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

FSIS DIRECTIVE

7310.5
Rev. 4

1/2/25

PRESENCE OF FOREIGN MATERIAL IN MEAT OR POULTRY PRODUCTS

I. PURPOSE

This directive provides the procedures that inspection program personnel (IPP) are to follow when foreign material such as metal, plastic, rubber, glass, wood, steel, or lead shot is found in meat or poultry products. FSIS has revised this directive in its entirety to remove previous obsolete task terminology and instructions are reformatted for consistency and readability.

KEY POINTS:

- *Provides IPP instructions addressing foreign material in product as a possible hazard that needs to be considered under the Hazard Analysis and Critical Control Point (HACCP) regulations*
- *Defines and lists potential foreign materials*
- *Provides instructions for IPP for documentation of HACCP system verification results related to foreign material*

II. CANCELLATION

FSIS Directive 7310.5, Revision 3, *Presence of Foreign Material in Meat or Poultry Products*, 5/30/03

III. BACKGROUND

Only wholesome, unadulterated product is eligible to bear the mark of inspection and to enter commerce. If an incident occurs in which product may have become contaminated with a foreign material, the establishment is to examine the suspect product and to sort out and properly decontaminate or dispose of any adulterated product. When examining suspect product to segregate contaminated product, FSIS expects an establishment to use the most sensitive detection technique available and to have a supportable justification as to how the procedures it employs will detect the foreign materials present. If foreign material contamination occurs, IPP are to verify that an establishment follows their detection, segregation and disposition procedures. If such procedures are properly followed, IPP are not to take any action. However, if IPP find that product contains foreign material because the establishment did not properly segregate and dispose of contaminated product, IPP are to take a regulatory control action (9 CFR 500.2(a)(2)).

IV. HAZARD ANALYSIS AND DECISIONMAKING PROCESS

A. 9 CFR 417.2(a) requires that an establishment conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures that the establishment can apply to control those hazards. The establishment's hazard analysis is required by 9 CFR 417.2(a)(1) to consider those hazards that can occur before, during, and after entry into the establishment. If IPP are uncertain whether the establishment has considered the appropriate hazards at each process step, they are to contact their supervisor for assistance in order to determine whether noncompliance with 9 CFR 417.2(a)(1) exists. IPP are to discuss any concerns about historical support or the possibility of foreign material in the particular type of product being processed with their supervisor.

B. Foreign materials are non-animal objects, such as metal, plastic, rubber, glass, wood, steel, or lead shot.

NOTE: Materials such as rust and rail dust are not covered by this directive. The sanitation regulations require establishment to control the presence of rust and rail dust (9 CFR 416.4(b)).

V. WHEN THE ESTABLISHMENT DETERMINES FOREIGN MATERIAL IS REASONABLY LIKELY TO OCCUR

A. IPP are to be aware that when an establishment determines foreign material is reasonably likely to occur, regulatory requirements include:

1. The written hazard analysis is to include all supporting documentation (9 CFR 417.5(a)(1)).

2. The establishment's HACCP plan is to list the Critical Control Points (CCPs) that are designed to eliminate, prevent, or reduce to an acceptable level foreign material in product produced under the plan (9 CFR 417.2(c)(2)).

3. The HACCP plan is also to have a critical limit, such as having a functional metal detector, calibrated to a specific standard (9 CFR 417.2(c)(3)).

4. The HACCP plan is to provide for CCP monitoring activities that the establishment will perform, such as ensuring that the detection equipment is operating properly to detect foreign material of the specified size, such as checking a metal detector with a seeded sample (9 CFR 417.2(c)(4)).

5. The HACCP plan is to provide for ongoing verification activities that the establishment will perform at an established frequency for calibration of the detection equipment, such as each day before start up checking the detection equipment to ensure it is calibrated to detect metal particles of the size stated in the HACCP plan for the types of metal of concern (9 CFR 417.2(c)(7), 9 CFR 417.4(a)(2)(i)).

6. The HACCP plan is to include corrective and preventive actions that the establishment will take when there are deviations from the critical limit, such as when the detection equipment has malfunctioned (9 CFR 417.3(a)).

7. The establishment is to have the appropriate documentation to support the selection of CCPs and critical limits, monitoring procedures and frequencies, and verification procedures and frequencies (9 CFR 417.5(a)(2)). The technical and scientific basis can include recommendations from scientific experts; scientific journal articles; FSIS guidance materials; and establishment history.

NOTE: See FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification Task* and FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, for instructions on reviewing the hazard analysis and HACCP plan.

B. IPP are to follow the instructions in FSIS Directive 5000.1 to verify that the HACCP requirements associated with a CCP for foreign material are met by performing the appropriate HACCP verification task. For example, IPP are to verify the requirements associated with a CCP for foreign material in a raw ground process by performing the Raw Non-Intact HACCP verification task. IPP are to consider the following:

1. Does the HACCP plan include CCPs that will prevent, eliminate, or reduce to an acceptable level any hazard presented by foreign material that the establishment identified in the hazard analysis as reasonably likely to occur?

2. Does the HACCP plan list a critical limit for the CCP?

3. Does the HACCP plan list monitoring procedures and frequencies for these CCPs?

4. Does the HACCP plan list verification procedures and frequencies for these CCPs?

5. Does the establishment have supporting data for the selection of the CCPs, critical limits, monitoring procedures and frequencies, and verification procedures and frequencies?

6. Is the establishment conducting its monitoring procedures and frequencies as designed?

7. Is the establishment conducting its ongoing verification activities as designed?

8. When there is a deviation from a critical limit, does the establishment implement corrective actions that meet the requirements of 9 CFR 417.3(a)?

9. Is the establishment recording the results of the monitoring and verification activities when they occur?

C. An answer of "no" to one or more of the above may support a determination of noncompliance. IPP are to follow the Gather, Assess, Determine methodology and the instructions in FSIS Directive 5000.1 to determine if the observations support a determination of noncompliance and, if so, what regulation is not in compliance. When IPP find noncompliance with one or more regulatory requirements, IPP are to follow the instructions in FSIS Directive 5000.1 and issue an FSIS Form 5400-4, *Noncompliance Record (NR)*, for a HACCP noncompliance.

NOTE: If the establishment's detection equipment is appropriately calibrated and finds product with foreign material contamination within the level of detection, the CCP is operating as designed (e.g., a metal detector rejects packages of hot dogs). The establishment should evaluate the rejected product and, based on the findings of the product evaluation, determine the cause of the contamination. This is not noncompliance. The establishment should evaluate the incident to determine whether additional controls are needed to prevent the presence of foreign material. If an establishment determines in their hazard analysis that foreign materials are reasonably likely to occur in their process, they should reasonably expect that product rejects will occur on a regular basis. Accordingly, product rejects should be considered a process step in the flow diagram and analyzed for food safety hazards, in accordance with 9 CFR 417.2(a)(1). To address potential foreign materials in the products and prevent adulterated products from entering commerce, the hazard analysis could reference procedures for evaluation and disposition of the rejected products, in accordance with 9 CFR 417.5(a)(1).

VI. WHEN THE ESTABLISHMENT DETERMINES THAT FOREIGN MATERIAL IS NOT REASONABLY LIKELY TO OCCUR

A. When, in its hazard analysis, an establishment concludes that potential foreign material contamination is a food safety hazard but that it is not reasonably likely to occur, the following requirements apply.

1. If an establishment determines that foreign material contamination is a potential food safety hazard, but that it is not reasonably likely to occur because it has not occurred in that process, a justification, such as historical data, is required to be available to support that determination (9 CFR 417.5(a)(1)). In this situation, the HACCP plan would not need to have a CCP for foreign materials.

2. If foreign material contamination occurs that involves a food safety hazard, the establishment must take corrective actions that meet the requirements of 9 CFR 417.3(b). This includes appropriate disposition of product and a reassessment to determine whether the newly identified food safety hazard is now likely to occur and therefore needs to be added to the HACCP plan. The establishment is required to maintain documentation to support the disposition of adulterated product and the decisions made during the reassessment (9 CFR 417.5(a)(1)).

B. IPP responsibilities for an establishment that concludes foreign material contamination is a food safety hazard not reasonably likely to occur because it has not occurred in that process include:

1. If IPP have questions about whether the establishment has appropriately addressed foreign material contamination in its hazard analysis, they should ask to see the justification that the establishment is using to support its decision (9 CFR 417.5(a)(1)). If IPP need technical assistance in evaluating the justification, they are to consult their immediate supervisor then contact askFSIS as instructed in Section VIII.

2. If foreign material contamination occurs, IPP are to verify that the establishment is applying appropriate criteria in making the determination whether the contamination poses a food safety hazard, and whether it should be addressed in the HACCP plan. If the establishment determines that the foreign material contamination is a food safety hazard, IPP are to verify that the corrective actions implemented by the establishment meet the requirements of 9 CFR 417.3(b). If IPP question the decisions made during reassessment, they should request the supporting documentation for those decisions.

NOTE: If the establishment finds an unforeseen hazard and implements corrective actions that meet the corrective action requirements in 9 CFR 417.3(b), there is no regulatory noncompliance. If the establishment does not implement corrective actions that meet the requirements in 9 CFR 417.3(b), or is unable to support the decisions made in the reassessment of the hazard analysis, there is HACCP regulatory noncompliance that should be documented on a NR.

3. IPP are to verify that when an establishment determines that foreign material is a food safety hazard that is not reasonably likely to occur in its products by having in place prerequisite programs (9 CFR 417.2(a)(1)), the establishment documents this determination in the hazard analysis, including the procedures it employs to ensure that the hazard is not likely to occur, and provide records that demonstrate the programs on-going support of the decision made in the hazard analysis (9 CFR 417.5(a)(1)).

    a) If IPP find that an establishment has a prerequisite program for the purpose addressed above, and have questions about the scientific design or validation of the prerequisite program, they are to contact their supervisor to request an establishment visit by an Enforcement Investigations and Analysis Officer.

b) The verification criteria used to assess prerequisite programs are different than the verification activities performed to verify HACCP system compliance. For prerequisite programs, IPP are to follow the instructions in FSIS Directive 5000.1 and assess the overall effectiveness of the prerequisite program to verify that it continues to support the decisions made in the hazard analysis that foreign material contamination is not reasonably likely to occur in the process. Unlike with HACCP plans, IPP do not verify specific regulatory requirements for such activities as monitoring, verification, and recordkeeping. If IPP find, based on records or verified incidents of foreign material contamination, that the prerequisite program is not continuing to support the decisions made in the hazard analysis that foreign material contamination is not reasonably likely to occur in the process, they are to follow the instructions in FSIS Directive 5000.6 and verify that the establishment reassesses its hazard analysis as required in 9 CFR 417.4(b) because the decisions made in the hazard analysis may no longer be supported (9 CFR 417.5(a)(1)). The establishment would be expected to have supporting data for the decisions made during this reassessment required in 9 CFR 417.5(a)(1). The prerequisite program and the records generated by the program are required by 9 CFR 417.5(a)(1) be available to FSIS upon request.

C. IPP are to verify that when the establishment has a history of foreign material contamination occurring in the process, it addresses the contamination in its hazard analysis (9 CFR 417.2(a)(1)), provides documentation that demonstrates that the contamination is not a food safety hazard (9 CFR 417.5(a)(1)), and indicates whether it controls foreign material contamination in its Sanitation Standard Operating Procedures (SOPs) or in a prerequisite program. IPP are to refer to FSIS Directive 5000.6 for additional instruction on hazard analysis verification. If the establishment incorporates controls in the Sanitation SOPs, IPP are to verify that establishments follow the requirements of 9 CFR part 416.

VII. WHEN THE ESTABLISHMENT DETERMINES FOREIGN MATERIAL DOES NOT NEED TO BE ADDRESSED

When an establishment determines foreign material does not need to be addressed in their hazard analysis, IPP are to verify that:

1. If an establishment determines that foreign material contamination is not a food safety hazard, and that it is not likely to occur in that process, a justification based on the nature of the operation or historical data is available to support that decision (9 CFR 417.5(a)(1));

2. If an incident of foreign material contamination occurs, the establishment will need to first determine whether the material is a food safety hazard. If so, the corrective actions in 9 CFR 417.3(b) are to be taken. This includes disposition of product and a reassessment to determine whether the newly identified food safety hazard should be incorporated into the HACCP plan;

3. The establishment has supporting documentation to support the disposition of product and the decisions made during this reassessment as per 9 CFR 417.5(a)(1); and

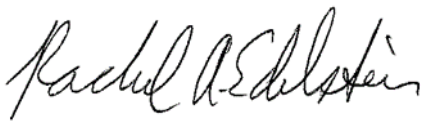
4. If the foreign material contamination is not a food safety hazard, the establishment takes corrective action under its Sanitation SOPs as described in 9 CFR 416.15 when contamination occurs.

NOTE: Isolated incidents of foreign material contamination that do not pose a food safety hazard do not indicate that the Sanitation SOPs need to be modified.

VIII. QUESTIONS

Refer questions regarding this directive to your supervisor or if needed to OPPD through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select General Inspection Policy as the inquiry type.

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



Deputy Administrator
Office of Policy and Program Development