

IKE Scenario 06-07: Foreign Material Contamination

Purpose: This IKE is being issued in support of FSIS Directive 7310.5 and addresses one example of when inspection program personnel would verify that establishments are properly addressing incidents of foreign material in their product.

Situation: You are a Consumer Safety Inspector (CSI) in a beef grinding facility that produces raw ground beef from beef trimmings. The establishment purchases trimmings from multiple sources. At the beginning of your tour of duty, you are notified by the establishment's Quality Control manager that they found metal in one box of incoming product used in the last lot of production the previous day.

You know that [FSIS Directive 7310.5](#) provides the procedures that inspection program personnel are to follow when foreign material such as metal, plastic, rubber, glass, wood, steel, or lead shot is found. You decide to review this Directive so you can verify that the establishment is properly addressing the foreign material. The directive describes different options how an establishment may address foreign material. Through your review of the Directive, you determine that:

- It is the responsibility of the establishment to examine the suspect product and to sort out and properly decontaminate or dispose of any adulterated product.
- An establishment should use the most sensitive detection technique available
- An establishment should have a supportable justification as to how the procedures it employs will detect the foreign materials present.

The directive further states that you are to verify the establishment follows its detection, segregation, and disposition procedures and that you are not to take any action if the procedures are properly followed.

You are scheduled to perform a 03B01 procedure today and you decide to verify the recordkeeping requirements. FSIS Directive 5000.1 Revision 1, states that you can verify compliance with the recordkeeping requirement by reviewing the hazard analysis, HACCP plan, and supporting documentation. Through your review of the hazard analysis, you find that the establishment determined that foreign material is a food safety hazard that is reasonably likely to occur in the operation. The establishment has developed a CCP for metal detection at grinding. The establishment has also determined the maximum size that foreign material can be and still not be considered a food safety hazard and has documents on file to support its decision.

You review the HACCP records associated with the metal detection CCP and you see no entries related to the previous day's production. You discuss your observation with the Quality Control manager and are informed that the establishment found a meat hook in a box of product prior to grinding the product. They determined that the meat hook did not meet the establishment's criteria for a food safety hazard and that they would address it as a Sanitation SOP issue.

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Discussion: You are scheduled to conduct a 01C01, so you review the establishment's Sanitation SOP corrective action records from the previous day to verify that the establishment is meeting the regulatory requirements. The records show that:

- The establishment had retained all the source material remaining from the previous day's production.
- The product that had already been ground was allowed to move freely as it had gone through the metal detection CCP, and no product had been found to be contaminated
- The establishment conducted a 100% visual examination of the source material, in addition to running the material through the metal detector. No other foreign material was found
- The segregated product was kept under QA control until it could be ground
- The establishment also contacted the establishment that produced the product and informed them what had been found. The grinding establishment elected to notify the producer of the source material that it would not purchase product from that establishment in the future if foreign material was found in the product again

You conclude that the establishment met the corrective action requirements of 9 CFR 416.15(b).

The segregated source material is being ground today following the establishment's HACCP plan. You decide to conduct the review and observation component of 03B01 to verify the establishment's monitoring at the metal detection CCP. The establishment monitors the CCP in accordance with the HACCP plan and documents the results appropriately. No additional metal is found and the resulting ground product is released from QA control.

Resolution: You conclude that the establishment has conducted their operations in accordance with the regulatory requirement of 9 CFR 416 and 417 as well as with the criteria addressed in FSIS Directive 7310.5. You document both the 03B01 and 01C01 verification procedures as performed. In addition, because the metal had been found in in-coming product, you complete FSIS Form 8140-1, Notice of Receipt of Adulterated or Misbranded Product in accordance with the instructions in [FSIS Directive 8140.1](#). You know that by documenting the incident on this Form, inspection program personnel at the producing establishment will, upon receipt of the form, know that adulterated product was put into commerce. The inspection program personnel at the producing establishment will respond to this important information by conducting appropriate verification procedures also outlined in FSIS Directive 8140.1.