

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

FSIS DIRECTIVE	7310.5	5/30/03
-----------------------	--------	---------

Presence of Foreign Material in Meat or Poultry Products

I. PURPOSE

This directive 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 in meat or poultry products.

II. CANCELLATION

RESERVED

III. REASON FOR ISSUANCE

The Agency is issuing this directive to provide instructions to inspection program personnel for verifying that establishments are properly addressing the possibility that foreign material is present in product, consistent with the requirements of the Hazard Analysis and Critical Control Point (HACCP) regulations, the Federal Meat Inspection Act, and the Poultry Products Inspection Act.

IV. REFERENCES

FSIS Regulations, 9 CFR 417, 310.18(a), 318.2(d), 381.78(a), 381.91 (a).
FSIS Directive 5000.1, Revision 1, Verifying an Establishment's Food Safety System
FSIS Directive 5400.5, Inspection System Guide
FDA Regulations 21 CFR 179.21

V. TERMINOLOGY

Foreign material: 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. FSIS expects an establishment to control the presence of rust and rail dust as part of compliance with the sanitation performance standards.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB;TSC; Import Offices **OPI: OPPD**

VI. POLICY

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, inspection program personnel are to verify that an establishment follows their detection, segregation and disposition procedures. If such procedures are properly followed, inspection program personnel should not take any action. However, if inspection program personnel find that product contains foreign material because the establishment did not properly segregate and dispose of contaminated product, inspection program personnel are to take a regulatory control action (9 CFR 500.2(a)(2)). If inspection program personnel have questions about an establishment's approach to addressing foreign material, they are to contact the Technical Service Center (TSC).

VII. Hazard Analysis and Decisionmaking Process

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 should consider those hazards that **can** occur before, during, and after entry into the establishment. The following outlines some possible outcomes of the hazard analysis, FSIS's expectations, and inspection program personnel's verification responsibilities.

A. What are the regulatory requirements if, in its hazard analysis, an establishment concludes that foreign material contamination is a food safety hazard reasonably likely to occur?

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 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 prior to 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 417.4(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.

B. What are inspection program personnel responsibilities?

1. Inspection program personnel should verify that the HACCP requirements associated with a CCP for foreign material are met by performing the appropriate HACCP 01/02 procedures. For example, inspection program personnel verify the requirements associated with a CCP for foreign material in a raw ground process by performing the 03B01/03B02 HACCP verification procedures. When verifying these requirements, inspection program personnel should seek answers to the following types of questions:

a. 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?

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

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

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

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

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

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

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

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

2. If the answer to any of these questions is no, there is regulatory noncompliance with 9 CFR part 417, and inspection program personnel should issue an FSIS Form 5400-4, Noncompliance Record (NR) for a HACCP noncompliance under the appropriate regulatory cite.

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.

C. What are the regulatory requirements if, 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?

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, should be available to support that determination (9 CFR 417.5(a)(1)). In this situation, the HACCP plan would not need to have controls 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 should be addressed in the HACCP plan.

3. The establishment must have documentation to support the disposition of product and the decisions that it makes during this reassessment (9 CFR 417.5(a)(1)).

D. What are inspection program personnel responsibilities?

1. If inspection program personnel 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. If inspection program personnel need technical assistance in evaluating the justification, they can contact the TSC.

2. If foreign material contamination occurs, inspection program personnel should 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 foreign material contamination is a

food safety hazard, inspection program personnel should verify that the corrective actions implemented by the establishment meet the requirements of 417.3(b). If inspection program personnel question the decisions made during reassessment, they should request the supporting documentation for those decisions. The TSC can be contacted for technical assistance, if necessary.

NOTE: If the establishment finds an unforeseen hazard and implements corrective actions that meet the corrective action requirements in 417.3(b), there is no regulatory noncompliance. If the establishment does not implement corrective actions that meet the requirements in 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.

E. What are the regulatory requirements if, in its hazard analysis, an establishment determines that foreign material is a food safety hazard, but that it is not reasonably likely to occur because the establishment has programs in place that make it not reasonably likely to occur?

An establishment can determine 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)). In its hazard analysis, the establishment would need to document this determination, include 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)).

F. What are Inspection Program Personnel and Consumer Safety Officer Responsibilities?

1. If inspection program personnel 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 should contact the Front-line Supervisor to request an establishment visit by a CSO.

2. The verification criteria used to assess prerequisite programs are different than the verification activities performed to verify HACCP system compliance. For prerequisite programs, inspection program personnel are to 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, inspection program personnel do not verify specific regulatory requirements for such activities as monitoring, verification, and recordkeeping. If inspection program personnel find, based on records or 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 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 must be available to FSIS upon request.

G. What are the regulatory requirements if, in its hazard analysis, an establishment concludes that foreign material is not a food safety hazard, but that it will have on-going controls for foreign materials?

If the establishment has a history of foreign material contamination occurring in the process, at a minimum, it should address the contamination in its hazard analysis (9 CFR 417.2(a)(1)), provide documentation that demonstrates that the contamination is not a food safety hazard (9 CFR 417.5(a)(1)), and indicate whether it controls foreign material contamination in its Sanitation SOPs or in a prerequisite program.

H. What are inspection program personnel responsibilities?

1. If the establishment incorporates controls in the Sanitation SOPs, inspection program personnel are to verify that establishments follow the requirements of 9 CFR part 416.

2. If the establishment incorporates controls in a prerequisite program, inspection program personnel are to follow the verification procedures in paragraph VI F.

I. What are the regulatory requirements if, in its hazard analysis, an establishment concludes it does not need to address foreign material contamination?

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 should be 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 must have supporting documentation to support the disposition of product and the decisions made during this reassessment as per §417.5(a)(1).

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

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.

J. What are inspection program personnel responsibilities?

Inspection program personnel verify that the establishment took the appropriate corrective actions.

Direct questions to the Technical Service Center.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy and Program Development