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MEMORANDUM

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Re: FSIS Releases Draft Guideline on Complaint Handling and Foreign Materials

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has issued a Draft Guideline detailing the Agency's expectations of companies that identify foreign material in their meat and poultry products and more generally providing recommendations for how establishments should craft their complaint handling policies. 1/ FSIS states that it developed the document in response to an increase in the number of recalls of meat and poultry products adulterated with foreign materials, many of which occurred after the recalling establishments had received multiple customer complaints. Though the document is intended to address foreign material customer complaints specifically, FSIS notes that establishments can apply the information in the document to other customer complaints of adulterated or misbranded products in commerce. The Draft Guideline marks a significant expansion in FSIS's formal guidance about complaint handling programs and signals continued Agency focus on foreign material issues.

According to FSIS, the Draft Guideline reflects the Agency's current thinking and "should be considered useable as of the issuance date." The document technically "is not regulatory" (*i.e.*, is not binding), and establishments may choose to adopt different procedures than those outlined in the Draft Guideline, although in practice FSIS will typically expect the establishment to justify alternative practices. Comments are due by May 10, 2019 and should be submitted to Docket Number FSIS-2018-0034.

This memorandum first summarizes FSIS's statements in the Draft Guideline on foreign material control generally, followed by the Agency's guidance on complaint handling.

Foreign Material and Reporting Obligations

The Draft Guideline articulates a number of Agency positions on foreign material control, FSIS's view of the adulteration standard, and establishment reporting obligations under 9 C.F.R. § 418.2 (Section 418.2). Of particular significance, the Draft Guideline states FSIS's position that "[m]eat

1/ FSIS Guideline for Industry Response to Customer Complaints (Mar. 2019), available at https://www.fsis.usda.gov/wps/wcm/connect/8d0a0e73-1e6f-424f-a41f-ea942247a5ff/Guideline-for-Industry-Response-Customer-Complaint.pdf?MOD=AJPERES. A copy of the Draft Guideline is also attached.

and poultry products that are contaminated with foreign materials are adulterated under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) regardless of the physical characteristics of the foreign material (e.g., shape, size, hardness, etc.)."

FSIS states that under the FMIA and PPIA, a meat or poultry product is adulterated if it is "injurious to health or is for any other reason unsafe, unsound, unhealthful, unwholesome, or otherwise unfit for human food." 2/ According to FSIS, even if an establishment determines that foreign material in a meat or poultry product does not present a physical or chemical food safety hazard, the presence of the foreign material in the food causes it to be "unfit for human consumption" and adulterated.

The Draft Guideline also discusses FSIS's interpretation of the 24-hour notification requirement for adulterated or misbranded product found in Section 418.2. Under Section 418.2, an official establishment is to notify its district office "within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened." FSIS explains this requirement in two different ways in the Draft Guideline, stating first that, "When an establishment has reason to believe that adulterated or misbranded product has entered commerce, the establishment must notify FSIS within 24 hours," and later explaining that "24 hours starts when the establishment learns or determines that adulterated or misbranded product may have entered commerce." Both explanations suggest a broad Agency interpretation of the reporting requirement which, when coupled with the Draft Guideline's statements about when foreign material adulterates a product, could lead to broad Agency expectations regarding foreign material reporting.

FSIS also clarifies that the 24-hour reporting period includes weekends and non-work days, including days when an establishment is not in operation. This reporting requirement applies to both producing and receiving official establishments.

The Draft Guideline elaborates that producing establishments are not required to notify FSIS when they discover their products are adulterated or misbranded if the products remain under their direct control. Reiterating existing policy, FSIS explains that it considers product to be in commerce even if it has not yet reached retail or institutional users. In general, FSIS considers product to be in commerce when it is no longer under the direct control of the producing establishment, including when product is moving between official establishments and not yet available to institutional or household consumers at the retail level. According to the Draft Guideline, absent any other written methods to demonstrate direct control over the product, FSIS considers product to be in commerce when pre-shipment review is signed and the product is in distribution.

FSIS considers the following circumstances to demonstrate that product remains under an establishment's control, so long as the controls are sufficiently documented and HACCP system decisions are consistent with the expressed controls:

- The products are moved between two establishments owned by the same corporation, under a tamper-resistant seal applied by the producing establishment;
- The products are moved under FSIS seal; or
- The products are at the establishment or located on premises owned by the producing establishment.

FSIS suggests that when an establishment is uncertain if a finding should be reported to FSIS, the establishment should seek guidance from Inspection Program Personnel (IPP) or the District Office.

2/ FSIS was paraphrasing the adulteration standard; there are other ways under the statutes that food could be considered adulterated articulated in the statute.

The Draft Guideline also clarifies the reporting roles of producing establishments and receiving establishments and the differences between reporting obligations under Section 418.2 and FSIS internal communications using Form 8140-1 under FSIS Directive 8140.1. In particular, when an establishment receives adulterated or misbranded food, it is required under Section 418.2 to notify either the District Office or IPP. If the receiving establishment notifies IPP instead of the District Office, IPP at the receiving establishment will complete FSIS Form 8140-1 to notify IPP at the producing establishment and the applicable District Offices.

Even though FSIS will provide a copy of FSIS Form 8140-1 to the producing establishment, FSIS recommends that the receiving establishment notify the producing establishment to expedite the producing establishment's investigation. If a producing facility receives notice from a receiving facility that it produced adulterated or misbranded product without having been notified by the local IPP that FSIS Form 8140-1 was received from the District Office, FSIS expects it to notify its District Office within 24 hours.

Customer Complaint Program Recommendations

In addition to addressing issues related to foreign materials generally, the Draft Guideline offers recommendations for establishments' programs for handling customer complaints. Though customer complaint handling programs are not mandatory, FSIS notes that the records from these programs can be used to fulfil regulatory requirements in 9 C.F.R. §§ 418.4, 416.16, and 417.5.3/

FSIS recommends that a customer complaint program include the following components:

- **Customer Complaint Reporting**: FSIS advises that each establishment develop mechanisms to receive and process customer complaints. Establishments also should consider how complaints will be relayed from corporate headquarters to the producing establishment, if complaints are directed to a corporate address. Similarly, establishments in co-manufacturing or co-packing relationships should consider how complaints will be communicated from the company named on the label to the contract manufacturer (or vice versa).

- **Substantiation of the Customer Complaint**: The customer complaint program should include criteria or procedures for assessing the validity of the complaint. They should include verifying that the product is under FSIS jurisdiction, the establishment where the product was produced, and whether any tampering occurred after shipment. Establishments also should identify the specific employee(s) who will be responsible for initially substantiating a claim. In the Draft Guideline, FSIS recommends as a "best practice" to notify the local FSIS inspector "as soon as an establishment begins investigating a potential complaint of adulterated or misbranded product in commerce." FSIS explains that it uses this information to verify establishments in the distribution chain have prevented further distribution of adulterated or misbranded products. If an establishment determines that a complaint is not valid or applicable to FSIS-regulated products, it should document how it made that decision.

- Establishment Response to a Customer Complaint: When an establishment determines that a customer complaint represents adulterated or misbranded product that has entered commerce, the complaint handling procedures should require that the establishment initiate an investigation, notify FSIS of the adulterated or misbranded product, and take corrective actions.

3/ If a complaint handling program were made part of one of these programs, the corresponding records would need to be maintained and made available to FSIS consistent with the recordkeeping requirements for the various regulations.

- Establishment Response Plan and Investigation: FSIS explains that it is a best practice to draft and maintain a written response plan for instances when adulterated or misbranded product enters commerce. This plan should include steps to identify any affected product (e.g., lot, date, line) and the distribution of the affected product.

- FSIS Notification: The Draft Guidelines explains that once an establishment determines that adulterated or misbranded product has entered commerce, the notification procedures of Section 418.2 must be followed. FSIS advises that establishment response plans include steps to gather the information required to be reported under Section 418.2 (e.g., amount of product, origin, destination). Once again, FSIS emphasizes that it must be notified of every instance of adulterated or misbranded product that has entered commerce. FSIS will then determine whether to convene the Health Hazard Evaluation Board (HHEB), which can be a precursor to a product recall.

- Corrective Actions: The Draft Guidelines address corrective actions, relying primarily on the HACCP and SSOP regulatory frameworks. FSIS advises that the complaint handling procedures also should include steps to determine what part of the establishment's HACCP system failed and allowed for adulterated or misbranded product to enter commerce. The establishment also should assess whether any modifications to the HACCP program must be made to ensure wholesome product is produced. When a food safety hazard has occurred, FSIS explains the corrective actions must satisfy the regulatory requirements for HACCP corrective actions in 9 C.F.R. § 417.3 and must be documented as required in 9 C.F.R. § 417.5. When no food safety hazard exists, FSIS explains the regulatory requirements for contaminated or adulterated products in 9 C.F.R. § 416.15 and 9 C.F.R. § 416.16 apply.

  In situations in which foreign material poses a safety hazard after it was identified as reasonably likely to occur and a corresponding critical control point (CCP) was established, establishments must implement the corrective actions identified in 9 C.F.R. § 417.3(a). If the hazard analysis identified the foreign material as not reasonably likely to occur (NRLTO) due to a prerequisite program, it would be considered an unforeseen hazard, and the establishment must perform corrective actions as detailed in 9 C.F.R. § 417.3(b), including reassessing the hazard analysis. This corrective action requirement includes a reassessment to determine if the decision in the hazard analysis is still supportable or if changes need to be made to the hazard analysis. Establishments must document their HACCP corrective actions as described in 9 C.F.R. § 417.5. The Draft Guideline also includes steps for taking corrective action following misbranding events.

- Documentation of the Customer Complaint: According to FSIS, it is a best practice for establishments to document all customer complaints, regardless of whether they are substantiated. For substantiated claims of adulterated or misbranded product in commerce, an establishment's documentation should include how FSIS was notified, the corrective actions taken, whether a HACCP reassessment was performed, and the results of any reassessment.

In addition to the guidance offered in the document, the Draft Guideline also includes a list of additional resources for preparing complaint handling procedures, including a best practices guide prepared by several meat and poultry trade associations entitled, *Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products*.

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The Draft Guideline evidences a continued Agency focus on foreign material control and has the potential to lead to increased reporting of foreign material contamination to FSIS, which in turn could cause an increase in related recalls and enforcement. We will continue to monitor developments related to FSIS's policies and enforcement concerning foreign material. Please contact us if you would like further information on this issue.