



USDA-FNS

White Paper: Food Safety Enforcement and Inspection Actions and Terminology

MULTI-AGENCY TASK FORCE FOR USDA FOODS

USDA, Food and Nutrition Service

This document provides an overview of basic food safety enforcement terminology used by FSIS that may impact school distributing agencies, school food authorities, and processors of USDA-regulated foods, including meat, poultry, and egg products. It is important to note that this document applies only to FSIS-regulated products. A variety of resources are provided at the end of this document for readers who would like additional information.

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Food Safety Inspection Service

Food Safety Enforcement and Inspection Actions and Terminology

Overview

The mission of the United States Department of Agriculture’s Food Safety and Inspection Service (FSIS) is to protect public health by ensuring compliance with laws and regulations governing the production of meat, poultry, and egg products. The food-producing establishment (hereafter, establishment¹) has the responsibility to comply with the regulations and to produce a safe and wholesome food product. FSIS has the responsibility to verify that the establishment meets regulatory requirements.

FSIS works to ensure that meat, poultry, and egg products are safe, wholesome, and correctly labeled through enforcement of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act and the Humane Methods of Slaughter Act, where applicable. FSIS works to protect public health and prevent foodborne illness through various activities, including:

- inspection of establishments,
- conducting public education and outreach to increase safe food handling practices, and
- strengthening collaboration among stakeholders to prevent foodborne illness.

FSIS coordinates with food safety partners at the Food and Drug Administration, which regulates other food products sold in commerce such as leafy greens, bakery goods, and beverages, and at the Centers for Disease Control and Prevention, which investigates and identifies causes of foodborne illnesses. When food safety problems are identified, we work closely with the affected food producing establishment to protect the public health, using both voluntary and regulatory actions.

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¹ “Establishment” refers to any establishment that produces meat, poultry, and/or egg products regulated by USDA’s Food Safety and Inspection Service pursuant to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. Each establishment must apply for and obtain a grant of inspection from FSIS prior to initiating operations at the facility.

VOLUNTARY ACTIONS

Recall

A recall is an establishment's voluntary action to remove product from commerce in order to protect the public from consuming adulterated or misbranded products. FSIS does not have authority to mandate that a company conduct a product recall. Although it is an establishment's decision to recall product, FSIS coordinates with the establishment to ensure it has properly identified and removed recalled product from commerce by verifying the effectiveness of its recall activities. FSIS also notifies the public about product recalls by issuing a recall press release, which is posted on FSIS' website.

FSIS does have the authority to detain and seize adulterated or misbranded products in commerce. Therefore, a voluntary recall may be an alternative to FSIS detention or seizure actions. However, a recall does not preclude FSIS from detaining and seizing products if an establishment has inadequately removed recalled product from commerce. The Agency will investigate if it appears that an establishment's recall strategy, or execution of that strategy, is ineffective and, based on its findings; FSIS may seek enforcement action against the recalling firm or its consignees.

Market Withdrawal

A market withdrawal is an establishment's removal or correction, on its own initiative, of a distributed product that involves a minor quality defect or regulatory program infraction that would not cause the product to be adulterated or misbranded. For example, a product that does not meet company quality standards because of discoloration would be eligible for a market withdrawal.

Stock Recovery

An establishment's removal or correction of product that has not been marketed or that has not left the direct control of the establishment. For example, product that is located on the premises owned by the producing establishment or under its control, and that has not been released for sale or use would be eligible for a stock recovery.

REGULATORY ACTIONS

Terminology

In fulfilling the agency's mission, FSIS inspection personnel ensure that establishments comply with food safety regulations by conducting inspection verification activities and taking enforcement action when needed to ensure food safety compliance. FSIS uses these terms as follows:

Compliance means that the establishment's processes are working properly in accordance with the laws and regulations.

Inspection includes all actions the Agency may take to examine the establishment and its processes, products, and systems.

Enforcement actions are taken by FSIS personnel upon a determination that the establishment is not in compliance with regulatory requirements or that its plans and systems are not in compliance with laws and regulations. There are a range of enforcement actions that FSIS may utilize, as described below. The **Rules of Practice**, 9 CFR part 500, are FSIS's enforcement regulations.

A. Enforcement Action Definitions and Explanations

There are three types of enforcement actions defined in the Rules of Practice regulations (9 CFR part 500):

1. Regulatory control action. (9 CFR 500.2)

Regulatory control actions are most commonly used by in-plant inspection personnel and include the retention of product, rejection of equipment or facilities, or the slowing or stopping of production lines. Regulatory control actions are taken to prevent potentially adulterated or misbranded product from leaving an establishment or to prevent the production of adulterated or misbranded product. Examples of such circumstances include:

- Insanitary conditions likely to result in contamination of product, such as improperly cleaned equipment;
- Conditions in the establishment that prevent an inspector from determining that product is not adulterated, such as inadequate lighting to determine whether product is adulterated.

Regulatory control actions are taken in situations that require immediate correction. It is not necessary to notify the establishment in advance. Once FSIS takes action, however, federal regulations require that the inspection personnel taking the action immediately notify establishment management. This can be done orally or in writing. The written notification is called a noncompliance record (NR).

2. Withholding Action or Suspension. (9 C.F.R. 500.3; 500.4)

A withholding action is the refusal to allow the marks of federal inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process. Because the marks of federal inspection are required to appear on product labels, withholding the marks of inspection effectively prevents an establishment from distributing affected product produced during the time that the withholding action was in effect. Withholding is generally a more severe enforcement action than a regulatory control action because it can affect a larger part of an establishment or multiple products.

A suspension action occurs when FSIS refuses to assign inspection personnel to all or part of an establishment. Because FSIS inspection is required by law, a suspension action effectively causes the establishment to cease operations in all or part of the establishment.

A withholding action or suspension can be taken either with or without prior notification to the establishment, depending on the seriousness of the regulatory violations. If the situation involves an imminent threat to public health, FSIS will initiate a withholding or suspension action without prior notice to the establishment. FSIS may also initiate a withholding action or suspension without prior notice if the establishment violates the terms of a regulatory control action, has threatened or intimidated an FSIS employee, refuses to destroy condemned product, or handles animals inhumanely. If FSIS initiates a withholding action or suspension without providing prior notice to the establishment, it will notify the establishment of the suspension orally and, as promptly as circumstances permit, in writing.

If FSIS provides notice to the establishment prior to initiating a withholding or suspension action, it does so by issuing a letter called a Notice of Intended Enforcement Action (NOIE). The establishment is given an opportunity to submit actions that will correct the non-compliance and prevent it from recurring in the future. If FSIS accepts the establishment's planned corrective and preventive measures, it will hold the withholding or suspension action in abeyance.

Examples of circumstances that may result in a withholding action or suspension include:

- Sanitary conditions in the establishment are such that products produced in the establishment are or would be rendered adulterated.
- The establishment does not have the required Hazard Analysis Critical Control Point (HACCP) plan or Sanitation Standard Operating Procedures.
- The HACCP plan is inadequate based on multiple or recurring non-compliance reports.

3. Withdrawal of Inspection. (9 C.F.R. 500.6)

Withdrawal of the grant of inspection is the most severe enforcement action that can be taken by FSIS against an establishment. Withdrawal terminates the grant of inspection which generally means that the establishment can no longer operate as an FSIS-inspected establishment. Therefore, the establishment could not produce, sell or distribute product in commerce. . Withdrawal actions can be the culmination of a lengthy process. Establishments that have been subjected to withholding actions and suspensions can eventually be subject to a withdrawal action for repetitive non-compliance. FSIS can also initiate a withdrawal action if the owner or operator or anyone responsibly connected with the establishment has been convicted of certain crimes or if establishment personnel have intimidated or harassed FSIS personnel in the performance of their official duties.

Resources

- 9 CFR 500 (Sections 1 – 8). Food Safety and Inspection Service: Part 500—Rules of Practice. Available online at <http://www.gpo.gov/fdsys/granule/CFR-2012-title9-vol2/CFR-2012-title9-vol2-sec500-1> Access Date 5/7/2015.
- Centers for Disease Control and Prevention (CDC). Surveillance for Foodborne Disease Outbreaks, United States, 2013, Annual Report. Atlanta, Georgia: US Department of Health and Human Services, CDC, 2015. Available Online at <http://www.cdc.gov/foodsafety/pdfs/foodborne-disease-outbreaks-annual-report-2013-508c.pdf>. Access Date 5/7/2015.
- Egg Products Inspection Act (EPIA), 1970. Available online at <http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/egg-products-inspection-act> Access Date 5/7/2015.
- Federal Meat Inspection Act (FMIA), 1906. Available online at <http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/federal-meat-inspection-act> Access Date 5/7/2015.
- Poultry Products Inspection Act (PPIA), 1957. Available online at <http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/poultry-products-inspection-acts> Access Date 5/7/2015.
- USDA Food Safety Inspection Service. About FSIS. Available online at <http://www.fsis.usda.gov/wps/portal/informational/aboutfsis>. Access Date 5/7/2015.