Recall Prevention and Planning

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A food safety plan starts with prevention, but must also include the actions to take should an incident occur.
Food and beverage processors work hard to produce safe products by using HACCP, quality assurance, certified suppliers and more. But in reality, no one can eliminate all chances of a problem occurring. Consequently, all processors must face this reality and prepare for recalls.
FDA defines a recall as the removal or correction of products (including labeling and/or promotional materials) that it considers to be in violation of the laws it administers. While FDA's definition of a recall does not include market withdrawal or a stock recovery, processors' food safety plans must address these issues as well.

A market withdrawal is the removal or correction of a distributed product that involves either no violation or a minor violation for which FDA would not initiate legal action. It includes the removal of products as the result of actual or alleged tampering where there is no evidence of manufacturing or distribution problems.

Stock recovery is a firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm and been released for sale or use.

Cost of a Recall

The figures below are based upon industry examples for a mid-sized processor.

Cost	Low $	High $	Comments
Value of recalled products and customers' lost profits while off sale	10K	15M	Difficult to quantify but it can easily escalate to very large figures.
Value of unaffected products that are returned or implicated due to poor traceability	0K	10M	Often in a recall other products are returned that are completely OK. This may be due to poor traceability in the supply chain resulting in the need to "over-recall" or it may be some consumers trying to return "good" products under cover of a recall – "buyer's remorse".

Point of sale notices	30K	100K	Notices are often shown on store notice boards or in store windows. These are not very effective as they are largely ignored, but they do demonstrate that you are making the effort to contact your consumer. Costs will probably involve a charge back from your retail customer.
Publication of recall notices in the press	20K	200K	You should investigate how to do this in advance. The figures here assume single country incident.
Public relations advice	10K	80K	Charges from PR consultants who are specialists in "crisis PR" can easily run into tens of thousands of dollars.
Consumer carelines	10K	300K	Cost of setting up a free phone number. As with recall notices in the press this is not straightforward and should be investigated in advance.
Remediation	25K	750K	Vouchers, replacements, etc. This is very variable and dependent upon volume of products affected and complexity of the remediation process to set up and administer
Retailer administration charges	10K	200K	These relate to removing stock from shelves, notifying the store network and other activities related to withdrawing products from the shelves of major retailers.
Shipping and additional logistics charges	15K	800K	This involves collecting products from stores or consumers, related reverse logistics and other freight and distribution charges.
Disposal	10K	200K	Disposal may be low or high cost depending upon the reason for the problem and the type of product. If certified destruction is required due to toxic components, this can easily reach tens of thousands of additional dollars.
Warehousing	0K	150K	Rental of 3rd party storage space to house returned products. You may need multiple locations across a larger geographic area.
Value of loss of contract to supply	0K	2M	This could be hundreds of thousands or millions of dollars.
Specialists (laboratories, consultants)	1K	80K	Depending upon the test required, lab costs may be low or high. Microbiological tests are only a few dollars per sample while detection of a trace contaminant (e.g. dioxin) can be $1000 – $1500 for a 3 day turnaround.
Cost of production stoppage / shutdown	75K	150K	If a production line or lines have to be shut down, the daily costs quickly mount up to

			hundreds of thousands and ultimately millions of dollars.
Repair / correction	0K	150K	If the products are not disposed of, they may be fixed. This is more likely with a non-food item but may still run into tens of thousands of dollars.
Replacement costs	0K	1M	This is effectively the same as the cost of lost sales because you have to make the product again. It is not necessarily a new cost unless you have to outsource your production due to the recall.
Packaging design or wording changes	20K	200K	Changes to correct inaccurate or incorrect wording or design
Post recall advertising – brand recovery	10K	2M	Additional promotional activities may be required to promote your product or your brand to entice customers to return.
Fines and penalties	0K	5K	If you are found to have contravened legislation, fines can be costly in both monetary and reputational terms. Fines may also be imposed by retail customers.
TOTAL INITIAL COSTS	300K	40M	

Other potential costs of a recall

1. Reduced sales
2. Reduced profits
3. Increased regulatory scrutiny by government authorities
4. Increased testing and quality assurance / safety procedures
5. Unfavorable resolution of litigation
6. Ongoing legal fees
7. Management time
8. Increased retailer slotting fees
9. Prosecution of board of directors in relation to product safety breeches
10. Risk of increased insurance premiums
11. Cost to reputation
12. Reduction in share price and therefore company value
13. Cost to change or correct manufacturing process
14. Temporary suspension of ability to import products from specific countries imposed by governments
15. Increased threats from competitors

Source: RQA Consulting; www.rqa-group.com.

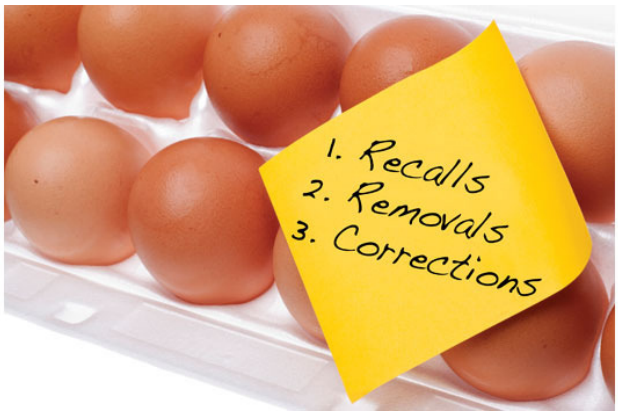
Preparedness pays

According to Dan Hinkebein, manager of recall business services at Recall Results, developing a recall plan is a team effort involving a wide variety of functional areas, such as the operations, quality assurance, legal, accounting and marketing departments. In addition, Hinkebein stresses the plan must be a living document that is reviewed on a periodic basis and updated to reflect changes in products, distribution patterns and suppliers. Therefore, it should also include a document for sign off by key department managers and top management.

In addition, the recall plan should set standards for which records are to be maintained, how the information will be collected and stored, how it will be retrieved and within what time frame, and how long it will be retained. At a minimum, these records must include supplier lot numbers and shipments. However, a more effective set of records tracks lots through each step of the supply chain, including production. An even more complete record includes quality and logistics data (carrier ID, delivery time, etc.).

A key section of the plan must address how a potential incident will be detected and evaluated, who is responsible and what powers they have. The recall plan also must include how the scope and urgency of the problem are evaluated once an incident is detected, and which person determines the actions to be taken.

Communications is another key element of any recall plan. As a rule of thumb, authorities must always be provided with as many details as possible. These include a robust accounting describing what happened, a risk assessment and details on what action is being taken (if any) and why. Manufacturing or retail customers also must be involved at an early stage. And, since many of a recall's negative impacts come from the market, a public relations effort should be part of any recall plan. (Information on communications to the trade and the public can be found in the FDA Compliance Manual at www.fda.gov/food.)



Having a written recall plan and updating it quarterly or semiannually are essential. But how can a processor ensure the plan's effectiveness? Hinkebein suggests a full mock recall at least once per year, with an outside resource validating its results. The mock recall should be complete, exercising all the functions outlined in the plan including simulated customer notifications, PR activities, lab tests and more.

What about insurance?

Most companies have general liability insurance that typically covers legal actions as a result of a recall, but this does not cover the cost of the recall itself. Recall insurance is available from a number of companies, but the coverage is often misunderstood. A product recall does not have to result for the insurance to be triggered. For example, a contamination in a plant, distribution center or in transit will trigger the policy. Often, insurance companies also offer risk management and incident support in the form of expert consultants who can help with prevention as well as offer emergency response services. These “added policy benefits” help minimize risk for both the insured company and the insurer.

Recall insurance is made up of two elements: malicious product tampering and accidental product contamination. Typical costs covered by the insurance include:

- The cost of activities to clean or repair the location, including the increased cost of co-packing
- Loss of gross profit as a result of an incident
- Recall costs including newspaper advertising, transportation, additional warehouse space, overtime, inspection and analysis costs, and the cost of replacing the contaminated goods
- Rehabilitation expenses to re-establish the product to the reasonably projected level of sales or market share
- Consultant costs.

Processors work hard to avoid recalls, but they need to assume the worst and plan for it. Recalls can threaten the very existence of a business and, at a minimum, cost a lot of money. The better you plan in advance, the more effectively and efficiently you will be able to react to a recall.