Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products

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Purpose and Overarching Principles

The purpose of this best practices document is to provide a method of receiving, investigating, and responding to foreign material complaints. Foreign material contamination can be found: 1) in the source raw material, 2) in the processing plant during production, or 3) by a customer or other purchasing group that may notify government agencies. The response procedure assumes that the establishment maintains preventive measures to protect product from foreign material introduction from all sources and documents actions when customer complaints are reported.

This document contains recommended best practices that are general in nature and may not be appropriate for each individual company or establishment. Companies and establishments should develop customer complaint handling programs that work for their specific situations and may consider these recommendations when doing so. For the purpose of this document, customers may include end users, retailers, food service companies, etc. Additionally, this document is specific to foreign material complaints. It is recognized that establishments may also receive complaints for a variety of reasons including misbranding concerns such as errors in labeling substances, or undeclared allergens; however, this document is not intended to address the process for handling those misbranding complaints.

Overall, a comprehensive foreign material complaint handling program should reflect the following overarching principles:

- There should be a mechanism for collecting complaints however they may be communicated to the company and directing those complaints to a centralized function;
- Every complaint should be analyzed for veracity, completeness, food safety risks, potential trends, and other relevant considerations, with triage and escalation procedures as appropriate;
- Relevant information should be communicated internally within the company when applicable between centralized corporate functions and individual establishments, and externally when appropriate to suppliers, customers, and/or government regulators; and
- All complaints and related investigations and analysis should be documented.

Relevant Regulations and Directives

There are several regulatory requirements and articulated policies set forth by the Food Safety and Inspection Service (FSIS or the Agency) regarding foreign material and the handling of foreign material complaints. These requirements are listed below.

According to FSIS, meat and poultry products that are contaminated with foreign material are adulterated under the Federal Meat Inspection Act (FMIA) and the Poultry Product Inspection Act (PPIA) regardless of the physical characteristics of the foreign material (e.g. shape, size,

hardness, etc.). Also according to the Agency, product containing foreign material is unsound, unhealthful, unwholesome, or otherwise unfit for human food, and is adulterated. Specifically:

> As per the Federal Meat Inspection Act Section 601(m) the term "adulterated" shall apply to any carcass, part thereof, meat or meat food product if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; and
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> As per the Poultry Products Inspection Act Section 435(g) the term "adulterated" shall apply to any poultry product if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.

FSIS issued Directive 8140.1, (Rev. 1) to assist inspection program personnel (IPP) in understanding how notification can be made for product, shipped between federally-inspected establishments, intended for further processing that is adulterated, including product that has foreign material contamination. Specifically, when an official meat or poultry establishment receives adulterated product intended for further processing, IPP are to use FSIS Form 8140-1 to notify IPP at the producing establishment and the applicable DO.[1]

The IPP are instructed not to use the FSIS Form 8140-1 if:

- The establishment receiving the adulterated product elects to notify the DO directly as required in 9 CFR § 418.2;
- The establishment receives adulterated or misbranded product for further processing under USDA seal and accompanied by FSIS Form 7350-1, Request and Notice of Shipment of Sealed Meat/Poultry; or
- The establishment receives adulterated or misbranded product under other control measures with the intent to treat the product to make it not adulterated or misbranded (e.g., *E. coli* O157:H7 positive product received for cooking under appropriate controls).

It is important to note that receiving establishments may make product unadulterated if they have the appropriate procedures in place to do so. The FSIS Form 8140-1 is to be used only for products intended for further processing that are shipped between federally-inspected establishments. The FSIS Form 8140-1 serves as the tool to provide notification to the Agency of the shipment of product between federally-inspected establishments that is adulterated, including product that has foreign material contamination.

9 CFR § 418.2 requires establishments to notify the District Office (DO) within 24 hours of determining that an adulterated or misbranded product has been received by or shipped from the establishment into commerce. The 24-hour notification requirement begins when the receiving or shipping establishment learns or determines there is a foreign material finding associated with product from their establishment.

[1] This requirement applies to misbranded product as well, but misbranded product is outside the scope of this document.

Though expired in 2013, FSIS Notice 34-12 provides additional information on the Agency's expectation related to foreign material as well as some pertinent examples.

Scope

This best practices document applies to the control of ***all*** foreign material objects whether they create a food safety hazard or not. This complaint handling program does not relate to quality issues such as flavor, color, size, piece count, or misbranding.

Response Procedure

The foreign material response procedure applies to all establishments which process meat or poultry products. The procedure should be initiated upon receipt of every customer complaint of foreign material in a product produced at a company-owned establishment. Each notification by a customer must first be triaged to determine if it is a legitimate complaint which could involve a series of questions, photos if available, returned product, *etc.* (see Substantiation section below). Though not all foreign material is a food safety hazard, every foreign material complaint should be evaluated and determined if a food safety risk is associated with the foreign material.

Customer Complaint Reporting

Mechanisms should be provided to customers for reporting a foreign material complaint to the company or establishment. Examples of reporting mechanisms may include a postal address devoted to complaints, a toll-free number, website, or e-mail, among other reporting mechanisms. A prudent establishment should report on a regular basis to the company quality assurance, which could include corporate quality assurance, all complaints that were received, substantiated, and resolved.

Establishments that handle product on behalf of another establishment may also be the recipient of customer complaints. For example, if Establishment A relies on Establishment B to conduct part of its production process, but Establishment A's brand is carried on the product, all complaints may come back to Establishment A. Establishment A needs to include Establishment B in the communication process of any complaints that are directed towards the products they have processed; the investigation will assist in determining the source of the foreign material. Alternatively, Establishment C and Establishment D may carry the brand for Establishment E. Establishments C and D may receive some of the complaints. They too would be responsible for providing this information to their supplying establishment(s) and should be part of the investigation team. Communication efforts between establishments that work together in the supply chain are essential with regards to receiving, investigating, and responding to complaints of foreign material by customers.

General Complaint Handling Procedure

All foreign material complaints should be documented, reviewed, and acted on using the following steps. The order outlined below is designed to facilitate an orderly review and response, but the steps should be taken in the order most appropriate to the given situation. In particular, various aspects of steps 3 through 5 might be taken in a different order or even simultaneously:

1) Each foreign material complaint should be analyzed to substantiate the veracity of the complaint. The results of the analysis should be documented. If the complaint is substantiated as valid, the company or establishment proceeds further with its analysis.
    a. If the establishment determines the complaint is not valid, the establishment should document the information used to make this determination.
2) A risk assessment is performed on each substantiated complaint to determine whether it presents a public health risk. The risk assessment will consider the end-user of the product.
3) Product control, recovery, and/or recall actions should be initiated if indicated by the results of the risk assessment.
4) If the company or establishment determines that the complaint gives reason to believe that product in commerce is adulterated, FSIS must be notified within 24 hours of reaching this determination.
5) The company or establishment should conduct a root cause analysis to identify potential root cause and identify and take corrective actions to prevent recurrence. The results of the root cause analysis and the corrective actions should be documented.

Substantiation

The nature of the foreign material complaint should be substantiated, where possible, in order to appropriately allocate personnel resources. Evidence to substantiate a claim may include:

- Review of actual object (does the material exist anywhere in the establishment, is it embedded in the product or on top of the product, *etc*.)
- Photographs
- Code dates
- Multiple complaints potentially indicative of a trend. Note: Trends should be over time periods long enough for the data to be meaningful.

Customer Complaint Documentation

All foreign material complaints should be recorded. Appropriate parties responsible for responding to a foreign material complaint should have access to the complaints and any relevant complaint trends. Depending on the size of the company, this process might involve appropriate parties being notified each time a complaint is received or updated. All relevant information about the complaint should be recorded as soon as possible. This may include but not limited to the following:

- Date
- Establishment number and/or manufacturing location
- Product coding
- Identifying label information
- Possible identification of foreign material including size, composition, shape, hardness, and other relevant information (*e.g*., how it was found by the customer)
- Other

It is important to note that if an establishment determines that a foreign material claim is not substantiated, the record should include the detailed information that describes the basis for this decision. If substantiated, then subsequent activities taken should be documented.

An investigation of each potentially valid foreign material complaint should be conducted and documented, and should include the following information when possible:

- Date
- Establishment number and/or manufacturing location
- Product details and tracing
- Identification of foreign material reported (size, composition, shape, hardness, and other associated characteristics)
- Potential causes
- Corrective actions

Each instance must be reviewed and evaluated on a case-by-case basis to determine if there is a risk to public health.

Determination of Isolated or Systemic Complaints

Each complaint situation is evaluated to determine if it is isolated or indicative of a systemic problem. As part of the analysis the review may consider:

- Other similar complaints
- Review of production records
- Review of maintenance records
- Review of any remaining product

For example, metal incidents typically would not be considered to be the same unless the root cause analysis found the incident to be from a common source. Product, production time, time elapsed between incidences[2], previously documented findings (by the establishment or by FSIS) and processing line should be taken into consideration when evaluating the same root cause. The establishment should consider what the root cause information is telling them with regards to the process and resulting foreign material. For example, if an establishment has a worn belt break on "Line 1" and foreign material is found in product as a result, the establishment should consider examining the wear and potential for belt breakage on similar belts as part of their corrective and preventative actions. If the establishment does not examine similar belts as part of their corrective and preventative actions, subsequent incidents related to a second belt breaking due to this failure to examine and take any necessary actions on additional belts may be considered to be from the same root cause. Once it is determined that there are multiple, same source foreign material incidents and it is determined the cause is or is likely to be the same, the complaint status may change from an isolated complaint to systemic complaint.

However, if the establishment had a foreign material incident from a worn belt, they respond by taking all the appropriate corrective/preventative actions and the establishment has another issue despite for-cause and routine belt inspections that does not necessarily mean that the issue is systemic. If an establishment has an intervening period of control (i.e. all reasonable corrective/preventative actions were taken following an incident and the facility was operating for a period of time without issues) such incidents should not be considered systemic. Similarly,

[2] All parameters should be considered when determining if a foreign material finding is isolated or systematic. The time elapsed between incidences is only one parameter in the decision making process.

if the belt breakage is attributed to a new or different root cause, such incidents should not be considered systemic. The incidents described are examples and there may be foreign material incidents (e.g.: intact meat hook) that are exceptions to these examples so every incident needs to be individually evaluated to determine if isolated or systemic.

Responsibilities

The company should have an established protocol for investigating foreign material complaints, with responsible parties' duties defined. An established process should be in place to communicate foreign material complaints to the producing establishment if complaints are received through a channel other than the producing establishment (*e.g.*, through a corporate customer relations office). This established process may differ between companies with regards to reporting structure, detail, and how information is communicated. It is up to the company who will determine the validity of the customer complaint then provide and document the supporting information. An example may be – Receive and Document Complaints; Review/Triage the Complaints; Communicate as Necessary to Establishment and Partners; Investigate Complaints; Corrective Actions and Documentation; Reassess HACCP plan as appropriate; Communicate with FSIS and customers as appropriate.

Individuals involved in the reporting process *may* include the following depending on establishment or corporate structure.

- Company Customer Relations/Corporate Food Safety and/or Quality Assurance (FSQA): The customer interface and/or Corporate FSQA department of the affected company may receive, monitor, and substantiate customer complaints, and may relay these complaints to the appropriate FSQA management member. Customer Relations should coordinate with Establishment and Corporate FSQA to identify the origin of the foreign material incident if appropriate.
- Corporate Food Safety/Quality Assurance: If applicable, Corporate FSQA should assist in the response to a foreign material incident through effective communication with the corresponding establishment FSQA, the company's Customer Relations department, and FSIS (if needed).
- Establishment Food Safety and Quality Assurance Team (FSQA): The producing establishment's FSQA team should investigate the establishment records, protocols, and equipment upon receipt of a foreign material complaint, and should notify Corporate FSQA (when applicable) if a foreign material complaint is potentially valid, or if it is invalid.
- Other entities that provide information into a company or companies that use contracted manufacturers should coordinate and integrate communication and reporting efforts.

Investigation

Every foreign material complaint should be reviewed. In the event of a potentially valid foreign material complaint, the establishment or FSQA (with support from Corporate FSQA if it exists and to the extent appropriate) should perform and document an investigation consisting of relevant records generated during the production of the affected product and a visual inspection of processing. An investigation report should include details of the foreign material complaint such as the size, composition, shape, hardness, and other associated characteristics. The

investigation findings may be communicated to Corporate FSQA upon completion for review and substantiation.

Risk Analysis

The risk associated with every substantiated foreign material complaint should be evaluated in order to assess whether the foreign material presents a food safety risk that warrants a voluntary recall of the affected product or other appropriate action. The risk analysis should be documented. This information should be considered for inclusion as part of a 9 CFR § 418.2 notification (if applicable) to the DO (see notification process below). Risk assessment should be based on appropriate internal and/or, if necessary, third party expertise and may include such details as:

- Risk according to appropriate hazard standards;
- Current inventory sampling results (re-evaluation of remaining product if available);
- Scope of foreign material introduction; and,
- Intended customers of the product and their potential risk of illness or injury as a result of the foreign material. Intended customers such as school children, hospitals, and military would be considered a higher risk and may warrant more immediate attention.

FDA CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects may be used as a guide to assist in determining the risk of the foreign material.

NOTE: If foreign material is in commerce, the Agency may determine the need to convene the Health Hazard Evaluation Board (HHEB) as per FSIS Directive 8090.1, Rev.1. The HHEB may be convened if there is a unique shape, size, hardness, intended end-user, reports of injury, *etc*. The HHEB will consider mitigations the establishment has in place as well as other information the establishment may have available to support product disposition. Current and archived recalls of meat and poultry products produced by Federally-inspected establishments can be found on the Agency's Recalls and Public Health Alerts website.

Records and Corrective Action(s)

All substantiated foreign material complaints should prompt an investigation into the source of the foreign material introduction, with details of the investigation documented. The establishment should review all relevant food safety and establishment records, as well as previous reports of foreign material. Corrective actions for substantiated foreign material complaints should be designed to prevent recurrence of the foreign material incident, and all actions should be recorded and reviewed for effectiveness. Corrective action reports and related records include the following information, where applicable:

- Root cause analysis;
- Documented corrective action;
- Documented preventive measures;
- Documented disposition of all affected, and potentially affected products;
- Review of relevant HACCP procedures and prerequisite programs, including reassessment when a pre-requisite program has failed to control the hazard;
- Documented decision whether to notify potentially affected suppliers and,
- Documented decision whether to notify the FSIS DO.

Complaint Response

Where reasonable, the company and/or establishment may inform the customer reporting the foreign material of the corrective actions taken in response to the complaint. Additionally, customer service expectations may necessitate generation of formal letters, rebates, *etc*. regardless of whether the company views the complaint as valid or serious.

Notification Process

- Establishments will handle all customer complaints via company procedures.
- The company and/or establishment should keep and periodically update the procedures for response to a customer complaint. The company and/or establishment should also retain records of foreign material complaints for audit and review.
- 9 CFR §418.2 requires that establishments are to notify the DO within 24 hours of determining that an adulterated or misbranded product has been received by or shipped from the establishment into commerce. Information provided to the DO as part of the notification could include:
    - Date
    - Notifier (Name and Title)
    - Notifier's Contact Information (Phone #)
    - Receiving Establishment Name and Number
    - Originating Establishment Name and Number
    - Type of Product (Name, Package Type, and Size)
    - Category of Product (Beef, Chicken, Pork, Turkey, Veal, etc.)
    - Is the product adulterated? If so, type of adulteration?
    - Is the product in commerce?
    - Amount of product in commerce (numerical value in pounds)
    - Location of product (name and address)
    - Product disposition (condemned, returned, reconditioned, on-hold, etc.)
    - Investigation Findings
        - If the company became aware of a foreign material issue based on a consumer complaint, include how the company determined the information is valid, *e.g*., is it your product; the basis for the product being adulterated.
        - Relevant information regarding the investigation, nature of the foreign material, risk analysis (see above), etc.
- The documentation and support provided as part of the notification will assist in the determination of the need for a voluntary recall or other action by the establishment. Notification does not equal recall.
- If product is adulterated due to foreign material contamination and shipped between inspected establishments of different companies, the IPP should be informed. The DO is not required to be notified if the receiving company or establishment notifies the IPP. The producing establishment must notify the DO per 9 CFR §418.2 unless the producing establishment is contacted by IPP first.
- FSIS Form 8140.1, *Notice of Receipt of Adulterated or Misbranded Product* is the tool FSIS will use to notify the DO that product with foreign material contamination has shipped between federally-inspected establishments. This form is not to be completed by the establishment.

Supporting Documentation

FDA Compliance Policy Guide. CPG Sec 555.425. Foods, Adulteration Involving Hard Sharp Foreign Objects. Issued March 23, 1999. Revised May 2006.

FSIS Directive 8091.1 (Rev. 1). Procedures for the Food Safety and Inspection Service (FSIS) Health Hazard Evaluation Board (HHEB). Issued January 13, 2014.

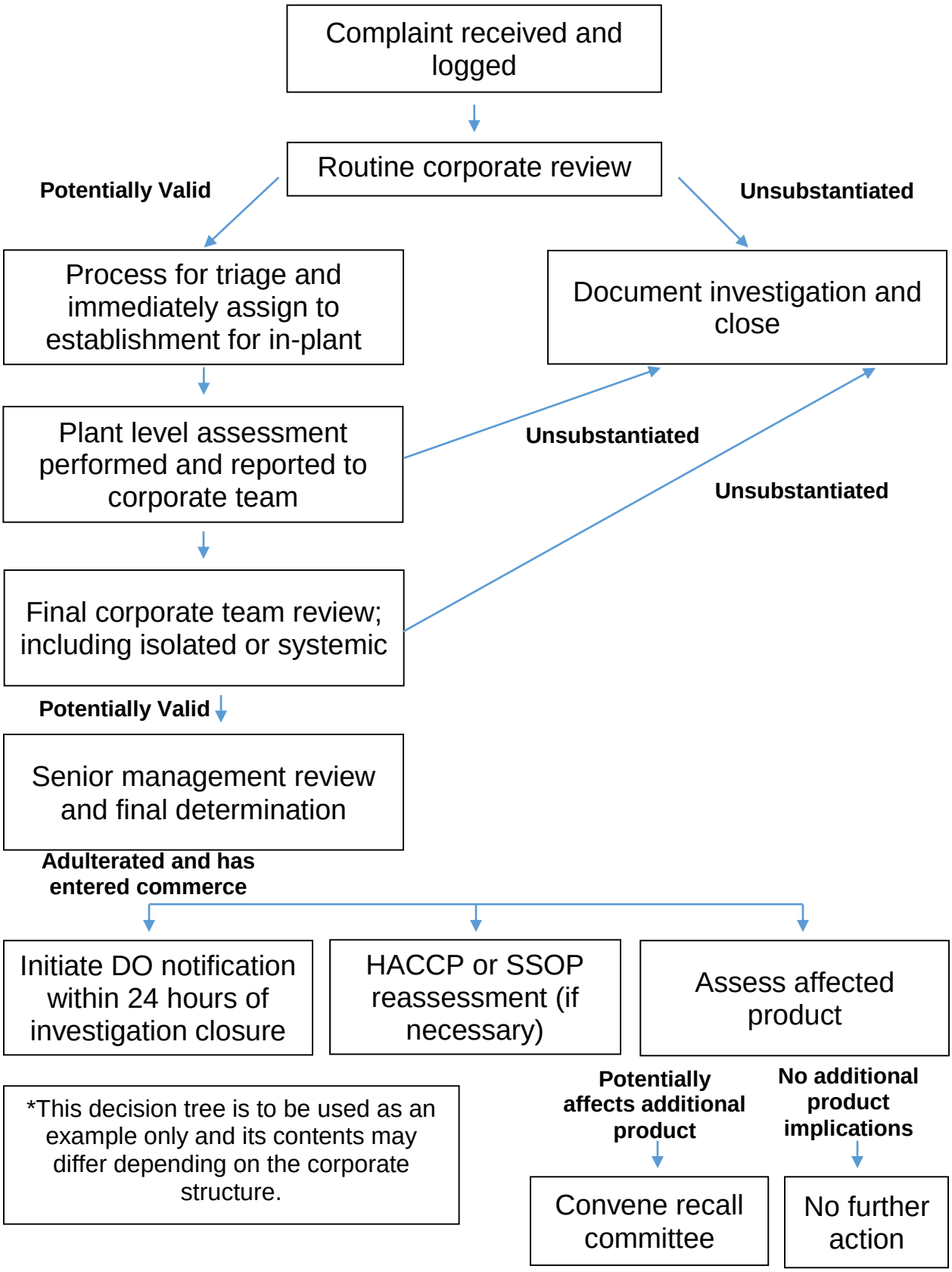
FSIS Directive 8140.1 (Rev. 1). Notice of Receipt of Adulterated or Misbranded Product. Issued July 3, 2017.

FSIS 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. Issued May 23, 2012.

The Dirty Dozen: Ways to Reduce the 12 Biggest Foreign Materials Problems. Food Safety Magazine. Published April/May 2013.

The Physical Hazards of Foreign Materials. Public Meeting on Foreign Material Contamination. Dr. David P. Goldman, USDA-FSIS. Presented on September 24, 2002.

Example Corporate Complaint Handling Decision Tree



*This decision tree is to be used as an example only and its contents may differ depending on the corporate structure.