowable percent positive (MAPP). Establishments are assigned to Category 2 when the percent positive for the 52-week window is over one-half of the product's MAPP but does not exceed the product's MAPP. Establishments are assigned to Category 3 when the percent positive for the 52-week window exceeds the product's MAPP. The November 2018 *Federal Register* notice specified that FSIS would no longer include follow-up sampling results as part of the moving window when determining establishment category status.

B. Another Federal Register notice (81 FR 7285) stated that when an establishment does not meet a performance standard, FSIS will schedule a PHRE. During the PHRE, an EIAO will assess the establishment's Hazard Analysis and Critical Control Points (HACCP) system, focusing on the establishment's corrective actions and HACCP plan reassessment (if applicable). Based on the PHRE, FSIS will determine whether to schedule a FSA.

C. As described in FSIS Notice 17-19, *Follow-Up Sampling in Raw Poultry Establishments Not Meeting Salmonella Performance Standards*, FSIS will assign no more than one set of follow-up samples for the same reason within a 120-day period. Establishments that cycle out of and into Category 3 for a product during this period will not receive additional follow-up sample assignments.

III. REQUIREMENTS FOR AN ESTABLISHMENT THAT EXCEEDS A RAW POULTRY *SALMONELLA* PERFORMANCE STANDARD

A. IPP and EIAOs are to note that:

1. An establishment that does not meet a *Salmonella* performance standard may not have adequately addressed the food safety hazard, *Salmonella*, in its HACCP system;

2. If the establishment considered *Salmonella* reasonably likely to occur (RLTO) and addressed *Salmonella* in its HACCP plan, it must take corrective actions as required in 9 CFR 417.3 (a);

3. If the establishment considered *Salmonella* not reasonably likely to occur (NRLTO), it must take corrective actions and reassess its HACCP plan for that product to determine whether the HACCP plan needs to be modified to address the hazard as required in 9 CFR 417.3 (b). To maintain an adequate HACCP system, the establishment may need to address *Salmonella* in its HACCP plan; and

4. Corrective actions taken in response to exceeding a *Salmonella* performance standard must be documented in records subject to verification by FSIS as required in 9 CFR 417.3 (c).

IV. IPP ACTIONS

A. Communication with the establishment.

1. When an establishment is assigned to Category 3:

   a. IPP assigned to the establishment, the Frontline Supervisor (FLS), and the District Manager, will receive an alert entitled, "Failure to Meet a *Salmonella* Performance Standard," through the Public Health Information System (PHIS) dashboard. During the next weekly meeting with establishment management, IPP are to explain that FSIS will be verifying that the establishment is taking corrective actions and reassessing their HACCP system (if necessary);

   b. As described in FSIS Notice 17-19, IPP are to notify management that FSIS will assign follow-up sampling of the raw poultry product which exceeded a *Salmonella* performance standard. FSIS will schedule follow-up samples to begin 4 weeks after the PHIS alert to allow establishments time to initiate a reassessment and corrective actions if they hadn't initiated them earlier.

2. At establishments in Category 3, IPP are to use weekly meetings to discuss and document:

   a. Observations from FSIS's verification tasks for establishment programs or procedures that specifically control *Salmonella* (including, but not limited to, procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operations as required by 9 CFR 381.65 (g), if applicable, as well as the HACCP plan, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite programs;

b. Results and data generated from the establishment's programs or procedures related to *Salmonella*, including microbiological sampling data, verification of sanitary dressing operations or process control, and any regulatory waiver data, if applicable; and

c. The status of the establishment's actions to identify the cause of the failed performance standard, corrective actions, and reassessment of the HACCP plan (if applicable) if the establishment has not done this already.

3. During the weekly meeting, IPP are to discuss and document their concerns when the establishment:

a. Proposes or implements corrective actions that are the same as or similar to actions taken previously when exceeding a similar *Salmonella* performance standard, because continued failure to meet a performance standard brings into question the effectiveness of those actions;

b. Proposes or implements corrective actions for which the supporting rationale is not clear;

c. Produces validation data that does not appear to support the effectiveness of the intervention(s); or

d. Is a slaughter establishment that fails to review programs or procedures that control *Salmonella*, including but not limited to procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operations as required by 9 CFR 381.65 (g), as well as the HACCP plan, Sanitation SOPs or other prerequisite programs); and

e. Fails to review its written procedures as required by 9 CFR 381.65 (g) during a reassessment, or when any significant changes were made to those procedures.

4. IPP are to document weekly meeting discussions in Memorandums of Interview (MOIs) as described in FSIS Directive 8010.2 *Investigative Methodology*, and summarized in FSIS Notice 17-19. At a minimum, IPP are to document the status of the establishment's corrective actions and reassessment, if applicable.

B. Verifying the Establishment Meets Corrective Action and Reassessment Requirements.

1. IPP are to determine *if and how* the establishment responds to exceeding a performance standard.

a. While performing routine food safety tasks, IPP are to determine if corrective actions have been identified and implemented as written.

i. If the establishment considers *Salmonella* RLTO in its HACCP plan, IPP are to verify whether the establishment has taken corrective actions as required in 9 CFR 417.3 (a) (1-4); or

ii. If the establishment considers *Salmonella* NRLTO in its HACCP plan, IPP are to verify whether the establishment has taken corrective actions as required in 9 CFR 417.3 (b) (1-3).

2. IPP are to perform directed PHIS HACCP verification tasks to verify:

   a. If the establishment has reassessed its HACCP plan if required; and

   b. If the establishment modified its HACCP plan, how it supports those changes.

3. IPP are to correlate with the EIAO and the DO through supervisory channels to help them determine whether the establishment's response to being assigned to Category 3 satisfies regulatory compliance.

4. If applicable, following the conclusion of an FSA, IPP are to follow guidance from the DO to implement a verification plan.

V. DO ACTIONS

A. Every month, OPARM will send the DO a list of establishments in Category 3 to review and to use to schedule PHREs. As described in FSIS Directive 5100.4 *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*, the DO is to schedule a PHRE within 30 days of receiving this list from OPARM. When feasible, EIAOs are not to initiate PHREs at Category 3 establishments until the follow-up sampling set has been collected and analyzed.

NOTE: If the establishment produces the product infrequently, it may not be possible to collect the entire follow-up sample set before the EIAO initiates a PHRE.

B. The DO may elect to schedule the PHRE (or FSA) before receiving the monthly OPARM list. In this case, the DO is to schedule a PHRE in the PHRE PHIS tool, select the reason as "establishment in PR/HACCP *Salmonella* Category 3," and enter in the free text field "for cause PHRE due to establishment failed performance standard; poultry (identify product group).

C. The DO may elect to perform a PHRE for multiple product groups in Category 3, but is to verify that the establishment identifies and implements corrective actions for all affected product groups. In this case, for one of the product groups, the DO is to specify the other product groups covered in the free text field of PHRE PHIS tool. For the other product groups, the DO is to enter into the free text field: "PHRE performed with PHRE for failed (name other failed performance standard) on MM/DD/YYYY."

D. The DO may elect to not schedule a PHRE when an establishment cycles in and out of Category 3, and had recently been assigned a PHRE or FSA for the same reason. In this case, when the DO receives the OPARM list, the DO is to enter the free text field, "PHRE performed for failed (name other failed performance standard) on MM/DD/YYYY." The DO, in consultation with the EIAO that has performed the PHRE, is to determine whether to perform an FSA.

VI. EIAO ACTIONS

A. The EIAO is to:

1. Conduct a PHRE using the methodology described in FSIS Directive 5100.4. The PHRE is to focus on the establishment's corrective actions and HACCP plan reassessment (if applicable), and the effectiveness of the establishment's system for controlling *Salmonella* in raw poultry products;

2. Review the establishment's information and historical data from the PHIS PHRE report, other background information described in FSIS Directive 5100.4 Section VII.E, and MOIs generated from each weekly meeting as described in Section IV.A.3 of this notice. The EIAO is also to

consult with the Inspector in Charge (IIC) or the Front Line Supervisor (FLS) if there are questions about the status of the establishment's corrective actions and HACCP plan reassessment;

3. Determine whether the establishment is receiving a waiver of a regulatory requirement. A current list of such establishments can be accessed at:

   https://www.fsis.usda.gov/wps/wcm/connect/188bf583-45c9-4837-9205-37e0eb1ba243/Waiver_Table.pdf?MOD=AJPERES;

   If the establishment is receiving a waiver, the EIAO is to access and review the approval letter.

4. Verify that the establishment has been made aware of any *Salmonella*-characterizing data provided in the quarterly establishment letter, including serotype, antimicrobial susceptibility, and Whole Genome Sequencing (WGS) results. The EIAO is to document the establishment's response to this information; and

5. Determine whether the establishment's WGS results match recent PulseNet cluster code(s). The EIAO is to make a request for this analysis through askFSIS using the title "PulseNet cluster analysis." The EIAO is to be aware that FSIS considers samples with WGS closely related to a PulseNet cluster code to be of potential concern. The EIAO may be able to receive additional information about a matching cluster, including potential suspect product and where it may have been produced. This information, in combination with epidemiology and traceback, can be used to identify a product associated with a foodborne illness outbreak. The EIAO is to make establishment management aware of any WGS closely related to recent clusters but is to take no further actions, unless instructed to do so through supervisory channels.

B. At the conclusion of the PHRE, the EIAO is to review Section VII of this notice, and document why an FSA is or is not recommended, after considering:

1. Whether the establishment identified the cause for exceeding a performance standard, and if applicable, how this identified cause guided the establishment's design of corrective actions, and HACCP plan reassessment. The EIAO is to explain how the establishment supported its decision-making process;

2. The current implementation status for the establishment's corrective actions and HACCP plan reassessment if applicable;

3. Whether the establishment documented *Salmonella* as a biological hazard RLTO in its HACCP plan. If the establishment considers *Salmonella* as NRLTO after exceeding a performance standard, explain how the establishment supported this decision. See Section VII.F;

4. Whether the establishment's corrective actions were effective, based on an assessment of FSIS's *Salmonella* results and inspection findings (e.g., visible fecal contamination and other inspection observations), and the establishment's microbial sampling programs before and after implementation;

5. Whether the EIAO was able to adequately assess any establishment-generated data in support of Parts B 1 - 4 above and the results of this assessment, if applicable;

6. Whether the establishment has been assigned to Category 3 for a significantly long time (for example, over one year), has repeatedly been re-assigned to Category 3, or produces multiple products which are assigned to Category 3; and

7. Whether the establishment is receiving a waiver of a regulatory requirement. If so, the EIAO is to determine whether the establishment fully complied with requirements as documented in the approval letter. If not, see Section VIII.E.

C. If an FSA is scheduled, the EIAO is to conduct it using the methodology described in FSIS Directive 5100.1 *Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology*. The FSA is to focus on the establishment's corrective actions and HACCP plan reassessment (if applicable) performed in response to exceeding a performance standard, and the establishment's system for controlling *Salmonella* in raw poultry products as described in Section VII of this notice.

VII. ASSESSING *SALMONELLA* CONTROL IN RAW POULTRY DURING A PHRE OR FSA

A. Establishments typically incorporate multiple interventions or preventative measures to control *Salmonella* in raw poultry. Therefore, the establishment may not be able to identify a single intervention or preventive measure as responsible for not meeting a performance standard. Rather, the establishment's HACCP system, which incorporates all interventions and preventive measures, may not be effective to meet the performance standard. During the PHRE or FSA, the EIAO is to review documents supporting *Salmonella* control in raw poultry products throughout the process. For example:

1. If the establishment receives and further processes raw poultry (carcasses, parts, or comminuted product), does it understand the controls used by its suppliers to reduce *Salmonella* levels in raw poultry, does it receive letters of guarantee that suppliers meet purchase specifications or certificates of analysis, or does it verify the effectiveness of any supplier controls through audits or by sampling raw poultry at the receiving step?

2. If the establishment routinely measures *Salmonella* levels when receiving live birds or raw poultry products, does it understand whether the combined effects of the interventions documented in its HACCP system are sufficient to reduce *Salmonella* to a level that will consistently meet FSIS's performance standard?

3. If the establishment does not routinely measure *Salmonella* levels when receiving live birds or raw poultry products, does it provide a rationale to justify that the system will be capable of meeting FSIS's performance standards for *Salmonella* moving forward without this data?

B. The EIAO is to review the establishment's HACCP system documents and microbial sampling program results (i.e., for *Salmonella* or a suitable microbial indicator or a surrogate organism) if applicable, to assess whether the establishment was able to identify and respond appropriately to evidence that it is not controlling *Salmonella* in its raw poultry products.

More specifically, the EIAO is to:

1. Assess the establishment's response when its microbial sampling program results are consistent with FSIS's *Salmonella* results during the same time periods to determine:

   a. Why the establishment did not implement corrective actions in response to its own microbial sampling program results that indicate a failed performance standard and poor process control; or

   b. If the establishment did take corrective actions in response to its own microbial sampling program results, why the actions taken were unable to prevent the establishment from failing a performance standard.

2. Assess the establishment's response when its microbial sampling program results are inconsistent with FSIS's *Salmonella* results, or if the establishment fails to provide support that it has implemented an effective program. As applicable, the EIAO is to verify whether the establishment:

   a. Initiated or revised a microbial sampling program with acceptable procedures for sample collection, sample preparation, laboratory analysis, and data (trend) analysis; or

   b. Specifically indicates its intention to implement additional corrective actions once its microbial sampling program is generating data.

NOTE: Developing or adjusting its microbial sampling program may be the only change in its HACCP system proffered initially by the establishment following system reassessment due to a failed *Salmonella* performance standard because the establishment determines it must first be able to identify the problem through sampling and testing before it can accurately reassess its HACCP plan and determine where additional changes are needed.

C. In addition to evaluating microbial data, the EIAO is to determine whether there are trends in non-compliance, corrective actions, or other inspection findings of visible fecal contamination and septicemic/ toxemic carcasses, which may be evidence of poor process control.

D. If the establishment considered *Salmonella* to be RLTO when it exceeded a *Salmonella* performance standard, the EIAO is to verify that the establishment identifies and eliminates the cause for exceeding the standard (9 CFR 417.3 (a) (1)), ensures that the critical control point (CCP) is under control (9 CFR 417.3 (a) (2)), takes measures to prevent recurrence (9 CFR 417.3 (a) (3)), and documents this response in records available for review by FSIS (9 CFR 417.3 (c)).

E. If the establishment considered *Salmonella* to be NRLTO when it exceeded a *Salmonella* performance standard, the EIAO is to verify that the establishment takes corrective actions as required in 9 CFR 417.3 (b) (1-3), reassesses its HACCP plan as required in 9 CFR 417.3 (b) (4), and documents these actions as required in 9 CFR 417.3 (c). The EIAO is to determine whether the establishment's reassessment considers whether *Salmonella* can be controlled at all stages in their process (refer to Section VII.A).

F. If an establishment has performed a reassessment and continues to consider *Salmonella* as NRLTO (i.e., it addresses *Salmonella* outside of its HACCP plan, through its Sanitation SOP, or other prerequisite programs), the EIAO is to:

1. Verify that the establishment's reassessment documents include a rationale for continuing to consider *Salmonella* as NRLTO, and that this rationale is supportable;

2. Assess microbial sampling results from FSIS and the establishment before and after implementing corrective actions to understand the impact of any changes to the establishment's HACCP system on the rate of *Salmonella* positive samples, or a suitable microbial indicator or a surrogate organism;

3. Verify that the establishment has determined the cause for exceeding a *Salmonella* performance standard, and has fully implemented corrective actions;

4. Verify that the establishment uses microbial sampling results from FSIS and the establishment's programs (including, but not limited to, FSIS's follow-up sampling set) to demonstrate it is better able to control *Salmonella*; and

5. Verify that the establishment has considered its history of meeting FSIS's *Salmonella* performance standards. For example, whether the establishment has been assigned to Category 3 for a

significantly long time (for example, over one year), has repeatedly been re-assigned to Category 3, or produces multiple products which are assigned to Category 3.

G. The EIAO is to verify that all interventions cited in the HACCP system (including critical control points (CCPs), Sanitation SOPs or other prerequisite programs) are validated to effectively control *Salmonella* in raw poultry as required by 9 CFR 417.4 (a) (1). Each intervention must be demonstrated as capable of reducing *Salmonella* when used under the validated conditions by the level described in the scientific or technical support. To verify that this requirement is met, the EIAO is to refer to FSIS Directive 5100.1 Chapter V, Section VII.

H. For establishments that do not meet a *Salmonella* performance standard while operating under one or more waivers of FSIS regulations, the EIAO is to assess whether the establishment's HACCP plan reassessment (if applicable) specifically addresses the impact of its waivers on failing a performance standard. The reassessment should assess any applicable data and other supporting documentation to determine if the procedures under which the establishment is operating as a result of the waived regulation are sufficiently preventing *Salmonella* contamination and not contributing to the failed performance standard.

VIII. ENFORCEMENT

A. DOs are not to issue a Notice of Intended Enforcement (NOIE) or suspend inspection based solely on the fact that an establishment exceeded a performance standard. However, exceeding a performance standard can indicate that applicable criteria in 9 CFR 500.2 through 500.6 are met (e.g., if a HACCP system is found to be inadequate, Sanitation SOPs have not been properly implemented or maintained, or sanitary conditions have not been maintained). DOs are to take an enforcement action when an establishment exceeds a performance standard and applicable criteria in 9 CFR 500 are met.

B. Per 81 FR 7285, if an establishment fails to implement corrective actions after 90 days of being notified that it is in Category 3, and the establishment continues to be assigned to Category 3, the DO is to determine whether additional enforcement action is needed, including issuance of a NOIE, Notice of Suspension (NOS), or Notice of Reinstatement of Suspension (NROS) as described in 9 CFR 500.

C. When making and documenting enforcement actions under 9 CFR 500, the DO is to refer to:

1. 21 USC 453 (g) (3) after assessing compliance with parts of 9 CFR determined to be relevant to controlling *Salmonella* in raw poultry products, including, but not limited to, 9 CFR Parts 416 and 417, and 9 CFR 381.65 (f) and (g);

2. 21 USC 456 after verifying non-compliance with 9 CFR part 416, if the establishment is failing to prevent processing cross contamination or identifies equipment-related zero tolerance failures; or

3. 21 USC 453(g) (4), if the establishment's products were associated with human illness.

D. If IPP or the EIAO determine that the establishment is producing adulterated product, FSIS personnel are to follow instructions in FSIS Directive 8080.1 *Recall of Meat and Poultry Products*, Chapter II Section II.

E. If the EIAO determines that an establishment's procedures allowed under a waiver are contributing to the failed performance standard, and that the establishment has not satisfactorily addressed this determination, the DO is to refer to FSIS Directive 5020.1 *Verification Activities for the Use of New Technology in Meat And Poultry Establishments and Egg Products Plants*, to determine if the waiver should be rescinded.

F. FSIS does not consider raw poultry containing *Salmonella* to be adulterated as defined by 21 USC 453 (g) (1) unless other circumstances make the product adulterated. Establishments are not required to segregate or hold product when the establishment exceeds a *Salmonella* performance standard. However, if the DO determines that the product is injurious or otherwise adulterated as defined by 21 USC 453 (g) (3) or (4) or 456, IPP and the EIAO are to verify that the establishment segregates and holds affected product.

IX. QUESTIONS

Refer questions regarding this notice to the Office of Policy and Program Development 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:	Enter **Notice xx-19.**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Sampling - *Salmonella*** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question.**

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

Assistant Administrator
Office of Policy and Program Development