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ExpertSOLUTIONS™

Looking to the Future

Practical Exercise on What a Facility Should be Doing to Prepare for Product Recalls & FSMA

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The Recall Lifecycle

To fully understand how a recall works, it is important to look at the complete process and consider how it can differ depending on a variety of factors, including which regulatory agency oversees the recall, the size of the recall, the risks involved, and the customers affected. The diagram below illustrates the entire recall lifecycle, from preparation to final resolution.

1. Preparation before and during a Recall. It may seem obvious, but preparation makes the difference. Companies that fail to prepare can pay a heavy price when they suddenly face a recall. Cutting corners, either in the preparation phase or during the recall itself, may save pennies in the short run, but can cost thousands, if not millions, of dollars in the long run.

2. Vendor, Client, Consignee, and Consumer Identification. Effective recall management requires that you quickly and accurately determine who is affected (and who is not) across the entire distribution chain. Effective record keeping and the ability to extract data is critical to understanding the affected distribution population. A warranty registry or online database can assist with having record of individuals using their affected product.

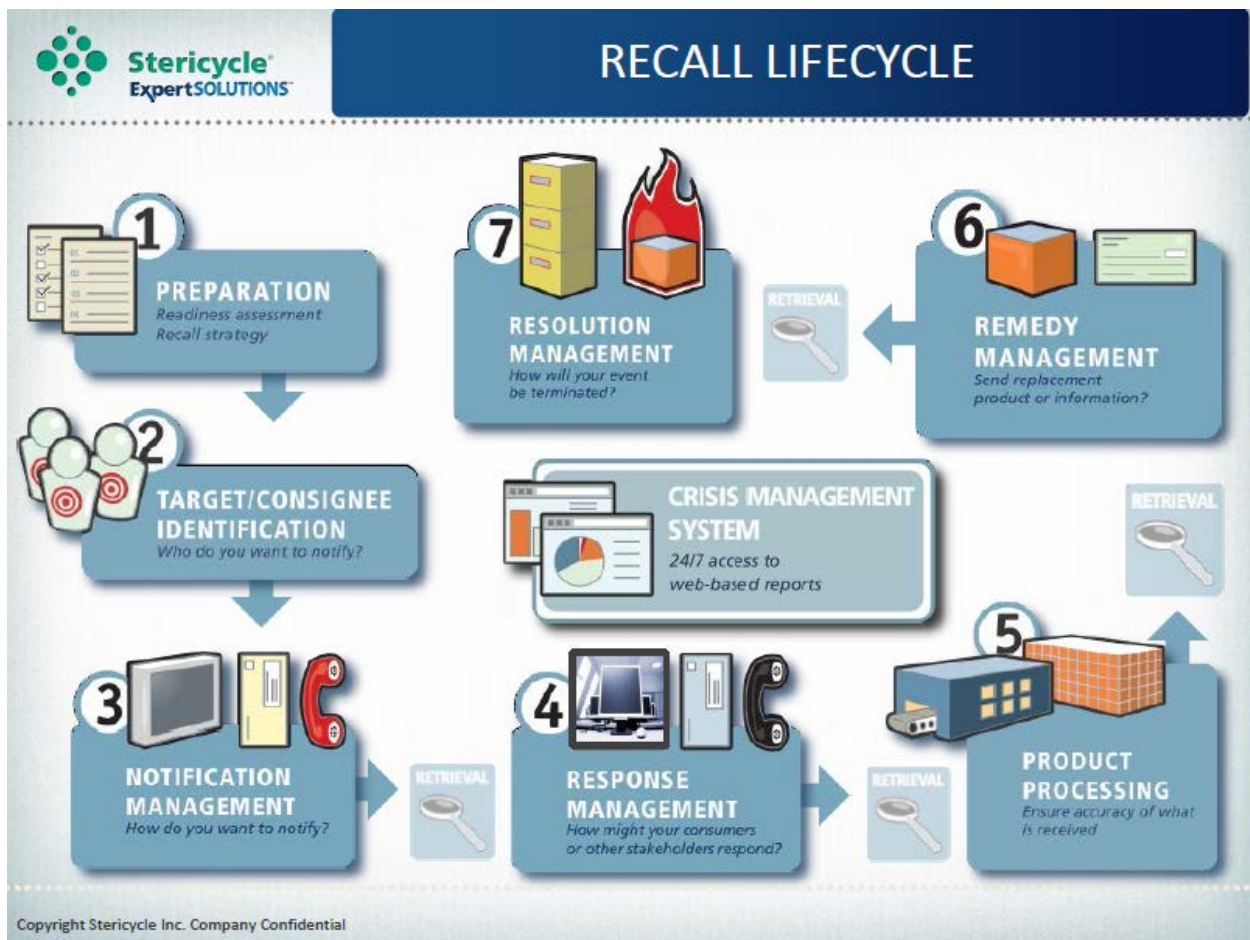
3. Notification Management. Effective notification is critical to recall response. The appropriate regulatory agencies will judge recall effectiveness on whether those who may have been affected are informed about the recall and respond to it. There are a variety of ways consumers and consignees can be notified, including traceable physical delivery (UPS/FedEx), untraceable physical delivery (postal/mail), a news release, posters, and electronic communications, but the method should be selected with each specific audience in mind as some methods are more effective than others, or can be used to supplement primary notification.

4. Response Management. Once the recall is announced and those affected are notified, it is critical that they have a simple, fast, and accurate way to respond if they are affected, and to indicate how much product is in their possession. This includes managing inbound communication through various means, including an Integrated Voice Response (IVR) system and Business Response Cards.

5. Product Processing. It is critical that all recalled products are accounted for. Handling the recalled product can involve accounting for product returns, product, and coordinating field repair. This includes identification and segregation of affected and non-affected products.

6. Remedy Management. Selecting and delivering the right remedy in a timely and cost-free manner will have a significant impact on recall response and effectiveness. Common remedies range from crediting supply chain partners, to mailing out coupons or reimbursement checks, to fulfillment of replacement product through authorized dealers or directly to the consumer's home.

7. Resolution Management. As a recall is closed out, appropriate means of destruction must be determined. A number of factors should be considered during this phase of the recall, including securing the appropriate witnesses, completing the necessary paperwork, and identifying opportunities for sustainable alternatives that reduce waste.





Making a Plan

Recall Readiness Assessment

Companies that are best prepared to manage recalls are those armed with a recall plan that complies with all regulations and is tailored to their specific needs. Companies of all types and sizes should conduct periodic recall readiness assessments (also known as mock recalls or recall drills) to evaluate current recall capacity and procedures, and to identify and make necessary updates or improvements to the plan. In doing so, companies provide themselves with a strong foundation of recall management tools and standard operating procedures that will serve as the action plan for managing a recall whenever one is required.

What to Include

A solid recall plan helps facilitate quick action to effectively locate the recalled product, remove it from the marketplace or out of the hands of consumers, and correct the defect as appropriate. It should provide the means to determine the root cause that will be helpful in determining the remedy or fix for the corrected product while also aiding the company in future product deficiency prevention. A recall plan should provide the critical information the recall management team needs to ensure consumer response and regulatory compliance. Most important, a well-coordinated, effective recall plan will help reassure the public of your ability to protect consumers. While every recall plan is different, there are several broad components that are universally applicable, including:

- **Corporate organizational structure:** Beyond a visual and descriptive organization chart, this section should clearly map out all supply chain operations, including raw and component material or finished product suppliers, processors (sterilization, packaging, labeling, etc.), distribution centers, wholesalers, retailers, users, and consumer consignees.
- **Definition and responsibilities of the recall management team:** This section should include a clear outline of the specific authority and responsibilities of each individual, department, and affiliate. The plan should also include contact information for each member of the recall management team and backup personnel.
- **Fact gathering:** This section should explain the process for gathering information about the defective product. Fact gathering is essential for determining the following, which will help define the parameters of a recall:
 - **Root Cause:** Determine the cause of the product defect, which will shed light on a solution, as well as future prevention strategies.



- **Product Inventory:** Define the process for determining how to get affected product back (i.e. through product retrieval or returns), as well as how to determine where affected product is in the supply chain so you can halt and control movement. At the same time, you need to assess current levels of non-affected product that can be utilized for fulfillment remedy.
- **Health significance:** This section should provide the procedure for determining the actual or potential hazards posed by the recalled product in order to develop an appropriate recall strategy that addresses the type and level of notification and correction or removal required.
- **Regulatory agency notification:** This section should designate personnel responsible for, the means of, and the timing for providing the appropriate regulatory agency with necessary information to classify, monitor, and terminate the recall.
- **Recall communication:** This section should outline when and how to appropriately inform affected parties and answer questions from the distribution chain, the media, and consumers. This section should detail who is responsible for communicating with third-party advocates, supply chain partners, consumers, government officials, the media, and the public.
- **Closing out a recall:** This section should clearly define your company's policy and procedures for closing out a recall. Your recall plan should be created well in advance and should describe in detail your recall procedures, including a breakdown of specific employee and outside expert responsibilities. By the time your company finds itself in the eye of the storm, it will be too late.

Six questions to ask when developing a recall plan:

1. *What are your company's most likely recall scenarios?*
2. *Who needs to be involved in the recall? What are the key stakeholders and responsibilities for each team member?*
3. *What business partners (i.e. vendors, suppliers, retailers, etc.) will need to be involved in your company's most likely recall scenarios?*
4. *What readiness measures, if any, do your business partners have in place?*
5. *What regulatory obligations will your company face during its most likely recall scenarios?*
6. *What is the scale of resources that your company can devote to its most likely recall scenarios?*



Testing the Plan

Recall Readiness Assessment (*Mock Recall*)

The best way to determine just how prepared your company is for a recall is to put your people and procedures to the test. Recalls involve multiple phases and processes. By running your team through a hypothetical simulation based on your most likely recall scenarios, you will not only help them prepare, but also enable your company to evaluate its recall plan and make adjustments where necessary. A well thought out mock recall can provide an analysis of your organization's decision-making and logistics processes as the recall simulation unfolds. The mock recall also provides insight into the communication flow both internally and externally, with regulatory bodies, financial markets, and consumers.

A recall readiness assessment should be customized to best suit your needs and help your recall management team prepare. Preparation makes the difference between an effective recall and one that has a negative impact on your brand and bottom line.

Eight questions to ask when planning a recall readiness simulation:

1. *Does upper management fully support and encourage recall preparation?*
2. *Do you have a recall coordinator and team in place? If so, is each member fully aware of his or her responsibilities?*
3. *Have third-party allies been identified and are they on board to assist as needed with legal, medical, laboratory, communications, and logistics issues?*
4. *What are your company's most likely recall scenarios?*
5. *What unforeseen challenges might arise during your company's most likely recall scenarios?*
6. *Are communications directives and systems in place?*
7. *Are you prepared to simulate notifications, customer responses, product returns, storage and disposition, effectiveness checks, and termination requests?*
8. *Do you have a means by which to collect data and run reports throughout each step of the recall process?*



Food Recall Case Study – Scenario #1

- Several customer complaints were received in a very short period of time saying that upon consuming your product, they became ill. Through research and additional testing of product, you received two positive tests for salmonella. There is one report of a consumer who sought medical attention due to becoming ill from the product.
- The FDA has asked the manufacturer what steps the firm plans to take to remedy the situation. The firm has concluded that an immediate recall is necessary.

Additional Information:

- Best By date code for customer complaints include Jul 02 15 and Jul 05 15.
- Production range in question spans Jun 27 2014 to Jul 16 2014.
- 75,000 cases (6 units/case) of product were produced.
- 95% of product has been distributed to 53 retail/wholesale customers.

Issues to be Addressed by Team

- How do we execute the recall?
- Who should be involved?
- To what level does the recall go?
- Complaints and Health Hazard Evaluation?
- Root cause investigation?
- What about a press release(s)?
- How do we document receipt of notification, compliance with the requested action and effectiveness of the recall?
- How are returns to be handled?
- What is the disposition of quarantined and returned product?
- How should we work with FDA?
- Who is the firm's contact person for FDA?
- When/Who do we notify at FDA?



Roles and Responsibilities:

- **Regulatory Affairs / Quality**
 - Coordination and assistance with any regulatory issue**
 - Root Cause of hazard**
 - Adverse Events / Complaint Handling**
 - Internal team discussions**

- **IT**
 - Data on product location /total product sold in supply chain**
 - New product availability based on known manufacturing efforts**

- **Medical Affairs**
 - Assessment of the hazard**
 - Review of Adverse Events & Complaints**

- **Customer Service**
 - Providing the best service to your clients**
 - Understanding all issues associated with the recall**
 - Notification contents**
 - FAQs & Training of CS team**

- **Commercial (Sales)**
 - Brand protection / customer retention**
 - Communication to internal and field sales team**

- **Operations**
 - Execution and process**
 - Replacement product availability/product shortage consideration**
 - Return and disposition of product**

- **Finance**
 - Effect of the effort and cost on the organization**
 - Budget**
 - Effect on normal supply of product**

- **Legal / PR / Corporate Communications**
 - Product liability & consistent / accurate information to the public (notifications, press releases, web site updating, call center training for appropriate responses, financial markets, employees, etc)**



Food Recall Case Study – Scenario #2

- During routine testing, a customer has informed you that a specific batch of an ingredient you produced tested positive for excessive levels of lead. This same batch of product was shipped to five customers as an ingredient.
- Additionally, two batches of finished product were produced and distributed to retail customers. Through additional testing, it does not appear any additional product is impacted and the issue was isolated to a period of time when renovations were taking place at the facility and the source was dust from lead paint. No illness complaints have been reported to date.
- The FDA has asked the manufacturer what steps the firm plans to take to remedy the situation. The firm has concluded that an immediate recall is necessary.

Additional Information:

- Batch 457 contained 16,000 lbs of ingredient. 15,000 lbs was sent evenly to five customers for manufacturing other finished goods. One customer is located in Canada.
- 1,000 lbs of Batch 457 was used to produce 3 days worth of your finished product starting on August 14, 2014.
- Best Buy dates of the finished product are August 14, 2016 to August 17, 2016.
- 6,000 cases (6 units/case) of product were produced.
- 100% of product has been distributed to 9 retail/wholesale customers.

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