



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. **FSIS-2018-0034**]

Availability of FSIS Guideline for Industry Response to Customer Complaints

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated version of the guideline for industry on how to respond to customer complaints of meat and poultry products contaminated with foreign materials. FSIS originally published the guideline in March 2019. Additionally, FSIS is responding to comments received on the March 2019 guideline.

ADDRESSES: A downloadable version of the guideline is available to view and print at <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>. No hard copies of the guideline have been published.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) to protect the health and welfare of consumers. The Agency is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged.

Updated Guideline

On March 11, 2019, FSIS announced the availability of a guideline to assist all FSIS-regulated establishments that slaughter, or further process inspected meat and poultry products to develop and implement procedures for responding to customer complaints of adulterated and misbranded meat and poultry products (84 FR 8662).

FSIS has updated the guideline based on comments received. Specifically, FSIS revised and reorganized the guideline to improve readability; further clarified that a customer complaint program is not required; included methods for establishments to demonstrate control of products; added information on when establishments must notify FSIS that adulterated or misbranded products have entered commerce; added and clarified when establishments are required to address foreign material contamination in their Hazard Analysis and Critical Control Point (HACCP) plan; and clarified applicable regulatory requirements for corrective actions, reassessments, and recall

procedures.

While FSIS specifically developed this document to address foreign material customer complaints, establishments can apply the information to other customer complaints of adulterated or misbranded products in commerce. FSIS encourages establishments that may receive customer complaints regarding adulterated or misbranded meat and poultry products to follow this guideline. This document does not present or describe any new regulatory requirements. This guideline represents current FSIS thinking, and FSIS will update it as necessary to reflect comments received and any additional information that becomes available.

Comments and Responses

FSIS received public comments from six trade associations, a poultry products producer, a pork products producer, a consumer advocacy organization, a HACCP consulting group, and an equipment manufacturer. A summary of the comments and the Agency's responses follows:

Foreign Material Adulteration

Comment: Several trade associations stated that the guidelines applied an overreaching and overly broad concept of the term "adulteration" by suggesting that any amount of foreign material, regardless of size or nature, adulterates meat and poultry products. The comments asserted that not all contaminants are food safety hazards and that the guidelines should reflect a risk-based approach to foreign material

adulteration, taking into account whether the foreign material would present a health hazard.

Response: The FMIA and the PPIA (21 U.S.C. 601 and 453) and FSIS regulations (9 CFR 301.2, 381.1, and 531.1) state that the term "adulterated" applies, among other circumstances, to meat or poultry products:

- if it bears or contains any poisonous or deleterious substance which may render it injurious to health;
- 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;
- if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

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

FSIS assesses the public health concern or hazard presented when a recall action is initiated for products adulterated with

foreign materials. FSIS categorizes the recall as Class I (reasonable probability that the use of the products will cause serious, adverse health consequences or death), Class II (remote probability of adverse health consequences from the use of the products), or Class III (products will not cause adverse health consequences). FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, provides further information on recall classifications: FSIS Directive 8080.1.

In response to these comments and related concerns raised, FSIS intends to revise and update the recall directive to clarify recall classification issues and instructions to FSIS personnel concerning recalls as necessary. In addition, FSIS intends to review recalls of meat and poultry products associated with foreign materials over the past several years to determine whether the Agency should make additional changes to this guidance or instructions to inspection program personnel to prevent or reduce related recalls.

Comment: One FSIS-regulated company comment agreed that the presence of any foreign object meets the definition of adulteration and requested that the Agency clarify that objects inherent to the product, such as bones and feathers, would not render the product adulterated.

Response: Objects inherent to a product are not "foreign material," however, the presence of these objects can render meat or poultry products adulterated. The FMIA and PPIA definition of "adulterated," states that, "... in case the

substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health" (21 U.S.C. 601(m)(1) and 453(g)(1)). Thus, for example, if the size and amount of bone in a product would present a health hazard, the product is adulterated. When bone or other materials inherent to products, such as feathers or hair, do not present a health hazard, they may make the products unwholesome or unfit for human food, and therefore, adulterated, depending on the amount of these materials and the nature of the products. For example, boneless skinless chicken breast with noticeable amounts of bone or feathers may be unwholesome and unfit for consumers.

Hazard Analysis and Critical Control Point (HACCP) Systems and Food Safety Hazards

Comment: Several trade associations and the consulting group commented that not all foreign materials are food safety hazards, and therefore, do not have to be addressed in an establishment's HACCP system.

Response: An establishment may not find in its hazard analysis that foreign material contamination is reasonably likely to occur in its meat or poultry products. Further, some foreign material contamination may not cause meat or poultry to be unsafe for human consumption. If establishments can support that foreign material contamination is not reasonably likely to occur, or if it has occurred, the contamination has not caused

the products to be unsafe for human consumption, establishments would not need to address foreign material contamination in its HACCP plan.

However, if direct product contamination or product adulteration has occurred, the establishment must address the event in the HACCP system (e.g., the HACCP plan, Sanitation Standard Operating Procedures (SOPs), and prerequisite programs) and take applicable corrective actions. If the presence of foreign material is a deviation from a critical limit, the establishment is required to take the corrective actions in the establishment's HACCP plan. If foreign material contamination has occurred, has caused products to become unsafe, and the establishment has not addressed the hazard in its HACCP plan, the establishment would be required to take corrective actions in 9 CFR 417.3(b), which would include reassessing its HACCP plan to determine whether the establishment needs to address foreign materials in its HACCP plan. If the establishment has found that foreign material contamination has occurred but does not constitute a food safety hazard, the establishment would need to assess whether it needs to make changes to its Sanitation SOP (9 CFR 416.14 and 416.15). An establishment should address any foreign material contamination issues related to sanitation in its Sanitation SOP. FSIS recognizes there may be foreign material contamination not related to sanitation issues or public health hazards. Establishments may be able to

support addressing those foreign material contamination issues in other prerequisite programs under the HACCP system.

HACCP Preshipment review

Comment: Many of the trade associations stated that the guideline expands the definition of a HACCP System to include any programs associated with a production lot, and that the expanded definition would impact the documents included in the preshipment review. The comments also stated that the preshipment review should only encompass corrective actions and documents related to monitoring and verification of critical control points (CCPs).

Response: The HACCP system includes the HACCP plan and all prerequisite programs associated with the HACCP plan (78 FR 32184). The HACCP regulations (9 CFR 417.5(c)) state that, "Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section." This regulation encompasses all records and does not limit the preshipment review to only CCP and corrective action records. When an establishment completes a preshipment review, it indicates that the establishment takes full and final responsibility for applying its HACCP controls to the products that it has produced.

HACCP reassessment

Comment: Many trade associations requested clarification on when a HACCP plan reassessment is required. The consumer

advocacy group commented that establishments should be compelled to reassess their HACCP plans to identify those points in production where there is a possibility of extraneous material contamination. One trade association commented that HACCP reassessment is only required and appropriate when the adulterant results from an unforeseen food safety hazard.

Response: An establishment is required to reassess the HACCP plan whenever changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)(i)). For example, if there is an equipment change that could result in contaminated products if the equipment is not properly maintained. In addition, as is noted above, whenever an establishment determines an unforeseen hazard has occurred, it must perform a reassessment as part of the corrective actions to determine if the hazard should be incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Establishments are not required to reassess the HACCP plan after every customer complaint. For example, an establishment is not required to reassess its HACCP plan after receiving a customer complaint if:

- The establishment determines that the complaint is not valid or the complaint is unsubstantiated;
- The complaint concerns a hazard already addressed in the establishment's HACCP plan;
- The complaint does not describe contamination that posed a risk to human health; or

- The complaint does not concern a problem with the hazard analysis or HACCP plan, e.g. misbranding unrelated to allergens.

When the establishment addresses foreign material contamination in its HACCP plan and a customer complaint represents a deviation from an existing critical limit, the establishment must perform corrective actions (9 CFR 417.3(a)) but is not required to perform a reassessment.

FSIS does not agree that an additional requirement that establishments reassess their HACCP plans specifically for extraneous material is necessary.

Sanitation Standard Operating Procedures (SOPs) Corrective Actions

Comment: One trade association requested more information on the regulatory requirements for Sanitation SOP corrective actions (9 CFR 416.15) and recordkeeping requirements (9 CFR 416.16) if no food safety hazard exists.

Response: The Sanitation SOP regulations (9 CFR 416.11 - 416.17) require that an establishment identify the procedures sufficient to prevent the direct contamination or adulteration of products (9 CFR 416.12(a)). When an establishment's Sanitation SOPs fail to prevent adulteration of products, including contamination by foreign materials, it must take appropriate corrective actions, including appropriate reevaluation and modification of the Sanitation SOPs (9 CFR 416.15) and document those actions (9 CFR 416.16). An

establishment must address the Sanitation SOP corrective actions and recordkeeping requirements, even when a food safety hazard does not exist in that product. FSIS Sanitation SOP regulations do not provide for an "allowance" of direct contamination that is acceptable, the establishment must identify the procedures to prevent direct contamination or adulteration of products.

"In-Commerce" clarification

Comment: Many comments requested clarification on when adulterated products are considered "in commerce" and whether products on premises owned by the producing establishment, such as warehouses or other facilities, demonstrates that there is control of the products.

Response: FSIS stated in the guideline that, in general, products are considered to be "in commerce," or having "entered commerce," when they have left the direct control of the producing establishment and are in distribution, freely moving to consignees and customers. FSIS does not want to limit an establishment's flexibility and innovation for moving products by providing a strict definition of "direct control." Common methods that establishments use to demonstrate that they are maintaining direct control include written procedures, programs, or agreements that describe their process for maintaining control. For example, an establishment may have physical control over products, through a company seal on a trailer or tamper evident tape on containers. Products may move between two establishments or facilities owned by the same corporation under

direct control, provided the control is sufficiently documented and HACCP system decisions are consistent with the expressed control. The guideline was revised to include questions establishments can consider in determining if they have direct control and methods they can use to demonstrate control.

Reporting Adulterated Product in Commerce

Comment: Several trade associations requested clarification of the timeframe for establishments to notify the FSIS District Office when learning or determining that adulterated products have entered commerce. Commenters questioned whether an establishment is required to notify the District Office as soon as it has learned or has reason to believe adulterated products have entered commerce or instead when the establishment has completed its investigation and has determined that adulterated products have entered commerce. One industry comment suggested that the District Office be required to respond to the establishment within a specific time limit and provide the establishment information concerning whether the issue has been resolved, is pending review, or has been passed to an FSIS recall committee. The commenter also suggested that the District Office be required to provide guidance on whether the establishment would be required to take corrective actions or reassess their HACCP plan under the HACCP regulations.

Response: The notification regulation (9 CFR 418.2) requires an establishment to notify the District Office within 24 hours of learning or determining that an adulterated or

misbranded meat or poultry product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe this has happened. FSIS is not able to pinpoint a "start time" of the 24-hours, since every case is different. In many cases, the establishment will learn of a complaint and need to investigate the validity. During the investigation, the point at which the establishment "believes, or has reason to believe" adulterated product has entered commerce is when the establishment must report the event within 24 hours. The investigation does not have to be completed before the establishment believes, or has reason to believe, that adulterated product entered commerce.

The District Office will work with the establishment, but FSIS does not believe that providing detailed information will be necessary in all cases. District Offices will determine what information is appropriate and possible to provide to an establishment on a case-by-case basis. Official establishments should be familiar enough with the regulatory requirements in 9 CFR Parts 416 and 417 to determine when corrective actions are required, what actions will meet the regulatory requirements, when a reassessment is required, how a reassessment is documented, and when the establishment should implement recall procedures. FSIS has clarified reassessment, notification, and corrective action regulatory requirements in the updated guidance. Establishments can contact FSIS field personnel or headquarters personnel if they have additional questions about a

specific situation. The Agency recognizes that establishments need timely communication with the District Office and will ensure this communication continues.

Comment: A member of industry requested that FSIS clarify in the guideline what action domestic establishments should take if they shipped product adulterated by foreign material to a foreign country. The same commenter asked for clarification about what an establishment should do if they receive adulterated product from a foreign country.

Response: Official establishments are required to notify the District Office if they ship or receive adulterated products (9 CFR 418.2 and U.S.C 612 and 459(b)). The notification requirement applies to domestic establishments that ship products to another country (i.e., export). FSIS has added language in the guideline in the "*Responsibilities at the Producing Establishment*" section to clarify this requirement. *Isolated events versus systemic foreign material contamination*

Comment: Several trade associations stated that the guideline failed to address the difference between an isolated foreign material contamination event and systemic foreign material contaminations. One commenter stated that reporting an isolated event, with no evidence of other product in commerce, is premature and serves little purpose. Another commenter proposed notification only when an isolated event posed a public health risk, or when there were two or more foreign

contamination issues of a similar nature or on-going findings of the same root cause.

Response: The notification requirement allows the Agency to quickly determine whether a recall action is necessary. If an establishment has evidence that the event is isolated, the establishment is still required to report the event to the District Office and should present this evidence to the District Office.

Recall Notification (9 CFR 418.2) and Notice of Receipt of Adulterated or Misbranded Product (FSIS Form 8140-1)

Comment: Many commenters questioned whether Form 8140-1 was necessary, given the regulatory requirement of 9 CFR 418.2. Many comments also suggested that the notification process needed to be consolidated, streamlined, and standardized among District Offices. Many comments suggested that all District Offices have a designated e-mail account posted on the FSIS webpage so that establishments can report shipment or receipt of adulterated or misbranded products. A separate comment was submitted recommending that establishments utilize the Agency's Public Health Information System (PHIS) to report incidents.

Response: FSIS is in the process of modernizing inspector reporting methods and replacing the paper-based reporting with electronic reporting in PHIS. FSIS is also developing an optional industry interface in PHIS that will provide a centralized location for establishments to report to the applicable District Office that they have shipped or received

adulterated or misbranded products. Establishments may continue to notify the District Offices through traditional methods, such as phone calls, and each District Office lists a 24-hour phone number that is available for reporting listed at <https://www.fsis.usda.gov/wps/portal/informational/districtoffices>

Consumer Complaint Program Requirement

Comment: Many trade associations requested that the guideline clarify that there is no requirement that an establishment develop or implement a consumer complaint program and no requirement that a complaint handling program, if one exists, be incorporated into the HACCP plan or Sanitation SOPs. The consumer advocacy group commented that there should be a requirement for a consumer complaint program for all establishments.

Response: The guideline has been revised to further clarify that a customer complaint program is not required and, if one is developed, there is no requirement to incorporate the program into the HACCP system.

FSIS's regulatory requirements for HACCP (9 CFR part 417) and Sanitation SOPs (9 CFR part 416) address the requirements to prevent adulteration. As noted above, if changes occur that affect the hazard analysis or HACCP plan, including consumer complaints, or if hazardous foreign materials are found in the products and the HACCP plan does not address the hazard, the establishment is required to reassess the HACCP plan (9 CFR

417.4(a)(3)(i) and 417.4(b)) and make necessary changes to address the hazard. Based on the reassessment, the establishment may incorporate a new CCP into its HACCP plan to address foreign materials, or it may develop a prerequisite program (including the Sanitation SOP, as discussed below) to prevent the hazard that would be part of the HACCP system.

FSIS regulations require that an establishment's Sanitation SOPs describe all procedures sufficient to prevent adulteration of products (9 CFR 416.12(a)). When Sanitation SOPs, which are prerequisite to the HACCP plan, fail to prevent adulteration of products through contamination with foreign materials, the establishment is required to take corrective actions (9 CFR 416.15). Corrective actions include ensuring appropriate disposition of products, restoring sanitary conditions, preventing the recurrence of direct contamination or adulteration of products, and evaluating and making necessary modification of the Sanitation SOPs to prevent future adulteration with foreign materials.

Pet food

Comment: One trade association stated that adulterated meat and poultry products may be diverted to the pet food industry, specifically dog and cat food. The commenter requested that the guideline state that FSIS does not allow or condone downgraded human food material that presents a health or safety risk be diverted to a by-product stream for use in pet food. The comment also requests a statement that any human food by-products,

including adulterated human food processed at these facilities, is subject to FDA regulation under the Food Safety Modernization Act (FSMA) once it leaves the facility.

Response: These comments are generally outside the scope of this guideline. Except for the fee-for-service program for certifying products for dog and cat food in 9 CFR Part 355.29, FSIS does not inspect pet food or products intended for pet food. However, FSIS revised the guideline to include language recommending that FSIS-inspected establishments communicate with pet food manufacturers before sending products to a pet food facility to ensure that the products are eligible under FDA requirements and is acceptable to the pet food manufacturer.

Rail Dust

Comment: A comment from the equipment manufacturer stated rail dust and black specks are the most frequent causes of foreign material contamination and that the industry should switch to an oil-free contamination-free system.

Response: FSIS regulations (9 CFR part 416) require an establishment's sanitation procedures to prevent direct contamination of products and for non-food contact surfaces to be cleaned as often as necessary to prevent insanitary conditions or the adulteration of products. The regulations provide inspected establishments flexibility to meet these regulatory requirements and most establishments do. Therefore, FSIS disagrees with the need to establish prescriptive, new requirements concerning sanitation systems.

Providing Flexibility

Comment: Many trade associations expressed concern that the inflexible approach in the guideline could deter the implementation of new foreign material detection methods and encouraged FSIS to adopt policies that encourage establishments to identify and address non-hazardous foreign material before an actual health risk is posed.

Response: The guideline does not set up any new requirements or limit flexibility. The Agency agrees that establishments should be encouraged to identify and address non-hazardous foreign material before an actual health risk is posed. The changes and clarifications the Agency has made to the guidance should encourage establishments to develop policies and procedures to better address foreign material hazards.

Formatting and editorial comments

Comment: Several comments made recommendations and suggestions for reorganizing, reformatting, and clarifying the graphics and text in the guideline.

Response: FSIS appreciates these recommendations and made the recommended changes when the suggestions did not conflict with FSIS policy.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS provides information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done in Washington, DC:

Paul Kiecker,
Administrator.