

Food Processors Product Recall Risk Management

Introduction

A product recall can become a crisis, comparable to any other emergency or disaster, but it does not have to be. Having a plan that supports an organized, efficient, and timely response is critical to eliminating danger to the public and reducing the financial impact on an organization.

Any food processor that is involved in manufacture, processing, assembly or wholesale or retail distribution of food products needs to know how to conduct a product recall.

Just as important as knowing *how* to conduct a recall is determining *when* a recall is necessary. This may be determined for you by industry regulators such as the U.S. Food and Drug Administration (FDA) or the U.S. Department of Agriculture (USDA).

However, if a problem is apparent, a food processor should be proactive in removing a dangerous food product from the market to protect the public and, at the same time, to protect the company's reputation and financial health.

The Need for a Product Recall Plan

In spite of vigilant efforts to minimize the need for a product recall, the need can and does occur; and when it occurs, our natural instinct is survival in the face of potentially crippling circumstances. The most effective and logical way to survive a product recall is to prepare *in advance*.

Food industry companies unfamiliar with proper crisis management procedures could even compound an already unfavorable situation by reacting inappropriately and ineffectively to a crisis. Once the need for a product recall is identified, prior planning can prevent poor performance.

Failure to remove a "hazardous" product from the market can have serious consequences. First and foremost, members of the public might suffer injury, or even death. In addition, adverse publicity can damage a company's reputation and financial health. The longer a "hazardous" product remains in the marketplace, the potential for, and probability of, product liability claims and law suits increases, as does the potential for both civil or criminal action by federal or state regulatory agencies.

Regulation of Product Recalls

The FDA and the USDA, which are responsible for overseeing food related industries and products also have "recall" authority. If your product is regulated or monitored by either of these federal agencies, there is a good

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chance mandatory notification requirements exist for hazardous products. Check with local authorities to determine your requirements.

Food and Drug Administration (FDA). The FDA is responsible for all foods (other than meat and poultry), drugs (prescription and non-prescription), cosmetics, medical devices, radiation emitting devices, and veterinary products. Recalls are classified according to hazard classes (Class 1, Class 2, and Class 3), with Class 1 representing the most hazardous classification

US Department of Agriculture / Food Safety & Inspection Service (USDA/FSIS). The USDA and FSIS are responsible for the oversight, inspection, and regulation of interstate meat and poultry industry. Operations which are totally intrastate are the responsibility of state health or agriculture departments. Recalls are classified according to the potential danger to the public (Class I and Class II, where Class I represents the most hazardous).

Recall “Triggers”

Three predominant “Recall Triggers” for food products provide data which can help determine if a product has a “problem” or “hazard”. These sources are product liability claims, customer complaints, and test and inspection results. Each of these sources will “trigger” the need for management action.

Product Liability Claims

Each product liability claim should be thoroughly investigated, regardless of the severity potential. No matter how minor the alleged bodily injury or property damage, a claim could be an indication of a more widespread problem. In addition to investigating each loss, a listing or claim log should be maintained and analyzed to assist in the identification of claims that are similar in nature. If a product with recurring problems is identified, management should conduct a detailed evaluation of the product to determine the conditions that are responsible for the claims. Is a product recall warranted?

Customer Complaints

The speed and empathy with which a company reacts to customer complaints is essential. Productive interaction with the concerned customer can provide valuable information about the nature and severity of a problem. This information will contribute to a decision as to whether a recall is appropriate. An early response also reduces the liability potential from defective products. A formal complaint management plan should be in place that requires each complaint to be catego-

rized relative to importance. All complaints that have the potential to create a product liability claim or deal with product safety should be referred *immediately* to the Product Safety Coordinator. *Analysis of customer complaints is critical if management is to derive the greatest value from this data source.*

Test and Inspection Results

Good quality control requires that products be tested and inspected on an *on-going* basis. Inspection and testing should include incoming raw materials, in-process materials, and final testing and inspection. Identification of problems should initiate evaluation of whether the product is safe for use by a consumer. Does the severity of the problem require a recall?

Product Hazard Evaluation

Once a potential product hazard has been identified, it is imperative that a complete, detailed evaluation be performed. It is essential that management have as much information as possible when considering the necessity of a product recall. Several elements should be addressed in the evaluation process:

- Severity potential of the contamination or adulteration
- Probability of contamination or adulteration
- Method of contamination or adulteration
- Product life cycle
- Impact on public relations

No two incidents that develop within a product trigger are the same. In each situation, the product hazard evaluation process must be detailed and systematic. At a minimum, the process should address the following questions:

- First and foremost, what is the defect? Is it related to formulation, production or distribution?
- What hazard does it present to the user? What safety issue is being violated?
- Is the defect related to raw food ingredients or packaging materials supplied by others?
- When and where was the product made?
- How many/much was produced? How much is still in process?
- What has been shipped? How much is in inventory?

The more accurate and detailed the information gathered, the closer the “offending” product can be isolated, the more effective the recall, and the less its cost. Rather than condemning the output from an entire week or day of production, perhaps the output from only one shift or product

line need be diverted. Consider how much difference this fact would make in the efficiency and cost of a recall! The health of the public will also be better protected by a faster, more focused recall.

Product serialization and traceability are critical to the information gathering process. Without proper traceability, these four questions become impossible quandaries:

- 1) How is the product identified?
- 2) What type of markings are on the product or on its packaging?
- 3) Are the markings easily identifiable, and easily found by the end user?
- 4) Where did the product go after final testing and packaging?

Not being able to answer these four questions could greatly increase the cost of the recall, both in time and amount of affected product. It will also be more difficult to conduct an effective recall. Traceability should be in effect *upstream* (to suppliers and vendors of raw ingredients and packaging) and *downstream* (to the product distribution network, and to customers).

Product Recall Costs

Completion of the product hazard evaluation and analysis provides management with the information necessary to make the decision to initiate a product recall or take other appropriate action. What costs are associated with a product recall? There are several categories of cost.

Communication

The goal is communication to the user of what the hazard is and how to avoid the hazard. This involves press releases for the media, including television, radio, newspapers, advertising in industry periodicals, mailings (registered and certified in some cases), and mailgrams. Plan to cover costs for personal contact by employees making calls to distributors and customers, and perhaps for a dedicated toll-free phone line for consumers. In addition, there may be need for visits to distribution sites to provide assistance.

Product Disposition

This involves physically removing, shipping, and disposing of the defective product. In the case of replacement products, there is cost of shipping the replacement product to the customer. There could be a need for additional warehouse space to isolate the defective product for analysis, if current inventory occupies all available space. Part of the disposition cost could be refunds to consumers for the cost of the product.

Overhead

This includes costs for and expenses of redirected employees now focused on investigation, evaluation and analysis of the product hazard. Tasks that these employees were performing may now have to be accomplished by someone else. This can result in either overtime or “outsourcing” (using temporary employees or subcontractors). There could also be legal costs in dealing with regulatory agencies.

Intangibles

Loss of market share! Changes in motivation and attitudes of the formulation, manufacturing, production, quality control, and marketing staffs.

All of these costs can be reduced if a product recall plan has been developed and implemented and is actively supported by management.

To assist in the estimation of product recall cost, a Recall Cost Worksheet is included in this document. Not all the elements of the worksheet will pertain to every recall. The worksheet is offered as a starting point, with the knowledge that other costs may occur dependent on the circumstances and the product involved.

Key Elements of an Effective Recall Plan

Food processors and distributors who are *serious* about protecting the public and their reputation need recall programs. When a recall is necessary, time becomes a critical element. The longer it takes for the user/customer to be notified of the hazard, the more opportunity there is for an injury or other loss to occur.

As with other loss prevention plans, the recall plan should be in writing and must have the support of senior management. The degree of formality of the plan, not the need for it, depends on the size and sophistication of the organization. All food processors and distributors, *regardless of size*, should have effective recall management plans in place.

A product recall plan hastens the notification process and reduces cost by eliminating duplication of effort. It assists in speedy compliance with regulatory agencies, if required. A plan also helps to assure the effectiveness of the recall procedure by practice, accomplished through “dry runs”. A “dry run” helps identify problems before the “real thing” happens.

Product Recall Programs are essential. This is true whether the product is an industrial product or a consumer product. Causes of product recalls will vary from company to company,

as will the “problems” that develop with the products. Just as the causes of recalls vary, so will the simplicity or complexity of each company’s recall procedure. For any program to be effective, these basic elements must be present:

- *Prevention.* Prevention constitutes those actions that can be taken to minimize the possibility of an occurrence that will create the need for a product recall. Prevention begins in the formulation of the product, where hazard analysis is conducted to reduce the potential for a defective food product from getting into the market place. Prevention continues through the processing phase, where quality control assures that the product is made according to the formulation and FDA/USDA requirements. Last but not least, prevention continues with the development and use of any necessary precautionary labeling for the consumer.
- *Preparedness.* Preparedness is manifested through the recall plan, which identifies activities, resources, responsibilities, and authority levels in the event that the need for a product recall is identified.

Recall Plan Summary

At a minimum, a comprehensive recall plan should include the following elements in order to assure predictable and effective results:

- A statement of purpose including goals that should include:
 - Protection of the customer from injury
 - Removal of the product from the market, production, and inventory
 - Compliance with federal and state regulatory requirements
 - Protection of the company’s assets
- Assignment of responsibility and authority to a Product Recall Team, with an assigned Recall Coordinator or Team Leader.
- Requirements for education and training of all affected employees and external distribution systems of the overall purpose of the plan and their individual responsibilities.
- Periodic review of the plan to include “dry runs” to test the effectiveness of the process. What percentage of those contacted responded as required in a timely manner?
- Quality checks of documentation to assure that the established traceability and serialization of the product are effective.

Last but not least, the plan must be practiced. Weaknesses must be identified and corrected. When the decision to recall a product is made, speed and efficiency is safety and money!

References

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Product Recall Cost Worksheet

Costs associated with a recall begin as soon as a problem or defective product is identified. Activation of the Recall Team changes the responsibilities of the various team members and redirects their energies toward investigation of the product to define and determine the severity potential of the hazard. Upon completion of the investigation, management must make the decision to either recall or replace the product or do nothing and assume the risk that the hazard presents.

How much does activation of the Recall Team and Recall Plan cost? Recall costs include both direct expenditure of dollars and dedication of company resources. Factors to consider in estimating the cost of a product recall include:

NO. OF UNITS PER BATCH OR SERIES				
NO. OF BATCHES OR SERIES	x			
TOTAL AMOUNT OF PRODUCT INVOLVED	=			

Labor Costs

EMPLOYEE WAGES	=	NO. OF EMPLOYEES	x	HOURS WORKED	x	HOURLY RATE
\$ _____	=	_____	x	_____	x	\$ _____

(Note: Factor in overtime rates, as speed can be critical! This cost should consider labor cost for both Administration of the Recall and that necessary to replace, repair or dispose of the product.)

EMPLOYEE TRAVEL	=	NO. OF EMPLOYEES	x	NO. OF DAYS	x	COST PER DAY
\$ _____	=	_____	x	_____	x	\$ _____

SUB-CONTRACTORS	=	HOURS WORKED	x	HOURLY RATE
\$ _____	=	_____	x	\$ _____

(This cost should be estimated for each sub-contractor. External expertise could include; legal, technical writers, transportation, waste removal, and general labor.)

Notification and Administration Costs

TOLL-FREE HOT LINE	=	NO. OF WEEKS	x	COST PER WEEK
\$ _____	=	_____	x	\$ _____

POSTAGE	=	WEIGHT	x	COST PER POUND (BULK MAILING)
\$ _____	=	_____	x	\$ _____

NEWSPAPER	=	NO. OF LINES	x	COST PER LINE	x	NO. OF DAYS OR WEEKS
\$ _____	=	_____	x	_____	x	\$ _____

Notification and Administration Costs (continued)

$$\begin{array}{cccccc} \text{INDUSTRY} & & \text{NO. OF} & & \text{COST PER} & & \text{NO. OF} \\ \text{PUBLICATIONS} & = & \text{PUBLICATION} & \times & \text{ARTICLE OR AD} & \times & \text{DAYS OR WEEKS} \\ \hline & = & & \times & \$ & \times & \$ \end{array}$$

$$\begin{array}{cccccc} \text{INDUSTRY} & & \text{NO. OF} & & \text{COST PER} & & \text{NO. OF} \\ \text{PUBLICATIONS} & = & \text{PUBLICATION} & \times & \text{ARTICLE OR AD} & \times & \text{DAYS OR WEEKS} \\ \hline & = & & \times & \$ & \times & \$ \end{array}$$

$$\begin{array}{cccccc} \text{TELEVISION} & & \text{NO. OF} & & \text{COST PER} & & \text{NO. OF} \\ \text{AIR TIME} & = & \text{MINUTES} & \times & \text{MINUTE} & \times & \text{ANNOUNCEMENTS} \\ \hline & = & & \times & \$ & \times & \$ \end{array}$$

$$\begin{array}{cccccc} \text{RADIO} & & \text{NO. OF} & & \text{COST PER} & & \text{NO. OF} \\ \text{AIR TIME} & = & \text{MINUTES} & \times & \text{MINUTE} & \times & \text{ANNOUNCEMENTS} \\ \hline & = & & \times & \$ & \times & \$ \end{array}$$

Production Costs

$$\begin{array}{cccccc} \text{FREIGHT} & = & \text{NO. OF UNITS} & \times & \text{WEIGHT} & \times & \text{COST PER POUND} \\ \$ & = & & \times & & \times & \$ \end{array}$$

$$\begin{array}{cccccc} \text{DISPOSAL} & = & \text{COST PER UNIT} & \times & \text{NO. OF UNITS} & & \\ \$ & = & & \times & & & \end{array}$$

$$\begin{array}{cccccc} \text{WAREHOUSING} & & \text{COST PER} & & & & \\ \text{OR STORAGE} & = & \text{SQUARE FOOT} & \times & \text{NO. OF DAYS} & & \\ \$ & = & & \times & & & \end{array}$$

Product Recall Process Audit

	YES	NO
Regulatory Requirements		
1. Is the product subject to a regulatory agency? If <i>YES</i> , what agency?		
Traceability		
2. Are markings easily identified by end user?		
3. Would the markings be considered <i>indestructible</i> ?		
4. Do production records identify component parts and raw materials by batch/lot number, serial number, or by individual supplier?		
5. Do production, shipping, and sales records contain:		
– Batch/lot/serial numbers?		
– Model number?		
– Shipping date?		
– Customer identification?		
6. Are <i>Critical Parts/Ingredients</i> identified?		
Record Retention		
1. Is there a formal, written document control/retention program?		
2. How long are records retained?		
Complaint Management		
1. Is there a written process to monitor complaints?		
2. Are complaints analyzed for trends?		
Recall Program		
1. Is there a formal, written Recall Plan?		
2. Does the plan assign responsibility and authority?		
3. Have employees and outside distribution system organizations received training on the plan?		
4. Are critical elements in the plan outline in checklist?		
– Does the checklist cover pre and post recall activities?		
– Have the checklist been distributed to all responsible personnel and agencies?		
5. Does the plan address the following areas:		
– Suspension of production/manufacturing?		
– Notification of distributors, wholesalers, & end users?		
– Collection of recalled product?		
– Repair, refund, replacement of recalled product?		
– Disposal of recalled product?		
6. Has the plan been tested, with a “dry run”?		
– Date of last test:		
– Were results of test successful?		
7. Are all suppliers required to furnish Certificates of Product Liability insurance?		

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