



Extension FactSheet

Food, Agricultural and Biological Engineering, 590 Woody Hayes Drive, Columbus, OH 43210

Understanding the Recall Concept in the Food Industry

Gönül Kaletunç, Ph.D.

Assistant Professor, Extension Food Safety Engineer
Food, Agricultural and Biological Engineering

Ferhan Özadali, Ph.D.

Director of R&D/QA, Hirzel Canning Co. & Farms
Toledo, Ohio

What is a Recall?

A food recall includes any corrective action by a company needed to protect consumers from potentially adverse effects of a contaminated, adulterated, or misbranded product. A recall is a voluntary action, and the recall decision is made by the company management. If the company does not initiate a recall, the government agency responsible for the particular product category may request that the company do so. Recalls are conducted by industry in cooperation with federal and state agencies.

Manufacturers strive to prevent a recall. Employing Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) plans are vital to preventing a recall. Even the best managed businesses can make occasional mistakes. The objectives of this fact sheet are to introduce the recall concept in the food industry and the food recall classification system, to describe the role of government agencies, and to outline the steps of a recall process. It is important to be ready for a recall well before a problem occurs. Management must be part of an effective recall plan and team. The company management should not rely on product liability insurance in the event of a recall. Liability insurance might cover a portion of the losses due to recall, but it will not cover the expense of product retrieval and most importantly, liability insurance will not help the company regain customer trust.

Despite the undesirable nature of a recall event, it is in the best interest of the manufacturing company to complete the recall quickly. Because the manufacturer is responsible for all of the costs involved in this process, it is critical to have a plan to cover recall expenses, to expedite the process without creating negative public opinion, and to prevent down time. When crisis hits, it is too late to work on the recall plan. Preplanning is vital to mitigate a crisis. Generally, recall events should be included in the Crisis Management and Emergency Contingency Program for a company.

Factors prompting a food recall include but are not limited to unsafe, contaminated, or mislabeled product, nonconformities

to manufacturer's specifications, and missing allergen or other hazard warnings.

Purpose of a Recall

The basis of the recall concept depends on a company's food safety policies, ethical understanding, regulatory requirements, and financial constraints. A recall protects not only the consumer, but also the company. A smooth recall process can save a company's name and prevent further damage due to negative publicity. Destroying, replacing, or altering the product are the three main corrective actions. A recall plan should strive to achieve the following goals:

- Protect consumer health
- Comply with existing rules and regulations
- Minimize the cost of the recall
- Regain and improve the company's reputation

Role of Government Agencies

Even though a recall is a company management decision, a government agency can force the company to recall potentially misleading and/or hazardous product from distribution and marketing. Two government agencies, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture Food Safety and Inspection Service (USDA FSIS) share regulatory responsibility for food product recalls. Although all recalls are voluntary, these agencies may ask the company to initiate a recall. To date, no company has ever refused a request from these government agencies to recall a potentially unsafe or hazardous product. However, if a company refuses to recall a product, the FDA and the USDA FSIS have legal authority to detain the product and to stop operations for good reason if the product constitutes a danger to public health.

The products under the jurisdiction of these two agencies differ. The FDA is responsible for domestic and imported foods. The USDA FSIS is responsible for meat and poultry. As an exception, responsibility for eggs is shared by the FDA and the USDA. The USDA FSIS regulates pasteurized egg

Table 1. Recall Classifications

<i>Classification</i>	<i>Definition</i>	<i>Examples</i>
Class I	This type of recall involves a health hazard where a reasonable probability exists that eating the food would cause serious, adverse health consequences or death.	Meat contaminated with <i>L. monocytogenes</i> in a ready-to-eat food product; <i>E. coli</i> O157:H7 in raw beef; allergens such as peanuts or eggs (not listed on the label).
Class II	This type of recall indicates a potential health hazard where a remote probability of adverse health consequences from eating the food exists, or if the resulting condition is temporary or medically reversible.	Presence of FD&C Yellow #5 dye in candy; presence of dry milk, a Class II allergen, as an ingredient in sausage without mention of the dry milk on the label.
Class III	This type of recall involves situations in which eating the food will not or is not likely to cause adverse health consequences.	A package containing fewer or lower weight products than shown on the package label or improperly labeled processed meat in which added water is not listed on the label as required by federal regulations.

products (eggs that have been removed from their shells for further processing) and the FDA assumes responsibility for egg products after leaving the processing plant.

Recall Classification

Government agencies, FDA or USDA FSIS, evaluate a recall's potential seriousness. The government agency's assessment of severity determines the magnitude of the recall and the level of publicity. However, the company has the opportunity to eliminate or minimize publicity by submitting to the appropriate government agency additional information regarding the seriousness of potential harmful effects of product distribution. Recalls are designated as Class I, Class II, or Class III. Table 1 provides definitions of the recall classifications and typical examples of each.

Outline of a Successful Recall Process

1. **Planning ahead:** A successful recall process depends on planning of the recall management well before a problem occurs.
2. **Acting quickly:** Time is a vital factor in the recall process. The sooner harmful or misleading events are prevented, the faster the negative publicity and financial burden are eliminated.
3. **Effective communication during a recall:** The firm should immediately provide recall instructions to everyone in the product distribution channels. Public notification about the recall through press releases and specialized media is also an integral part of the recall process.
4. **Recall assessment:** Post-recall assessment is extremely important in determining the effectiveness of the recall plan in order to improve the efficacy of potential future

recalls. The current recall plan also should be evaluated through simulated recalls.

Conclusions

Planning ahead, rapid and well-coordinated action in the distribution channels, and truthful communication with the public are the most important elements for completion of a successful recall process and for regaining consumer confidence. The ultimate responsibility for removing the product from circulation before damage or injury are caused belongs to the manufacturer. A recall requires manpower and financial resources. When a traceability system and a well-conceived recall plan are in place, the recall is likely to be successful and less expensive. Government regulatory agencies, FDA and USDA FSIS, are available to help companies with their hazard assessments. If a company suspects a hazard, it should notify the Emergency Response Division (ERD), the Office of Public Health and Science (OPHS), or inform the nearest FDA or USDA FSIS office in the company's district so that the ERD office can be contacted as soon as possible.

For more information, refer to the other fact sheets in this series titled "Food Product Recall Fact Sheets" and the references listed below.

References

1. American Society for Quality Product Safety and Liability Prevention Interest Group, 1999. The Product Recall Planning Guide. ASQ Quality Press, 2nd ed., Milwaukee, WI.
2. <http://vm.cfsan.fda.gov/~lrd/recall2.html>
3. http://www.fda.gov/fdac/features/895_recalls.html
4. http://www.fsis.usda.gov/OA/recalls/rec_intr.htm

Visit Ohio State University Extension's WWW site "Ohioline" at: <http://ohioline.osu.edu>