Successfully Managing
Product Recalls and Withdrawals

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Foreword

The Grocery Manufacturers Association (GMA) has long been a source of expert technical and scientific information that has assisted the food industry with the effective implementation of and compliance with food safety regulations designed to ensure the safety of the world’s consumers. GMA’s manual for Successfully Managing Product Recalls and Withdrawals has served as a resource for the food industry for numerous years and we are pleased to present an updated edition with the most current information on planning for and conducting recalls and withdrawals. With recent updates to both U.S. FDA and FSIS requirements, the manual is a timely source of this new information. We trust it will be an invaluable resource to you in food safety management and look forward to receiving your comments and feedback on the content. We gratefully acknowledge and thank those whose contributions made this new edition possible. In particular, I want to acknowledge the leadership of GMA’s Mr. Lloyd Hontz and Dr. Melinda Hayman. Without their great efforts, this updated and enhanced edition of the GMA Recall Manual would not have been possible.

Leon H. Bruner,
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Protecting the health and safety of customers and consumers is the number one priority of food and consumer products manufacturers. Brand protection is also critical to the economic viability and success of all companies. The best way to ensure both of these key objectives is to strive daily to assure that only safe and wholesome product leaves the manufacturing facility. However, despite their best efforts, manufacturers sometimes find that product in the marketplace fails to meet those objectives and must be removed. How a company responds to these situations, especially when consumer illness or injury is possible and widespread media coverage ensues, can have a major impact on consumer confidence in the brand and in the company itself. Company actions will also be closely observed by the overseeing regulatory agency and can effect for better or worse the ensuing investigation and potential enforcement measures.

GMA’s revised and updated Recall Manual contains the information that companies need to be prepared for and to promptly react to both the routine and the most serious situations that dictate immediate and efficient withdrawal or recall of product that has entered commerce. It covers new authorities provided to FDA by the Food Safety Modernization Act (FSMA), including mandatory recall and proposed requirements that all firms develop and maintain a recall plan. It also addresses new notification requirements and the latest revisions to the recall directive, which are essential to recall preparedness for meat and poultry producing firms regulated by FSIS.

Familiarity with the content of this manual and adherence to its recommendations should well position any firm to effectively and efficiently recover product if or when the need arises, thereby protecting the firm’s customers and its brand.

Jim Flannery,
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1. Introduction

This manual is intended as a resource for food and other consumer product companies to properly prepare for the unlikely need to conduct a recall, market withdrawal, or other product retrieval, as well as how to effectively manage this process. The US food supply continues to be among the safest in the world, and most food and other consumer product companies regularly exercise diligence to prevent significant health risks. Even so, the safe production of billions of food units can never be perfect, and sometimes foodborne illness outbreaks or other food safety, food quality or mislabeling incidents trigger the need to recall products.

The food industry and regulatory agencies that oversee it are committed to making the food supply as safe as possible, as well as to ensuring all food products are properly labeled. They share the common goal of eliminating foodborne illness and preventing the entry of unsafe or mislabeled product into the marketplace. While this is the standard that both industry and government should always strive to meet, it is not possible to completely eliminate risk from the food supply. Thus, it remains necessary for all food and consumer products manufacturers to be prepared on short notice to efficiently and effectively remove their products from the marketplace when necessary to protect public health.

Some companies may never have to conduct a recall or market withdrawal, but every food and consumer products company should have plans in place and be familiar with the basic steps that must be taken to quickly and effectively implement a product recall or retrieval. Manufacturers of certain products are currently required by the U.S. Food and Drug Administration (FDA) or Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) regulations to develop and maintain recall plans. Manufacturers of FSIS-regulated meat and poultry products are in this group. FDA-regulated acidified and low acid canned food and infant formula firms are subject to a similar requirement in regards to maintain a recall plan, which will become applicable to all FDA-regulated food facilities if a proposed rule on preventive controls rule is finalized as proposed. Companies producing FDA-regulated foods are also subject to mandatory FDA recall authority.

There are a number of relatively new federal and state requirements for recalling food products. These topics, as well as recall requirements of the Consumer Product Safety Commission (CPSC), are covered in more detail elsewhere in this edition of the Grocery Manufacturers Association (GMA) Recall Manual.

The Bioterrorism Act of 2002, passed by Congress after the tragic events of September 11, 2001 to enhance the security of the US, included new traceability requirements regarding both the immediate source of incoming materials and the initial recipients of FDA-regulated products leaving a facility. It also provided FDA with new records access authorities under prescribed emergency conditions.
In the wake of several major recalls of FDA-regulated products, Congress mandated in 2007 that FDA establish a Reportable Food Registry for any food for which there is a reasonable probability that use or exposure will cause serious adverse health consequences or death to humans or animals. The Registry requires that FDA-regulated food firms promptly notify the Agency when they become aware of such a food. Details of company requirements under the Reportable Food Registry are addressed in Chapter 2, which also includes information on relevant provisions of the Bioterrorism Act of 2002. In response to a provision in the Food, Conservation and Energy Act of 2008 (2008 Farm Bill), FSIS, in 2012, finalized regulations requiring establishments shipping or receiving an adulterated or misbranded product to notify the Agency. This requirement became effective for establishments of all sizes in 2013.

Since publishing a final rule in 2008, FSIS has been posting on its website a list of retail consignees that may have received recalled products. Even before this new FSIS requirement went into effect, the State of California passed a law and issued regulations requiring submission of extensive consignee information to the State by any entity handling recalled meat or poultry products within the State. These consignee posting provisions are detailed further in Chapters 2 and 5.

The Food Safety Modernization Act (FSMA), enacted in January 2011, includes many new requirements for industry and enforcement authorities for FDA. Mandatory recall authority became effective in 2011. When FDA finalizes its proposed rule on preventive controls, firms will be required to develop and maintain food safety plans, which include development of a written recall plan.

The following actions are the subject of this manual:

A product recall is the removal and/or correction of a marketed product that is adulterated or misbranded or that violates any FDA or state law to a degree that would incur agency legal action, such as product seizure.\(^1\)

A product or market withdrawal is the removal from distribution and/or correction of products that do not meet a food company’s own quality standards or specifications or which in a technical but minor way violate federal or state law. Such products would not be subject to legal action by the regulatory agencies.

A stock recovery is the removal of a product that has not been marketed or that has not left the direct control of the firm, e.g., product on the manufacturer’s own premises or in warehouses from which the company can assure there will be no distribution.

A correction is an action taken to repair, modify, re-label, or otherwise adjust a product so that it may remain in distribution, or destruction of a product with agency approval.

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\(^1\) 73 FR 40939; Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls; July 17, 2008

\(^2\) FSIS does not define a recall as broadly as FDA. Recall of FSIS-inspected meat and poultry products is limited to situations involving adulteration or misbranding.
For example, a regulatory agency might allow a company to correct a mislabeled product on site by applying label stickers with the correct information.

In deciding whether to initiate a product withdrawal or recall, food processors should be aware of the ever evolving regulatory and consumer environment in which they operate.

**Agencies are using new tools to link foodborne illness outbreaks to specific foods.** In the past ten years, both FDA and FSIS have shifted their policies toward greater use of epidemiological data as the primary basis to pursue a food product recall. Regulatory agencies now regularly utilize PulseNet, a computerized network of linked public health laboratories overseen by the Centers for Disease Control and Prevention (CDC). PulseNet allows the comparison of “fingerprints” generated by pulsed field gel electrophoresis (PFGE) analysis of foodborne illness organisms isolated from sick patients with isolates from food products and/or food manufacturing facilities. This is a very valuable tool state health departments and CDC, which are primarily responsible for conducting epidemiological investigations to pinpoint the foods that cause foodborne illness outbreaks. Because of PulseNet’s effectiveness and a greater focus on obtaining food consumption histories from foodborne illness patients, the finding of a pathogen of concern in an unopened or intact package is no longer a prerequisite for a product recall.

**Prevention as a means to reduce the need for recalls.** Regulatory agencies have increased their focus on prevention as a mechanism to enhance public health and reduce the need for product recalls. Government policy continues to shift from inspection of finished products to requiring food companies to institute formal preventive control systems including Hazard Analysis and Critical Control Point (HACCP) plans for FSIS-regulated establishments and some specific FDA industry categories, such as seafood and juice, and, once FSMA is implemented, food safety plans for most FDA facilities. These preventive control systems would identify and control hazards reasonably likely to occur, monitor critical control points in the food production chain, from raw products to shipment of finished goods, and specify corrective actions. The objective of these systems is to identify potential problems so they may be prevented.

**Recalls due to problems with ingredients.** Unlike recalls caused by a manufacturing problem that affects a single branded product, recalls resulting from contaminated ingredients can affect many companies and products if the ingredients are widely distributed. Recent examples include a hydrolyzed vegetable protein (HVP) recall, black and red ground pepper recalls, and a peanut paste and peanut butter product recall. These examples highlight the importance of manufacturers verifying the quality of the food safety programs of their suppliers.

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4 [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm203344.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm203344.htm)