

FSIS Guideline for Industry Response to Customer Complaints

2020

This guideline is designed to help meat and poultry establishments develop a written program to respond to customer complaints. This guidance covers:

- How to respond to customer complaints of adulterated or misbranded meat and poultry products
- The recall notification requirements in 9 CFR 418.2

Preface:

FSIS developed this guideline to communicate what FSIS has identified as best practices for meat and poultry establishments to respond to customer complaints. The guideline was developed with appropriate review and public participation and has been revised in response to public comments. Some portions of the document have been rearranged to highlight FSIS recommendations for developing a customer complaint program and to further clarify existing FSIS regulatory requirements. This guideline follows the procedures in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). You can find more information on guidance documents on the Food Safety and Inspection Service (FSIS) [Web page](#). The meat and poultry trade associations, along with their members, have developed a related document, [Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products](#). Establishment personnel may want to use guidance from both documents when developing a response to customer complaints.

What is the purpose of this guideline?

The purpose of this guideline is to inform industry of the procedures FSIS has identified as best practices for responding to customer complaints of adulterated and misbranded meat and poultry products. FSIS developed this document in response to an increase in the number of recalls of meat and poultry products adulterated with foreign materials. In many cases, the recalling establishment had received multiple customer complaints prior to these recalls. FSIS specifically developed this document to address foreign material customer complaints, but establishments can apply the information to other customer complaints of adulterated or misbranded products in commerce. This guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date.

Who is this guideline designed for?

FSIS is issuing this document to assist all FSIS-regulated meat and poultry establishments in developing and implementing procedures for responding to customer complaints, and in preventing similar adulteration or misbranding occurrences.

Does the guidance reflect requirements?

This document is not regulatory. An establishment may choose to adopt different procedures than those outlined in this guideline. This guideline recommends each establishment develop a customer complaint program. However, an establishment can operate without a customer complaint program because there is no regulatory requirement to develop or implement a program to address customer complaints. If an establishment voluntarily decides to develop a customer complaint program, there is no requirement that a program be incorporated into its Hazard Analysis and Critical Control Point (HACCP) system. Customer complaints occur after the product has left the establishment, so a program to respond to complaints is not preventing hazards or adulteration. However, when a customer complaint results in findings of adulterated products, the establishment must meet applicable requirements as described below.

What if I still have questions after I read this guideline?

FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit questions through [askFSIS](#). Documenting the questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **FSIS Guideline for Industry Response to Customer Complaints**.
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Regulations/Agency Issuances** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

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Background:

FSIS is the public health regulatory agency responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. In 2008, Congress amended the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to require each establishment to promptly notify the Secretary if they believe, or have reason to believe, that adulterated or misbranded meat or poultry products have entered into commerce (21 U.S.C. 612 and 459(b)). The Secretary delegated this responsibility to FSIS. In 2012, FSIS issued final regulations reflecting these requirements ([9 CFR part 418](#)). Since the implementation of the regulation in May 2012, FSIS has observed an increase in the number of recalls associated with foreign materials and has developed this guideline to assist establishments in responding to complaints and meeting related regulatory requirements, when applicable.

FSIS recommends, but does not require, that each establishment develop a program to receive and process customer complaints concerning possibly adulterated or misbranded products in commerce. When an establishment chooses to implement a customer complaint program, FSIS recommends it develop and maintain a program that addresses the receipt and investigation of complaints, the implementation of corrective actions, and the notification of FSIS that adulterated or misbranded products have entered commerce. A discussion of regulatory requirements is included later in the guideline; however, a customer complaint program is not a regulatory requirement. The regulatory requirements are included for informational purposes and may result in a more robust customer complaint program.

KEY QUESTION

Question: Is a meat or poultry establishment required to notify FSIS every time they have reason to believe that an adulterated or misbranded product has entered commerce?

Answer: Yes, under [9 CFR 418.2](#), each establishment is required to notify the District Office within 24 hours of learning or determining that they have received or shipped *into commerce* adulterated or misbranded meat or poultry products. When a receiving establishment notifies FSIS inspection personnel, the establishment is in compliance with this regulation. The producing establishment is not expected to also notify FSIS if the receiving establishment has already notified the Agency of the issue.

Developing a Customer Complaint Program:

➤ Overview of the Program

A well-developed and implemented customer complaint program provides many benefits including assisting the establishment in complying with other regulatory requirements and reducing the long-term financial costs of recalls.

A consumer complaint program should include the following components (discussed in more detail in this guideline):

- Customer Complaint Reporting
- Substantiation of a Customer Complaint
- Response to a Customer Complaint
 - Establishment Response Plan and Investigation
- Documentation of a Customer Complaint
- Related Regulatory Requirements
 - FSIS Notification (when required by [9 CFR 418.2](#))
 - Corrective Actions (when required by [9 CFR 416.15](#) or [417.3](#))

➤ Customer Complaint Reporting

Customer complaints may originate from: another establishment, a household consumer, the USDA Consumer Complaint Monitoring System (CCMS), or another regulatory agency¹. Regardless of the source, each customer complaint should be evaluated as a possible report of adulterated or misbranded products in commerce. Each establishment should develop appropriate mechanisms to receive and process customer complaints.

The establishment should provide household consumers with a method for reporting a complaint, for example:

- Postal address;
- Toll-free number;
- Website address; or
- E-mail address.

The establishment should provide non-household consumers (e.g., other establishments, hotels, restaurants, or institutions) with a method for reporting a complaint, for example:

- Company representative contact information; or
- Instructions within the contract or bill of lading.

¹ Although other regulatory agencies are not “customers” they are included as possible sources of complaints and may be included in a robust program.

As technology and social networking change, other methods for reporting complaints may be developed and incorporated into the customer complaint program. The establishment may provide contact information and methods to report a complaint on product labels, shipping documents, or can post this information on the company's webpage.

An establishment that re-labels or co-packs products should be aware that a customer might direct complaints to the company name on the label. As a result, FSIS recommends that co-packers work with the company named on the label to develop a method for reporting and tracking complaints. When the establishment uses a third-party contractor to collect and process customer complaints or when complaints are directed to a corporate address, the establishment should consider how these complaints will be relayed to the producing establishment. The establishment customer complaint process may also include quality complaints; however, a system should be in place to prioritize or triage those complaints that indicate adulterated or misbranded meat or poultry products have been produced at the establishment.

➤ **Substantiation of the Customer Complaint**

An establishment should develop criteria and a mechanism for reviewing any customer complaint. The establishment should verify where the products were produced. Products are often similar and may be produced at multiple locations, so the establishment should verify that the products were produced at its location and, if not, notify the customer or other establishment when appropriate. The establishment should also develop criteria to determine whether tampering of the products occurred after shipment from the producing establishment. The establishment should determine what evidence, if any, the customer has of the adulteration and misbranding. Information that can be used to substantiate a claim includes:

- Evidence of the physical contaminant,
- Photographs,
- Video, or
- A sample of the product label, product, and any other applicable material.

The product label provides information to verify the source of the product, including the lot number, establishment number, and product name. An image or a sample of the product provides information to verify that the product matches the label and can show the condition of the product. An image or a sample of any physical adulteration, such as foreign material, provides information that can be used to start the investigation into the cause of the adulteration. The purchase location may also be helpful to identify distribution channels that may have contributed to the adulteration or misbranding.

NOTE: If the product does not match the label, this could be the basis of a misbranding claim and should be evaluated as evidence of misbranding.

Each establishment should begin to substantiate complaints as soon as possible when there is the possibility that adulterated products have been purchased by household consumers. Products available at the level of the household consumer add a degree of

urgency to removing adulterated products before they are consumed, especially when the adulteration is a food safety hazard. At this point in the process, initial substantiation, it may not be possible to determine if the adulteration is a food safety hazard, so it is important to move quickly to gather information. When the establishment determines that hands-on examination of the products, labels, or any other material is important in determining whether adulterated products have been produced, it should not delay the shipment of the identified foreign objects, samples of the products, or labels for examination by the producing establishment. The FSIS recommended practice is to perform an initial substantiation and investigation using immediately available photographic or video evidence and take appropriate action based on that evidence and then follow up with additional actions, as warranted, if the physical material, products, or labels are made available for a hands-on examination.

As soon as the establishment has reason to believe adulterated or misbranded products have entered commerce, then FSIS must be notified per [9 CFR 418.2](#). It may not be necessary to perform a physical examination of the products, material, or labels to have reason to believe adulterated products have entered commerce. For example, some customers may be able to provide a credible description of the product with adequate detail to have a reasonable belief that adulterated products entered commerce. Also, multiple reports of similar foreign materials, especially when the initial report has been validated, may be enough to take action without any physical evidence from the additional reports of adulteration. If there is epidemiological evidence that a specific product is implicated in a series of injuries or illness, that may be enough evidence to substantiate that adulterated products have entered commerce, without observing foreign material. Reports of adulterated or misbranded products from customers other than a household consumer are also critical and should be prioritized over quality complaints. Quick action on these complaints can prevent distribution to households and consumer injury.

Recommendation

Each establishment should develop the criteria and mechanisms for determining if the products were produced at that establishment, if a customer complaint is genuine, authentic, and that no tampering of the products occurred after shipment from the producing establishment.

The establishment should identify the specific establishment employee(s) (name or title) who will receive notification of complaints and will be responsible for their initial substantiation. Since complaints may occur on weekends, FSIS recommends that applicable contact information be included in the program. Early action is critical to identifying products in distribution channels, correcting the issue to prevent further adulteration or misbranding, and removing adulterated or misbranded products from households before they are consumed.

When an establishment determines that a customer complaint claim is not valid or not applicable to FSIS-regulated products, FSIS recommends that the establishment maintain documentation to support how that decision was made. Such documentation

could be used to support why the establishment did not take any actions related to the products, especially if new evidence, which does support the initial claim, is identified in the future.

The establishment must consider if any FSIS-regulated products are implicated by a complaint. The initial complaint may be related to a product under Food and Drug Administration (FDA) jurisdiction; however, when there are common ingredients or common production areas, the possible contamination of FSIS-regulated products must be considered. It is not an FSIS regulatory requirement to maintain documentation related to products that are not regulated by FSIS or whose production does not impact FSIS-inspected products. However, an establishment may want to maintain documentation regarding complaints about the FDA products that it produces and must comply with any FDA regulations regarding reporting and recalling adulterated products.

NOTE: A valid complaint for products under FDA jurisdiction must be addressed as required by FDA regulations.

Some examples of why a complaint may be found to be without merit related to FSIS principles include:

- Implicated products not produced, distributed by, or owned at any point by an establishment or corporation.
- A valid complaint determined not to involve an FSIS food safety hazard, adulterated products, or misbranding, e.g., a complaint about quality.
- Products that are not under FSIS jurisdiction and there are no implications for FSIS-inspected products.

When the establishment has identified a valid complaint and believes, or has reason to believe, that adulterated or misbranded products shipped or received by the establishment have entered commerce, the establishment must notify the FSIS District Office within 24 hours ([9 CFR 418.2](#)).

Depending on the procedures used to validate the complaint, further investigation may or may not be required to make this determination.

When an establishment receives a customer complaint and it is substantiated, the next two questions to ask are: 1) Is the product adulterated or misbranded? and 2) Has it entered commerce?

What are adulterated or misbranded products?

Adulterated: Meat or poultry products that are injurious to health or are for any other reason unsafe, unsound, unhealthful, unwholesome, or otherwise unfit for human food.

Misbranded: Meat or poultry products that bear a false or misleading label or if any required feature is not prominent.

➤ What are adulterated or misbranded products?

Meat or poultry products are adulterated, among other reasons, if they bear or contain any poisonous or deleterious substance that may render them injurious to health; are unhealthful, unwholesome, or otherwise unfit for human consumption; or were prepared, packaged, or held under insanitary conditions whereby they may have been rendered injurious to health (see 21 U.S.C. 453(g) and 21 U.S.C. 601(m)).

Meat or poultry products are misbranded if the label is false or misleading, or if it does not contain the required labeling features (see 21 U.S.C. 453(h) and 21 U.S.C. 601(n)).

Meat and poultry products that are contaminated with foreign materials are adulterated under the FMIA and PPIA 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. Material that is inherent to the species (e.g., bone, hide, feathers) can result in adulterated or misbranded products when the contamination's extent, size, or shape would render the products unwholesome or injurious to health. The establishment should evaluate each complaint and finding in the context of the specific product, intended use, HACCP system, and details of each incident to determine when meat or poultry products are adulterated.

➤ When are products in commerce?

An official establishment is required to report to FSIS when they believe, or have reason to believe, adulterated or misbranded products have entered commerce. In the context of this document and [9 CFR 418.2](#), FSIS considers products to have entered commerce when the products have left the direct control of the producing establishment and are in distribution. This includes products at retail and products moving between official establishments or other consignees and not yet available to institutional or household consumers at the retail level.

FSIS considers the following to be indications

What is “in commerce”?

When products are not under the direct control of the producing establishment and are in distribution, they have entered commerce, this can include movement between FSIS-inspected establishments.

- FSIS considers products to be in commerce when *preshipment review* is signed (unless there are other written methods to demonstrate direct control) and the products are in distribution.
- Individual determinations are made on a case-by-case basis using information including the establishment procedures to demonstrate direct control and the physical location of the products.

that the producing establishment maintains direct control of products, provided the controls are sufficiently documented and HACCP system decisions are consistent with the expressed controls:

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

There may be other methods for an establishment to demonstrate it has maintained direct control of the products. New technologies and other innovation are continually implemented to improve product movement and this document is not intended to capture all possibilities. When considering new technologies, business models, and distribution, an establishment may want to consider these questions to determine if they are maintaining direct control:

- Who owns the products now?
- Can we prevent an employee (possibly of a different company) from physically moving/using the products?
- What do we have in writing to demonstrate control?
- If we needed to get the products back to our establishment, can we do so without involving other companies?
- Do we have direct control of all comingled (possibly affected) products?
- Has preshipment review been signed?

This list is not all inclusive and the answers can vary, but these are the types of questions an establishment can ask when developing a distribution system or evaluating a current distribution system, to determine where “direct control” stops and the products have entered commerce.

One method an establishment may use to demonstrate direct control and determine when products have entered commerce is by using preshipment review. As required in [9 CFR 417.5\(c\)](#), prior to shipping products into commerce, the establishment must review the production records of the product, making sure that all processing requirements were met and, if necessary, all corrective actions were taken. The establishment should not sign preshipment review until it has reviewed all lot-specific documentation. Lot-specific documentation includes all records associated with that specific production including, but not limited to, critical control point (CCP) monitoring, HACCP verification, corrective actions, prerequisite programs, testing, and any other applicable programs associated with the production of that lot. Preshipment review indicates that the product has been determined to be free from food safety hazards as well as other causes of adulteration and is ready for commerce. The review of the appropriate documents and compliance with [9 CFR 417.5\(c\)](#) occurs before the product leaves the control of the producing establishment and enters commerce. This review may occur when products are at a location other than the producing establishment, as long as the producing establishment maintains control of the products.

➤ Establishment Response to a Customer Complaint

When an establishment receives a customer complaint and determines that adulterated or misbranded products have entered commerce, the establishment should perform an investigation to determine the appropriate corrective actions. While a written plan for addressing customer complaints is not a regulatory requirement, it may be helpful to facilitate training and to document corrective actions.

The establishment should quickly identify all affected products (e.g., lot, date, line) and identify where they were distributed. This is an important step in stopping further distribution and in implementing the establishment's recall plan. The FSIS recommended best practice is to draft and maintain a written response plan.

The response plan should include:

- Investigation of the production that incorporates a review of relevant records generated during the production of the affected products;
- Performing a visual inspection of any questionable products or labels available at the establishment;
- Observing ongoing production of like products; and
- Talking to employees who may have information pertinent to the investigation.

Affected products that have not been shipped should be held and inspected prior to shipping so the establishment can determine if there are additional adulterated or misbranded products. The establishment should use additional information to evaluate the design and implementation of the HACCP system, including laboratory sampling results, intended use of the products, supporting documentation, and expert analyses. The establishment is required to maintain a written recall plan ([9 CFR 418.3](#)). Because some customer complaints may result in a recall, an establishment may choose to incorporate a customer complaint response into the recall plan.

If the establishment determines that adulterated (and in some cases misbranded) products have been produced and shipped, the establishment must meet any applicable regulatory requirements, as discussed further below, under "Corrective Action Requirements".

➤ Documentation of the Customer Complaint

The FSIS recommended best practice is for an establishment to document all customer complaints (whether substantiated or not), to

21 U.S.C. 610 and 458 Prohibited acts

No person, firm, or corporation shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any such articles which are capable of use as human food and are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation or receipt for transportation.

include the investigative steps that were performed, and to describe how the claim was or was not substantiated. For substantiated claims of adulterated or misbranded products in commerce, the records should include how FSIS was notified, what corrective actions were performed, if a HACCP reassessment was performed, and the result of the reassessment. If the establishment did not reassess its HACCP plan, FSIS recommends that the establishment document how determinations were made and what evidence was used, even when a claim was not substantiated. If an FSIS investigation occurs at a future date and the establishment has documentation to support that past complaints were not substantiated, the documentation will help resolve the investigation and address questions about the complaint. The establishment should make records related to customer complaints available to FSIS for review upon request as required by [9 CFR part 320](#), [416.16](#), [417.5](#), and [418.4](#).

Records of the investigations should include the following information (where applicable):

- Dates of the complaint, any notification, corrective actions, recalls, etc.;
- How the complaint was or was not substantiated;
- Pictures;
- Summary of the complaint including the complainant information;
- Establishment number/manufacturing location on the product label;
- Injury or illness reported;
- Product details and trace back information (product code, lot numbers, date codes);
- Nature of foreign material (physical characteristics), as applicable;
- Nature of misbranding, label information, label approval;
- Notification of FSIS (who was notified, when, how);
- Potential causes or contributing factors;
- Other implicated products (same line, date, lot, ingredients, establishment);
- Corrective actions, when applicable;
- Preventive measures, when applicable; and
- HACCP system reassessment, when applicable.

The investigation documentation should also include how the establishment identified all implicated products and support for the determination. The establishment may wish to consider factors such as the physical layout of the establishment, Sanitation Standard Operating Procedures (SOPs), cleaning records, or testing results when developing the program to identify products that may be implicated by a complaint. The affected products will depend on the nature of the complaint.

FSIS Regulatory Requirements

Although the customer complaint program described in this guideline is not a regulatory requirement, the establishment may be required to perform certain actions in response to a finding of adulterated or misbranded products. Beyond the documentation and recordkeeping requirements already mentioned, several additional regulations outline the regulatory requirements an official establishment must meet to prevent direct

contamination or adulteration of products or to respond to a finding of adulterated products.

If a customer complaint credibly indicates that adulterated or misbranded products have entered commerce, the establishment must meet the reporting requirements of [9 CFR 418.2](#) as described in the “FSIS Regulatory Requirements: Notification” section below.

If the outcome of a customer complaint investigation shows that the establishment produced adulterated products, the establishment must prevent affected products from entering commerce and, if necessary, remove products which may have already entered commerce. Depending on the nature and cause of the adulteration and how that type of adulteration is addressed in the HACCP system, the establishment must meet any applicable corrective action requirements. These requirements are described in the “FSIS Regulatory Requirements: HACCP System” section below.

The establishment must also consider any relevant customer complaint findings with respect to the design of the HACCP system in accordance with these general regulatory requirements:

Notification

[9 CFR 418.2](#) – *“Each official establishment must promptly notify the local FSIS 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. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.”*

Hazard Analysis

[9 CFR 417.2\(a\)\(1\)](#) – *“Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment.”*

Reassessment

[9 CFR 417.4\(a\)\(3\)\(i\)](#) – *“Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The*

24 hours starts when the establishment has reason to believe that adulterated or misbranded products may have entered commerce



reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.”

Sanitation SOP

[9 CFR 416.12\(a\)](#) - *“The Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).”*

Maintenance of Sanitation SOPs

[9 CFR 416.14](#) – *“Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.”*

Sanitation Performance Standards

[9 CFR 416.4\(d\)](#) - *“Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.”*

Recalls

[9 CFR 418.3](#) - *“Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.”*

FSIS Regulatory Requirements: Notification

Once the establishment has reason to believe that adulterated or misbranded FSIS regulated products have entered commerce, they must notify FSIS as required by [9 CFR 418.2](#). The producing establishment must notify the FSIS District Office and the receiving establishment must notify either the FSIS District Office or FSIS inspection personnel. Contact information for notification is provided on the webpage [www.fsis.usda.gov contact us](http://www.fsis.usda.gov/contact-us). When FSIS personnel notify the official establishment that adulterated or misbranded products have entered commerce, it would be redundant for the establishment to also notify the District Office of the same adulterated or misbranded products and this could result in duplicate cases. Thus, when an establishment is notified by FSIS personnel that adulterated or misbranded products have entered commerce, the establishment does not need to notify the FSIS District Office unless additional product or production dates are involved.

Remember, “in commerce” includes movement between official establishments when the products are not under direct control of the producing establishment or have left the direct control of the producing establishment at any point. It is also a good practice to notify the District Office of the nature of the adulteration or misbranding (e.g., foreign material contamination, ingredient not present on the label, etc.). The specific nature of

each incident will determine the actions taken by FSIS in response to an official establishment producing adulterated or misbranded products that entered commerce.

FSIS recommends that the establishment include in the response plan how it will gather the information required in [9 CFR 418.2](#) for notification of the District Office when products have been shipped in commerce.

The information required in [9 CFR 418.2](#) is:

- Product type
- Amount of implicated products
- Origin
- Destination

When an establishment believes, or has reason to believe, that adulterated or misbranded products have entered commerce, the establishment must notify FSIS within 24 hours. The 24-hour period includes weekends or non-workdays. If an establishment believes, or has reason to believe, that adulterated or misbranded products have entered commerce on a Friday, they must still report it within 24 hours even if the establishment does not operate on Saturday. The regulation applies to both producing and receiving official establishments.

If a producing establishment discovers that their products are adulterated or misbranded while the products are still under their direct control, they are not required by [9 CFR 418.2](#) to notify the District Office.

When an establishment is unsure if a finding should be reported to FSIS, they should ask Inspection Program Personnel (IPP) or the District Office for clarification.

9 CFR 418.2 vs. FSIS Directive 8140-1

The regulatory requirement in [9 CFR 418.2](#) to notify the District Office when adulterated or misbranded products have entered commerce applies to official establishments. This regulatory requirement is separate from the instruction to FSIS inspection personnel found in [FSIS Directive 8140.1](#), *Notice of Receipt of Adulterated or Misbranded Product*. [FSIS Directive 8140.1](#) instructs FSIS personnel to use an internal notification tool when adulterated or misbranded products have moved between establishments, even if those products have not entered commerce. The instructions in [FSIS Directive 8140.1](#) concern verification of existing recordkeeping regulations ([9 CFR part 320](#), [416.16](#), [417.5](#), and [418.4](#)) and do not create a new notification requirement for establishments. FSIS personnel are responsible for gathering information, completing FSIS Form 8140-1, and following the instructions in [FSIS Directive 8140.1](#). The establishment is responsible for meeting the regulatory requirement as described in [9 CFR 418.2](#) and for providing information when requested by FSIS personnel to complete FSIS Form 8140-1. The notification requirements for the receiving and producing establishments are further discussed below.

Responsibilities at the Receiving Establishment

When an establishment receives adulterated or misbranded products and the products have entered commerce, the receiving establishment must notify FSIS in accordance with [9 CFR 418.2](#). The receiving establishment may notify the District Office directly using the contact information provided on the [FSIS Contact Us](#) page or notify IPP. If the receiving establishment elects to notify IPP instead of the District Office, then IPP will complete a paper or digital FSIS Form 8140-1 to notify IPP at the shipping/producing establishment and the applicable District Offices. Notification should only be done using official FSIS email addresses, phone numbers for FSIS offices, FSIS programs such as PHIS, and FSIS issued electronic devices.

NOTE: The receiving establishment is required per [9 CFR 418.2](#) to either notify the District Office directly or IPP, but not both.

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.

Responsibilities at the Producing Establishment

The producing establishment must provide notification to the District Office consistent with [9 CFR 418.2](#) when they have reason to believe adulterated or misbranded product has entered commerce. The producing establishment may find out about the adulterated or misbranded products directly from the receiving establishment, from a customer, or from local IPP. The producing establishment must notify its District Office within 24 hours of learning or determining that adulterated or misbranded products have entered commerce. Learning of the event provides an establishment reason to believe that adulterated or misbranded products have entered commerce and a final investigation does not need to be completed before FSIS notification. When the producing establishment receives a customer complaint from a location other than an official establishment (e.g., state inspected establishment, retail store, restaurant, household consumer, foreign establishment, foreign consumer, etc.) that indicates adulterated or misbranded products have entered commerce, then the producing establishment is solely responsible for the notification of the District Office.

NOTE: When FSIS personnel at the producing establishment receive e-mail notification from the District Office of products that have been shipped in commerce and discuss the report with the producing establishment, the producing establishment is not required to provide any additional notification to the District Office under [9 CFR 418.2](#), unless they identify additional implicated products. IPP will verify the producing establishment's corrective actions according to the instructions in [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*.

When adulterated or misbranded products have entered commerce, the Agency may determine the need to convene the Health Hazard Evaluation Board (HHEB) as per [FSIS Directive 8091.1](#), *Procedures for the Food Safety and Inspection Service (FSIS) Health Hazard and Evaluation Board (HHEB)*. The HHEB may be convened if there are circumstances that require further evaluation. Additionally, factors that are considered by the FSIS recall committee in evaluation of the public health significance of an

undeclared ingredient in meat or poultry products are described in Attachment 2 of [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*. An establishment may wish to use [FSIS Directive 8080.1](#) as a reference when developing its customer complaint program and when determining when a food safety hazard exists. Attachment 2 is specific to ingredients, but a similar thought process could be used to assess foreign materials, other contamination, and misbranding.

FSIS Regulatory Requirements: HACCP System

Does a customer complaint impact the establishment's HACCP System?

One part of responding to a customer complaint is determining what aspect of the establishment's programs failed to prevent the adulterated or misbranded products from entering commerce. The establishment's HACCP system consists of the plans, programs, measures, and procedures that are implemented to prevent, eliminate, or control identified food safety hazards and other adulteration in their products. The HACCP system includes the HACCP plan and Sanitation SOPs, prerequisite programs, and other plans in operation at an establishment to prevent products from becoming adulterated. Each establishment should customize the program for their unique products, operations, and system.

The establishment's HACCP system should function to prevent any adulterated products from entering commerce, even if the cause of the adulteration is not a food safety hazard (e.g., it does not result in a food to be unsafe for human consumption). For example, an establishment may determine that a specific foreign material does not pose a physical or chemical food safety hazard in the product; however, the presence of the foreign material in a food causes that food to be adulterated and unfit for human consumption. Each establishment must prevent human food containing foreign material from entering commerce through the proper design and implementation of its HACCP system. [9 CFR 417.6](#) indicates that an establishment's HACCP system may be inadequate if the establishment produced or shipped adulterated products. In addition, [9 CFR 500.3](#) authorizes FSIS to withhold the mark of inspection or suspend inspection when an establishment has produced and shipped adulterated or misbranded products.

Corrective Action Requirements

When adulterated products have been produced, the establishment must determine what part of the HACCP system failed to allow products to become adulterated. The incident may have occurred because of a deficiency in the Sanitation SOPs, HACCP plan, or a prerequisite program. The system must be evaluated to determine if safe and wholesome products can still be produced under the existing system or if modifications must be made. The specific requirements for corrective actions depend on which part of an establishment's HACCP system addresses foreign materials as described below.

The HACCP regulations require corrective actions when a food safety hazard occurs ([9 CFR 417.3](#)). [9 CFR 417.3\(a\)](#) describes the corrective actions that apply when the establishment determines that the adulterated products represent a deviation from a

critical limit and states, “*The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*” The second part of the regulation, [9 CFR 417.3\(b\)](#) describes the corrective actions that apply when the establishment determines that the adulterated products represent an unforeseen food safety hazard and states, “*(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.*”

If the establishment determines that the adulteration does not represent a food safety hazard, the Sanitation SOP regulations describe the corrective actions that must be performed: “*Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s). Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein*” ([9 CFR 416.15](#)).

Reassessment:

A HACCP reassessment is required when an establishment is performing corrective actions for an unforeseen hazard or when a change occurs that impacts the Hazard Analysis or HACCP plan.

A Sanitation SOP must be revised as necessary to keep them current and effective in preventing direct contamination or adulteration of the products.

It is important to consider each customer complaint on a case-by-case basis. When a complaint is reported, the establishment must determine if a food safety hazard exists. If a food safety hazard has occurred, the establishment must address the regulatory requirements for HACCP corrective actions in [9 CFR 417.3](#) and records as required in [9 CFR 417.5](#). If a food safety hazard does not exist, the products may still be adulterated, and the establishment must react accordingly. If no food safety hazard exists, the regulatory requirements for adulterated products in [9 CFR 416.15](#) and [9 CFR 416.16](#)

apply. Either way, when adulterated products have been produced and shipped, the establishment must implement a corrective action. The specific corrective action requirements are determined by the applicable regulation.

HACCP corrective actions

If a food safety hazard posed by foreign material was previously identified as reasonably likely to occur (RLTO), a CCP was established to prevent the hazard from entering commerce, and the hazard then does occur in products in commerce, the establishment must implement corrective actions as described in [9 CFR 417.3\(a\)](#).

If the food safety hazard posed by the foreign material was identified through the hazard analysis as not reasonably likely to occur (NRLTO) due to a prerequisite program, but it does occur and foreign material entered commerce, then it would be an unforeseen hazard and the establishment must perform corrective actions as described in [9 CFR 417.3\(b\)](#). 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. HACCP corrective actions must be documented as described in [9 CFR 417.5](#).

If products are adulterated and in commerce but the cause of the adulteration (e.g., foreign material) is determined not to be a food safety hazard, the establishment must still evaluate the efficacy of its HACCP system. Adulterated products that have been produced or shipped may indicate an inadequate HACCP system.

Sanitation SOP corrective actions

Sanitation SOPs must be designed to prevent the contamination or adulteration of products as outlined in [9 CFR 416.12\(a\)](#). When adulterated food products are found in commerce, the Sanitation SOP may have failed to prevent adulteration of products and the establishment must perform corrective actions as described in [9 CFR 416.15](#) and document the corrective actions as described in [9 CFR 416.16](#). The [9 CFR 416.15](#) Sanitation SOP corrective action regulation applies when adulterated food products have been produced and shipped even when the program that failed is not specifically included in the Sanitation SOPs (e.g., equipment maintenance, employee tool sign-out). The establishment will have to determine if the programs need to be incorporated into the Sanitation SOPs in order to prevent future adulteration as part of the routine evaluation of Sanitation SOPs described in [9 CFR 416.14](#).

Misbranding corrective actions

The establishment must not discount misbranding as a labeling issue alone, since misbranding may result in a food safety hazard. One example of misbranding that is also a food safety hazard is when allergens are present but undeclared on the label. When an establishment determines that misbranded products have entered commerce, it is to notify the District Office, as required by [9 CFR 418.2](#). Misbranding events may require relabeling; the establishment should consult with the FSIS Office of Policy and Program Development (OPPD) Labeling and Program Delivery Staff (LPDS) to determine how to correct or replace the inaccurate labels. Certain misbranded products may be eligible for donation. Misbranded and economically adulterated meat and

poultry products can be donated provided the label does not contain any undeclared ingredients of public health concern as described in [FSIS Directive 7020.1](#), *Verifying Donation Of Misbranded And Economically Adulterated Meat And Poultry Products To Non-Profit Organizations*.

Other Actions

Each establishment should be proactive in response to any adulteration or misbranding event, evaluate how the affected products were adulterated or misbranded, why they were shipped undetected, and assess the HACCP system for any other vulnerability.

For example, if a piece of plastic in a food product is determined to be from a single conveyor belt, the establishment should consider whether it is an isolated incident. FSIS believes the best practice would be to re-inspect all belts and reevaluate the preventive maintenance program and controls that failed to detect the faulty belt resulting in adulterated products. The establishment should consider replacing gaskets, belts, screens, and other loose items with components that are detectable (e.g., bright color, radiolucent). Increased lighting, employee training, and enhanced screening of raw material are some additional corrective actions that may produce a meaningful result. Any corrective action should prevent additional adulterated or misbranded products from being produced at the establishment.

Diversion to pet food as a corrective action

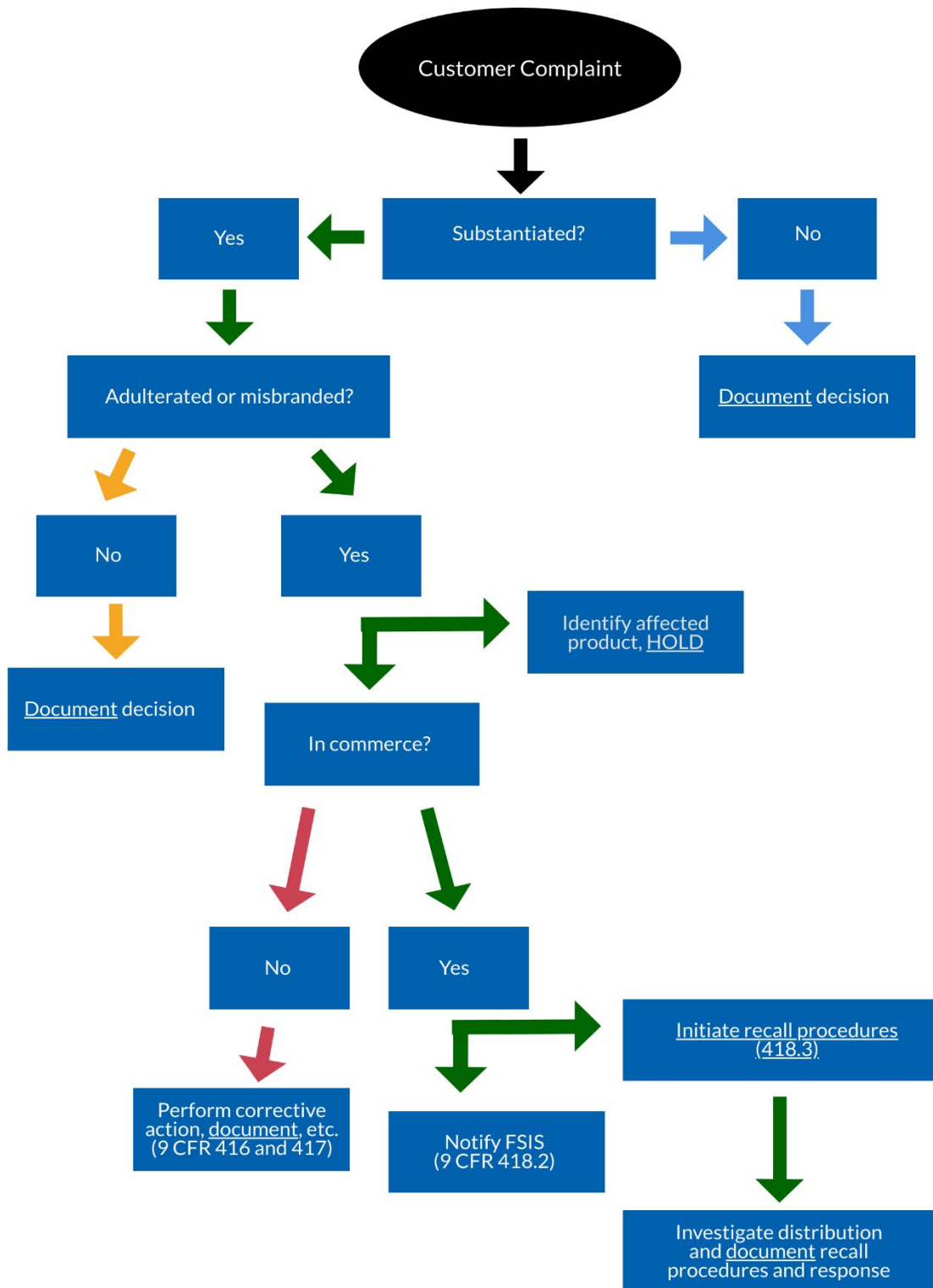
If an establishment determines that adulterated products are not logistically or practically eligible for rework to be made unadulterated, then the products are inedible and must be handled as inedible materials in accordance with FSIS regulatory requirements ([9 CFR 325.11](#), [381.193](#)). In some cases, inedible materials can be sent to a pet food manufacturer. However, because pet food production is under the jurisdiction of the FDA, the establishment is cautioned to check with the manufacturer or the FDA prior to sending the adulterated products to the pet food facility. Some types of adulteration are not eligible for pet food and are not permitted by FDA to be sent for pet food. If the products are not eligible for pet food, the remaining options are rendering or a landfill. Please note that rendering companies may not be willing to accept products adulterated with foreign material if the materials will damage the equipment. The establishment is encouraged to verify that the products will be accepted by the renderer.

Suggested Tips:

Follow these tips when writing a customer complaint program:

- Provide customers with a method to notify you:
 - Consider the impact of co-packing or products produced in multiple establishments
 - Provide multiple modes of communication: email, telephone, mail, etc.
- Facilitate the substantiation of any complaint:
 - Pay to have a label or foreign material mailed to you
 - Ask questions to gather as much information as possible
 - Develop investigation SOPs
- Identify establishment and FSIS personnel who need to be notified and provide the contact information in the document, so you don't have to look for it later:
 - District Office contact information is available on the Contact Us page of www.fsis.usda.gov
 - Inspection personnel office phone numbers are available to the individual establishment
- Evaluate the HACCP system and relevant programs;
- Document findings and make them available to FSIS upon request;
- Consider that the complaint may indicate a larger issue;
- Be proactive.
 - Put procedures in place now to prevent adulteration

Example Flow Diagram of a Customer Complaint



References:

REGULATIONS

United States Department of Agriculture, Food Safety and Inspection Service. 2012. Notification. [9 CFR Part 418.2](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2012. Preparation and maintenance of written recall procedures. [9 CFR Part 418.3](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1971. Reinspection, retention, and disposal of meat and poultry products at official establishments. [9 CFR Part 318.2](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1970. Handling and disposal of condemned or other inedible products at official establishments. [9 CFR Part 314](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1970. Transportation. [9 CFR Part 325](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1972. Disposal of condemned poultry products. [9 CFR Part 381.95](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1984. Poultry carcasses, etc., not intended for human food. [9 CFR Part 381.193](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1970. Definitions. [9 CFR Part 301.2](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2014. Definitions. [9 CFR Part 381.1](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2014. Sanitation. [9 CFR Part 416](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2014. Hazard Analysis and Critical Control Point (HACCP) Systems. [9 CFR Part 417](#).

DIRECTIVES

[FSIS Directive 8080.1](#), *RECALL OF MEAT AND POULTRY PRODUCTS*

[FSIS Directive 8140.1](#), *NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT*

[FSIS Directive 8091.1](#), *PROCEDURES FOR THE FOOD SAFETY AND INSPECTION SERVICE (FSIS) HEALTH HAZARD AND EVALUATION BOARD (HHEB)*

[FSIS Directive 7020.1](#), *VERIFYING DONATION OF MISBRANDED AND ECONOMICALLY ADULTERATED MEAT AND POULTRY PRODUCTS TO NON-PROFIT ORGANIZATIONS*

Helpful Websites (Control + click to be directed to website)

Food Safety and Inspection Service (FSIS)-

FSIS homepage: <http://www.fsis.usda.gov/wps/portal/fsis/home>

Contact Us Webpage: <https://www.fsis.usda.gov/wps/portal/informational/contactus>

How to Develop a Meat and Poultry Product Recall Plan:

https://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet_0513.pdf

The Physical Hazards of Foreign Materials, Presentation at Public Meeting on Foreign Material Contamination, September 24, 2002, David P. Goldman, MD, FSIS

https://www.fsis.usda.gov/wps/portal/fsis/newsroom/speeches-presentations/archive/presentations/ct_index999

Food and Drug Administration (FDA)-

FDA Compliance Policy Guide, CPG Sec 555.425 Foods, Adulteration Involving Hard Sharp Foreign Objects

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>

Red Meat and Poultry Industry Guidance-

Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products, August 2018.

https://www.nationalchickencouncil.org/wp-content/uploads/2018/08/Foreign-Material-Best-Practices_Aug2018.pdf



SMALL PLANT HELP DESK
A resource for small and very small plants
Est. 12-17-2010

Knowledgeable, USDA-FSIS specialists from the Outreach and Partnership Division are available weekdays 8:00 AM to 4:00 PM EST to give you personal assistance on matters relating to the regulation of meat, poultry, and processed egg products. We can also be reached by email at infosource@fsis.usda.gov.

Call Toll-Free 1-877-374-7435



askFSIS

USDA

a policy-related question

<http://askfsis.custhelp.com/>

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