



# FSIS Limits for Foreign Materials in Meat and Poultry Products

Literature Search

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# **FSIS Policy for Foreign Materials**

The USDA Food Safety and Inspection Service (FSIS) defines foreign materials as objects not inherent to a product, including glass, metal fragments, bullets/shot, machinery pieces, rubber, plastic, sand or rocks. Bone fragments are not classified as foreign materials since bone is a natural part of the carcass. FSIS regulates bone fragment in terms of size and calcium content in meat and poultry derived from advanced meat recovery (AMR) systems. If the size, shape or amount of inherent materials (e.g. bone, feathers) presents a human health hazard, then the product would be adulterated.

The FSIS Directive 7310.5, *Presence of Foreign Material in Meat and Poultry Products*, instructs FSIS inspection program personnel that meat and poultry products contaminated with foreign materials are adulterated under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). In 2020, FSIS issued guidelines for industry that stated meat and poultry products contaminated with foreign materials are adulterated "regardless of the physical characteristics of the foreign material (e.g., shape, size, hardness, etc.) because foreign materials are unfit for human consumption, may contain poisonous or deleterious substances, and may indicate conditions of filth" (FSIS, 2020).

Within the FSIS *Guideline for Industry Response to Customer Complaints* (2020), the agency clarified its policy toward foreign material:

"...under the FMIA and PPIA and the regulations, the presence of foreign materials adulterates meat and poultry products. Examples of foreign materials found in meat and poultry products include: Glass or metal fragments, which are deleterious substances that may injure health; machinery pieces, such as rubber or plastic, which are filthy, or unwholesome, or unfit for food; or sand or rocks, which typically contaminate food products because of preparation under insanitary conditions."

Directive 7310.5 states that "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." Moreover, Directive 7310.5 describes the FSIS policy for responding to foreign material contamination:

"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))."

The detection of a "non-sharp edged foreign material in a meat or poultry product" is an example of a health hazard situation that could result in a Class II recall under the FSIS policy (Directive 8080.1).

# **Guidelines for Foreign Materials**

FSIS has not published official limits for foreign materials in meat and poultry products, but the agency has supported guidelines presented at a FSIS public meeting on foreign material contamination (September 24, 2002). During the FSIS meeting, a presentation titled 'The Physical Hazards of Foreign Materials' (Goldman, 2002) provided information from a 1995 report by the Public Health Hazard Analysis Board that concluded: "The presence of a foreign material other than bone may pose a potential hazard, and each instance should be considered on a case-by-case basis, irrespective of size."

## FSIS Guidelines, continued.

The 2002 USDA conference evaluated criteria for identifying potentially hazardous foreign materials, and the "agency stated that the FDA standard was valid, and scientifically justifiable" (Peariso, 2006). The FDA standard known as Compliance Policy Guide (555.425) contains the criteria for the size of foreign materials in food:

- Criteria for direct seizure:
  - o Hard or sharp objects 7-25 mm and RTE product
- Criteria for recommending legal action:
  - 7-25 mm and food requires additional preparation
  - o <7 mm and food intended for special-risk group</p>
  - o 25 mm or larger

During the 2002 Conference, FSIS representatives confirmed the agency "follows similar size criteria (7 to 25 mm) in determining public health hazards presented by hard or sharp FM [foreign material]... [and] ...will evaluate complaints and sampling finds on a case-by-case basis (just like FDA) even if the size and preparation criteria are not met," (Peariso, 2006).

The following FSIS guidelines for bone particles and foreign materials were presented during a 2016 FSIS meeting with the North American Meat Institute:

Food Safety and Inspection Service **FSIS Updates: HHEB - Foreign Object Contamination and FSIS** Recalls ☐ FSIS Directive 7310.5, Presence of Foreign Material in Meat or Poultry Products, defines foreign materials as "non-animal objects, such as metal, plastic, rubber, glass, wood, steel, or lead shot" ☐ The FSIS (1995) Public Health Hazard Analysis Board on bone particles concluded the following: ☐ Bone particles smaller than 1 cm are not a safety hazard. ☐ Bone particles 1–2 cm are a low risk ☐ Bone fragments larger than 2 cm have the potential to be a safety hazard and may cause injury. Material other than bone may pose a potential hazard, and each instance should be considered on a case-by-case basis, irrespective of size ☐ FDA Health Hazard Evaluation Board found that hard or sharp objects 7 mm or longer in size were a potential health hazard due to laceration, perforation, and possible secondary infection. □ Objects less than 7 mm in size represent a possible hazard, particularly in at-risk groups, such as infants or the elderly (Olson, 1998)

Source: Goldman (2016).

# References

Goldman DP. (2016). Beef Product Attribution and Traceback: FSIS Perspectives. USDA Food Safety and Inspection Service. Presented at NAMI conference: Pathogen Control and Regulatory Compliance in Beef Processing (September 7-8, 2016).

Goldman DP. (2002). The Physical Hazards of Foreign Materials. Public Meeting on Foreign Material Contamination. USDA Food Safety and Inspection Service. Presented September 24, 2002.

Olsen AR. (1998). Regulatory Action Criteria for Filth and Other Extraneous Materials. I. Review of Hard or Sharp Foreign Objects as Physical Hazards in Food. *Regul Toxicol. Pharmacol.* 28(3): 181-189.

Peariso D. (2006). Preventing Foreign Material Contamination of Foods. Blackwell Publishing.

Stier RF. (2016). Foreign Materials in Foods: Control and Evaluation. *Food Safety Magazine* <a href="https://www.food-safety.com/articles/5113-foreign-materials-in-foods-control-and-evaluation">https://www.food-safety.com/articles/5113-foreign-materials-in-foods-control-and-evaluation</a>

U. S. Food and Drug Administration. (2005). Compliance Policy Guide. Sec 555.425. Foods, Adulteration Involving Hard or Sharp Foreign Objects. Accessed from: https://www.fda.gov/media/71953/download

USDA Food Safety and Inspection Service. (2020). FSIS Guideline for Industry Response to Customer Complaints. Accessed from:

https://www.fsis.usda.gov/sites/default/files/media\_file/2021-01/FSIS-Guideline-for-Industry-Response-to-Customer-Complaints.pdf

USDA. FSIS. (2013). Directive 8080.1: Recall of Meat and Poultry Products. Revision 7. Accessed from: https://www.fsis.usda.gov/sites/default/files/media\_file/2020-07/8080.1.pdf

USDA FSIS. (2002). USDA/FSIS Technical Conference on Foreign Material Contaminants, Prerequisite Programs, and Validation. Omaha, NE.

USDA. FSIS. (2014). Directive 8091.1 Procedures for the Food Safety and Inspection Service (FSIS) Health Hazard Evaluation Board (HHEB). Revision 1. Accessed from: https://www.fsis.usda.gov/sites/default/files/media file/2020-07/8091.1.pdf

USDA. FSIS. (2021). Directive 8140.1. Notice of Receipt of Adulterated or Misbranded Product. Accessed from: https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/8140.1.pdf

USDA. FSIS. (2012). Notice 34-12. Responsibilities Related to Receiving Notice of Adulterated or Misbranded Product, and Verifying Written Recall Procedures and Hazard Analysis and Critical Control Point (HACCP) Reassessment Documentation. [withdrawn 2013].