Frequently Asked Questions at the Food Safety Regulatory Essentials Training

Question: What should inspection program personnel do when they find that the establishment has determined that there are no food safety hazards reasonably likely to occur in its process?

Answer: *Inspection program personnel should request to see the establishment's supporting documentation for that decision. If the establishment can support the decision that there is no food safety hazard reasonably likely to occur, there is no further action required. If the establishment does not have documents to support the decision that there is no food safety hazard reasonably likely to occur, there is regulatory noncompliance with 417.5(a)(1) and this noncompliance should be documented on a Noncompliance Record (NR). If more information is needed to make a regulatory compliance determination, inspection program personnel can write a 30-day reassessment letter. If there are public health concerns associated with the production of these products, inspection program personnel should implement an enforcement action as described in 9 CFR part 500 and notify the district office through the front-line supervisor.*

Question: When is it appropriate for FSIS to issue the 30-day reassessment letter?

Answer: *It is appropriate for inspection program personnel to issue the 30-day reassessment letter when more information is needed to determine regulatory compliance. The 30-day reassessment letter is* ***NOT*** *an enforcement letter and should* ***NOT*** *be issued when there is regulatory noncompliance.*

Question: Is the establishment required to share records of its food safety programs with FSIS, even if those records are not part of the establishment's HACCP plan?

Answer: *Yes. FSIS Directive 5000.2 states that FSIS inspection personnel, on at least a weekly basis, must review the results of any testing and of any monitoring activities that the establishment performed that may have an impact on the establishment's hazard analysis.*

Question: Do the Sanitation SOP regulations require the establishment to have the records associated with the Sanitation SOP available to FSIS within 24 hours?

Answer: *9 CFR 416.16 states that each official establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The records associated with the Sanitation SOP are to be completed by the beginning of the same shift the next operating day.*

Question: How do inspection program personnel record the 10-bird zero tolerance check in a poultry slaughter operation?

Answer: *Procedure 03J01 should be marked on the Procedure Schedule each time that on the 10-bird check is performed. If inspection personnel are performing the 10-bird check in conjunction with verifying other regulatory requirements, 03J01 or 03J02 would be marked on the Procedure Schedule.*

Question: When inspection personnel write an NR, should the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), or Egg Products Inspection Act (EPIA) be referenced on the NR?

Answer: *FSIS has provided no instructions to inspection personnel to reference the FMIA, PPIA, or EPIA on the NR.*

Question: If an establishment does not respond to an NR, but documents immediate and further planned actions in its records, how is the NR closed?

Answer: *The establishment is not required to respond to an NR, but is required to correct the noncompliance. Preventive measures are not required unless there has been direct product contamination or a deviation from a critical limit. Inspection personnel should verify that the immediate actions corrected the noncompliance. If the noncompliance has been corrected, the NR can be closed.*

Question: If FSIS finds a deviation from a critical limit and documents that finding on an NR, is it acceptable for the establishment to record its corrective actions on the NR?

Answer: *The establishment can record the corrective actions implemented in response to a deviation from a critical limit found by FSIS on the NR. A copy of the NR would then become part of the establishment's HACCP records and this copy of the NR would have to meet all of the requirements in 9 CFR 417.5.*

Question: When an establishment has reassessed its HACCP plan as a result of an unforeseen hazard, how can FSIS verify that the reassessment is adequate?

Answer: *When an unforeseen hazard occurs, 9 CFR 417.3(b)(4) requires the establishment to perform a reassessment to determine if the unforeseen hazard should be incorporated into the HACCP plan. 9 CFR 417.3(c) and 9 CFR 417.5(a)(3) require all of corrective actions taken to be recorded. These records must be available to FSIS upon request. If inspection personnel have questions concerning the decisions made during reassessment, they should request the documents that support those decisions. If documents cannot be provided, there is noncompliance with 9 CFR 417.5(a)(1).*

Question: Can the same person conduct the monitoring, verification, and pre-shipment review activities?

Answer: *There is no regulatory requirement that different persons are to conduct each of these activities. However, these are 3 separate activities and require separate entries on the HACCP records.*