



Special Report

P.O. Box 269, Elizabethtown, PA 17022

Phone: (717) 367-1168 Fax: (717) 367-9096

Web: www.aamp.com Email: aamp@aamp.com

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PRODUCT RECALL DEVELOPMENT GUIDELINES

By Bernard Shire

FSIS's Pathogen Reduction; HACCP rule requires all federally-inspected meat and poultry plants to develop a HACCP plan covering the production of their products. It is anticipated that the corrective action section of many plans may include recall actions and market withdrawal procedures. Recall actions are initiated when it is determined that adulterated meat or poultry products have left the producing establishment and are available to distributors, retailers, or consumers. A market withdrawal is initiated when the company determines that product in commerce does not meet its quality criteria or consumer expectations. Guidelines for market withdrawals are not included here since they deal principally with economic issues, such as net weight or minor label indiscretions.

Recall systems should be designed to assure that rapid and complete control of suspect product takes place to minimize or eliminate illness and injury to consumers. A list of guidelines follow that can be used by plants for developing a recall system and may not include all the critical components needed since each manufacturer may have unique elements that must be considered when a recall is initiated.

RESPONSIBLE INDIVIDUALS A list of those who will be coordinating the recall of product should be maintained. The recall coordinator(s) should be given authority to call on others in the organization for priority assistance. Roles and responsibilities should be clearly defined. Include phone numbers and addresses that cover their whereabouts 24 hours a day, seven days a week

NOTIFICATION PROCEDURES When a manufacturer initiates a recall, the proper regulatory authorities should be notified in a timely manner, as delay may lead to increased injuries or illnesses. For example, FSIS notification within 24 hours of discovery that adulterated product may be in the marketplace. The notification should include the reason for the recall; product information; quantity and geographic distribution; and corrective action taken to prevent reoccurrence.

HAZARD CATEGORIZATION Depending on the product(s) produced, it may be necessary to categorize hazards, based on public safety, in order to prioritize the action needed to be taken. For

example, a labeling problem, such as excess salt, may not require immediate action, as would a problem dealing with under-processing.

PRODUCT CODING DETAIL An explanation of product coding that is applied during manufacture should be on file and updated as needed. Product codes should indicate lot or production date and should be linked to records that are maintained concerning critical areas of product manufacture.

LOCATION OF DISTRIBUTION RECORDS The location of distribution records that identify product type, product location, product codes and any other pertinent information that facilitates the location of product should be immediately available to the responsible individual. Records should be maintained for a length of time that meets regulatory limits or exceeds the shelf-life of the product

PROCEDURE DESCRIPTION A detailed plan of action should be on file. Step by step procedures should be included that detail a method of action. This may include starting with gathering the necessary information needed to confirm the type and nature of the contamination in the product and end with final disposition instructions for contaminated product.

CONTACT INFORMATION A list of necessary contacts should be maintained and updated as necessary. The list should include local, state, and federal regulatory agencies; distributors, retailers, and customers; laboratory and medical contacts; product carriers, such as transportation firms; media contacts, such as television and radio networks; legal counsel; public relations; insurance adjusters, etc. This listing should include phone, fax, addresses or other pertinent communication information such as beepers or answering services.

CONTROL MEASURES OF RETURNED PRODUCT Procedures describing the disposition of recalled product that is found in commerce or while still in the plant should be included in the recall system. This may include regulatory citations, reinspection and reworking guidelines, and disposal instructions. It is recommended that reworked product be given a unique lot or batch number and not be mixed with other products.

EFFECTIVENESS CHECKS Guidelines for assessing the effectiveness of the recalls should detail a system of assuring that the contaminated product is out of commerce and disposed of properly. This may involve the use of sales or route persons.

OTHER SUGGESTIONS

USE OF REWORK Records should be maintained on the practice of incorporating rework into other production lots or batches. These records should indicate the production lot that the rework represents and the new lot that has rework incorporated.

MAINTAIN A COMPLAINT TRACKING SYSTEM This system logs and tracks consumer complaints and can serve as an early warning system to alert the company of any potential recall situations.

CONDUCT PERIODIC TRIAL RECALLS This tests the recall system's ability to accurately reconcile production records with inventory and product in commerce and demonstrates that the product can be removed from the marketplace in a timely manner.

RECORD RECALL ACTIONS After the recall is completed, document and file the steps taken to locate and withdraw the product from the marketplace. This includes following up on corrective action that may be needed to avoid a reoccurrence. Prior to conducting another recall, this documentation should be reviewed and may serve to expedite future recalls.

For more information, contact:

Emergency Response Division

USDA – FSIS

Phone: (202) 720-3033

Fax: (202) 720-5514