

The Definitive Guide to Building a Product Recall Program

And why going digital is a 'must'

An effective recall strategy and management system is imperative for protecting your customers and your brand's reputation.

Taking a digital approach can help you identify issues faster and enable you to take decisive action quickly and efficiently.

Hello

Thanks for taking the time to download and read this eBook—we try to make sure everything we publish is a worthy investment of your time.

This eBook delves into exactly what constitutes effective recall management, how to build a team and a comprehensive plan, and then walks through how a leading restaurant chain and retailer do it. It even includes a step-by-step guide on performing a mock recall—a vital activity for any organization committed to improving their processes and procedures and getting ahead of future recalls.

How you respond to product recalls can have a monumental impact on your business. We wrote this eBook to help you get it right each and every time.

I trust you'll find it an insightful read, and please do get in touch with any questions or feedback as I genuinely love hearing from our readers.



Jim Hardeman CMO and CPO www.cmx.com

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Why is Effective Recall Management Necessary?



Global and domestic supply chains are more complex and interdependent than ever. As consumers, we all benefit from having more choices, lower prices, and the year-round availability of many food items that were once only seasonal. Unfortunately, this added complexity also increases risk and is a catalyst for product quality or food safety failures. The more moving pieces you add to the puzzle, the more things can go wrong somewhere along the way.

656

534 FDA + 122 USDA Recalls in 2018

+83%

Increase in Class I recalls of meat and poultry since 2013

\$10M

Average direct cost of a recall to a food company

Product recalls directly impact customer satisfaction. Grocery and convenience stores, restaurant chains, and food and beverage manufacturers who are unprepared for a product withdrawal or recall jeopardize their customer's well-being, their brand reputation, and can face significant economic and social consequences.

But, knowing how to perform an effective food recall or product withdrawal—through quick action and effective communication—is the best way to limit your company's exposure and mitigate the damage to your reputation and bottom line.

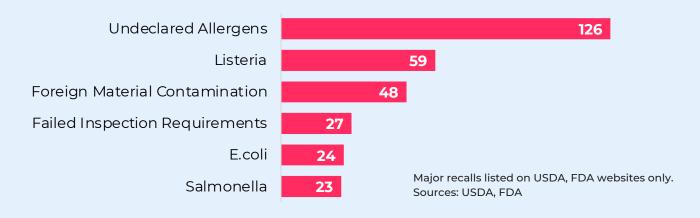
Food Recalls Impact Customer Trust

In an age of 24-hour news and ever-present social media—quality, food safety, and brand trust are at the forefront of customers' minds more than ever before. These concerns have only been compounded during the COVID-19 crisis. But even before the pandemic, food safety and product quality issues were on the rise and impacting customer trust.



Why foods are being recalled

Most common causes for food recalls in the U.S. in 2019



Food recalls are becoming <u>more common</u>, with news media reporting recalls almost every week.

Despite a manufacturer or producer's best safety control efforts, sometimes, unsafe products make it to market. These potentially harmful products could contain pathogens, foreign objects, have improper labeling, undeclared allergens, or fail to meet regulatory requirements. Regardless, if they pose a hazard to the general public, government agencies such as the Food and Drug Administration (FDA) and/or the U.S. Department of Agriculture (USDA) may issue a Class I, Class II, or Class III recall—with Class I being the most alarming and Class III being the least.

Some recent examples of recalled products include:

- <u>Tyson Foods Recalls 39,000 lbs of frozen chicken patties</u> for possible foreign matter contamination;
- Over 2 million pounds of P.F. Chang's frozen meals recalled for 'undeclared allergens';
- Michelina's recalls 4000 pounds of spaghetti due to undeclared allergen.

Put simply, this is a critical issue for every retail food brand and manufacturer, and it's growing larger.





How to Build a Comprehensive Plan for Food Recalls and Brand Protection



So, how do you set up a recall management plan and prepare your team to ensure that your food recall process is executed in a fast, effective, and accurate manner? These days, it comes down to having a product recall strategy and an effective recall management system.

But what does that look like? Let's find out.

Be Proactive with a Recall Management Program

The <u>Food Safety Modernization Act</u> (FSMA) marked a noticeable shift in how the FDA and CDC treated and monitored foodborne illnesses, transitioning from a reactive approach to a proactive one. Instead of waiting and responding, they sought to create a system that was preventing costly and deadly foodborne diseases from spreading.

Under <u>21 CFR 117.139</u>, FSMA requires food manufacturing facilities to establish a written recall plan that requires preventive controls. While manufacturing facilities are specifically called out, **it's prudent for retail food establishments** to establish and implement a written recall plan as well.

A well-designed recall plan and a recall process allow for the removal of products from the market as fast and efficiently as possible, which can protect you from liability, reputational harm, and significant economic loss.

So what must you do to create a comprehensive recall program?



Nominate a Predetermined Recall Management Team

To start, it's crucial that you identify a group of individuals with assigned roles and responsibilities as part of a recall management team for your company. The team will be responsible for handling your recall process and should be made up of individuals from across your organization.



According to Food Logistics:

"The team should be composed of representatives from throughout the organization... legal, quality, product development, manufacturing, risk management, finance, technical services, distribution/logistics, sales and marketing, consumer affairs, public relations, and any third parties involved in the recall process."

This group should be headed by a Recall Coordinator who will oversee the team's efforts to:



Communicate with internal stakeholders, supply chain partners, and "direct consignees" (retail locations and/or the public in some cases)—be sure to include legal, public relations, and marketing



Document processes and procedures



Decide how the decision to recall, or the product withdrawal will be made



Document decisions and actions taken



Track the identification and removal of food product

The team should also be responsible for conducting mock recalls (more on this later), ensuring the proper procedures are in order, and coordinating actual responses. To do this properly, with speed and accuracy, your hand-picked team should consider a digital tool like CMX's Product Recall Management Software with comprehensive automated record keeping and end-to-end recall process automation. During a recall, the system can act as the central information hub. With automated record keeping and real-time reporting, it can also be used for debriefing with internal stakeholders or during FDA audit checks.

Create an Effective Recall Management Plan

The goal of an effective recall management plan is to quickly identify each impacted product, know where it is in the supply chain, and know who to contact so that they can remove it. To do this, there are several steps your team must take when deciding to withdraw a product or taking action when a recall alert occurs.

Generally, they are:

Investigation – Oftentimes there may be early warning signs prior to needing to execute a product withdrawal or recall. It is important to be proactive and monitor quality incidents (aka product complaints) including feedback coming from your customers and retail locations. As you see issues and trends, it is critical to identify and document the sources or causes for issues. It's also important to evaluate and document the potential/actual health hazards involved.

Initial Actions – Once it appears action may need to be taken, gather your recall management team for additional analysis and decide a course of action. You may need to initiate a "product hold" to give your team more time to make a decision. If recalling, consider the depth of the recall (how widespread, which channels) and which stakeholders, partners, customers, and regulatory agencies will need to be notified..

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- O3 Identification Determine all the products that are impacted and require action. This should be as specific as possible and include identifying information such as product name(s), size(s), manufacturer(s), lot number(s), expiration or use by dates, and labels and photos if possible.
- **Recall Action** Put a hold on impacted products that are within your control and create a distribution list for potentially impacted parties.
- Notification Alert your distributors, locations, customers, and the press and public (when applicable), informing them how to proceed.

 Notification may include letters, emails, or even text messages. These all have permanent records. The FDA recommends when communicating by telephone, that the recalling organization be sure to document phone communications "in an appropriate manner".
- Removal Your team will need to determine what to do with the products being recalled. In many cases, perishable food products will need to be destroyed. In other cases, products may need to be returned (did you know that more and more brands are also setting up donation options when appropriate?). When sending notifications, it is imperative that your instructions are clear on how to identify the products and what action they are to take, and how to communicate back with the recalling firm.
- Proof Cause Analysis (RCA) and Corrective Action Despite the best efforts for preventative measures, when issues arise, it is critical to address the issue which caused the recall. Performing a Root Cause Analysis (RCA) will allow your team to identify "the what" and "how" behind the issue appearing, and what corrective action is required to prevent its recurrence. It is also advised that your recall management team perform a "post-mortem" after an event (more details later) to identify areas of improvement both internally and externally.



Conducting Mock Recalls, a Step-by-Step Guide



Stress Testing Your Recall Management Plan

Once you've designated your Recall Management Team and created your Recall Management Plan, it is important to stress test it. Repetition is all about creating muscle memory, which is why regularly performing mock recalls is such an important routine to practice. They prepare your team and familiarize them with the process. That way, when an actual recall occurs, they're ready to act confidently, swiftly, and effectively.

But how do you perform a mock product recall?

How To Perform a Mock Recall



The goal of any mock product recall or food recall is to poke holes in your process, identify weak spots, and highlight your deficiencies, so you can make improvements.

While there's no doubt that you want to strive for perfection, mistakes are expected, and it's better to get them out of the way now, when your business' reputation and your customers' health and safety aren't in jeopardy.



According to Quality Assurance Magazine, the keys to an effective mock recall mock are:

- **©** "Be realistic.
- **8** Be comprehensive.
- **©** Document everything.
- Critique/review yourself and your system.
- Assess the effectiveness of the mock recall."



So, what are the recommended steps to prepare for a mock recall, and ensure food safety in the supply chain?



Step 1: Get Management Involved

While it's important for management to be aware and on board with the mock recall, they should remain unaware of when it will happen. Enlisting their support and participation is the only way to ensure that every employee takes it seriously. So, focus on the importance of practicing, and the long-term impact it can have on the company and its customers.

By practicing now, you can protect the business in the future.

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Step 2: Select a Random Product and Don't Warn Your Team Ahead of Time

If you're trying to gauge the efficacy of your recall plan, systems, and processes, you can't cheat by broadcasting to your organization when it's going to happen. Like a fire drill, it needs to be conducted randomly, so that everyone treats it with the same seriousness they would in the case of the real thing.

So, on the appointed day, we recommend selecting one or more products and lot number(s) to be used for the mock recall. From there, provide a reason for the recall (stating this is a Mock Recall at this point is a good idea). There are a variety of mock product recall scenarios (from widely distributed products to more targeted), and although you don't want to incite a panic, you shouldn't pick something that is too narrowly focused in scope else you'll miss the benefits of conducting the mock recall. Testing different days of the week, hours of the day, multiple locations, regions, or even time zones are all good ideas.

Challenge your team. By doing so, you can accurately test how prepared your team and supply chain is for the real thing.



Step 3: Perform the Mock Recall

Once the mock recall has begun, it's time to monitor your recall team as they track products via traceability procedures.

The team will be tasked with determining:

- 1. The products involved (differing sizes and quantities may be in play here);
- 2. The amount of affected product in the supply chain;
- 3. Where the product is;
- 4. Customers who have received the product.

Ideally, your team would utilize a system like <u>CMX's Product Recall</u>

<u>Management Software</u> which can facilitate the mock recall process.

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Step 4: Send Notifications and Monitor Responses

Once you've created your distribution list and sent your communications (be sure to include an expected time frame to respond), you'll need to start tracking responses and the time it takes for parties to respond. It's important to gauge:

- Did recipients get the notification?
- Do you have good contact information?
- Were the instructions clear on how to act?
- Was the product identification information clear?
- Was the correct product found?
- Were all the correct SKUs included in the responses?
- What other identifying information would be helpful?
- Were the instructions clear on what to do with the product? (Be sure to let them know that the product doesn't have to be destroyed or sent back as this is just a test!)
- Did recipients respond within the expected time frame?

Asking these questions will help you determine the efficacy of your recall plan.



Step 5: Post-Mortem Review and Adjustments

Once your test has come to an end, you'll need to see how effective your team was, and you'll need to measure your effectiveness percentage. You can do so by comparing the recovered product amount to the amount in inventory. Your goal is to reach 100% reconciliation, but in all likelihood, it won't be. You might even end up well above 100%!

It is also recommended to spend time calling and debriefing with those who responded **AND** those who didn't. Identifying aspects that work and areas that need improvement is important.

Next, you'll want to spend time as a team reviewing your documentation and looking for areas to improve, such as:

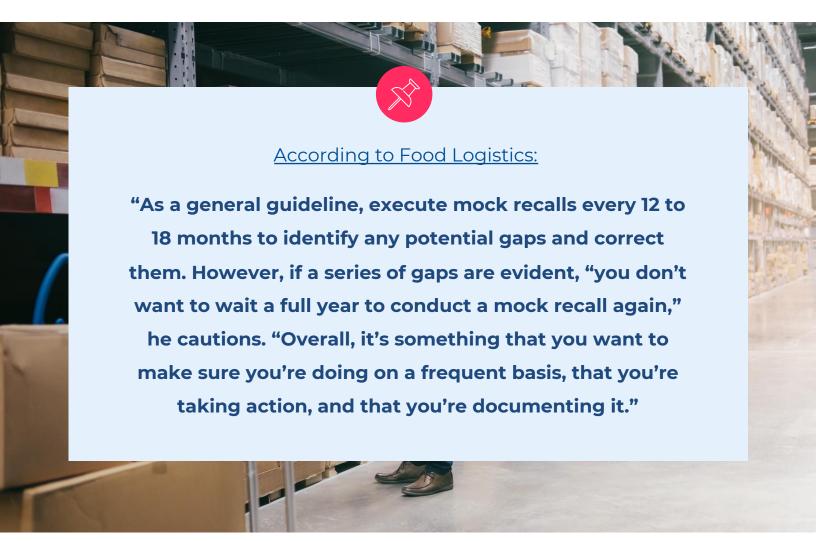
- Internal or external communication issues:
- Silos of information, incomplete information, or conflicting sources of information;
- Incomplete or inaccurate contact information;
- Team members or supply chain partners that failed to follow the recall procedures;
- Issues with instructions, identification or labeling errors;
- Lack of control over products that were put on hold;
- Slow or inadequate responses.

From there, take the necessary steps to rectify the issues and cover your exposure gaps.



Step 6: Practice, Practice

As we've stated throughout this piece, you don't simply do this one time and consider your job done—you do so regularly.



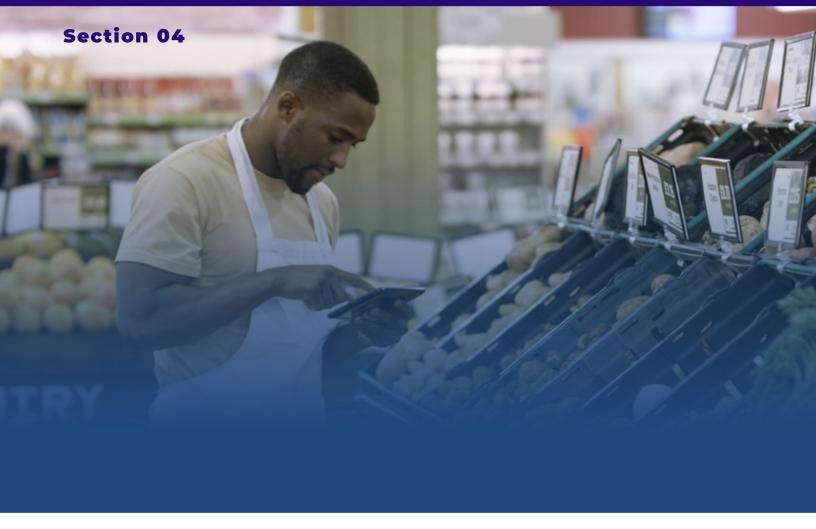


Remember, practice makes perfect. Get on the front foot with practice runs, and <u>take the crisis out of crisis management</u> when a real recall arises.



6 Benefits of Applying Automation and Software Designed for Managing Food Recalls





As you can see, creating a recall management team, designing your process, and conducting mock recalls is a critical function in protecting your customers and your brand. And while many companies try to manage these processes manually, or outsource to a service provider, there are many benefits to applying technology and managing the process yourself.

CMX's Product Recall Management Software is specifically designed for restaurants, grocery, and food and beverage manufactures and automates all the stages of a recall (and mock recall)—from initial investigation to resolution. It includes all the features needed by your recall team to manage the recall process. With it, your team can automatically communicate product hold/releases with impacted distributors and customers, and conduct product withdrawals for quality issues or execute Class I,II,III product recalls. Everything you need for end-to-end product recall management—all in one place.

Just a few of the benefits that will give you peace of mind



Identify Impacted Products and Parties Swiftly

When a withdrawal or recall needs to happen, there's no time for manual communication and data entry—prompt action is critical.

CMX's Product Recall Management Software allows you to shorten the time it takes to identify impacted products, create a distribution list and get the word out. The system can notify 1000s of impacted parties and stakeholders via email, voice, and text messages simultaneously. It can provide the product identification, photos, and instructions needed to quickly locate and recover products. The system leverages reminders and escalation notifications to ensure a response from every notified location or party.



Ensure Action is Being Taken

Once notifications have been sent out, you must get responses from every party and know how much product has been recovered. Doing this with email or outbound phone calls, and manually tallying up the results isn't efficient.

CMX's Product Recall Management Software automatically tracks responses and provides reporting in real-time to measure the completeness of your withdrawal or recall event. This also creates more transparency and actionable information to manage the recall process as it unfolds. You and all your stakeholders will know exactly the status of all requests and responses at any given moment.



03

Automated Record Keeping

When time is of the essence, and you are in the middle of a crisis, it can be a challenge to keep everything well documented. CMX's Product Recall Management Software does all the record keeping for you and keeps a detailed timeline of actions taken, so your recall team can stay focused. Additionally, you can add internal notes, attachments, risk evaluations, recall strategy, and related product incidents, to keep everything organized. Keeping the C-Suite informed of status and communicating with the FDA becomes a lot less stressful.

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Be Prepared with Mock Recall Functionality

As we've outlined earlier, it is important to be prepared for the real thing by practicing regularly. <u>CMX's Product Recall Management Software</u> provides the ability to perform mock recalls and test your recall plan, supply chain, and location's readiness.

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Detect Issues and Trends In Real-Time

When used with <u>CMX's Quality Incident Management Software</u>, <u>CMX's Product Recall Management Software</u> can also monitor your product complaints and automatically notify your team of elevated trends. From there it is easy to quickly start an investigation, or take further action with a hold, withdrawal, or recall, all within a few clicks.



How Do Leading Brands Manage Product Recalls Efficiently?



As we've outlined, there are many benefits to digitally transforming how you conduct product withdrawals and recalls. Let's look at how leading brands are leveraging CMX's Incident Management and Recall Management solutions.



Case Study 1 – The Defense Commissary Agency (DeCA)



The Defense Commissary Agency (DeCA) headquartered in Fort Lee, Virginia, operates a chain of commissaries that spans across the globe, with 238 stores and distribution centers worldwide.

DeCA exclusively serves military personnel, veterans, and select federal employees. The crucial service they provide enables personnel and their families to have convenient access to groceries and household goods in the areas where they're stationed..



The Challenge

Prior to leveraging CMX's Product Recall Management Software, DeCA used a manual process for product withdrawal and recalls, which included a combination of email and phone notifications, and a spreadsheet for tracking responses and reporting. With nearly 750 food and product recalls per year, the team sought to add additional automation to the process for managing responses and providing analytics and reporting.



"Ensuring the health and safety of our patrons is paramount and CMX1 met our criteria for having a very intuitive and easy-to-use solution, both for our team and store personnel, including the automation needed to monitor and report progress to our leadership team in real-time."



Richard C. Stith Jr.
Chief, Public Health Division, Defense Commissary Agency



<u>CMX's Product Recall Management Software</u> allowed DeCA to automate and streamline the product recall process—from initiation to resolution—with powerful features for:





The Results

CMX provided DeCA with product recall software enabling greater automation, efficiency, and visibility.

Want to read more on how DeCA utilizes CMX's Product Recall Management Software? You can read their client story on our website.



Case Study 2 - SONIC Drive-In

SONIC, America's Drive-In is the nation's largest drive-in restaurant chain serving approximately 3 million customers every day. For 65 years, SONIC has delighted guests with signature menu items, 1.3 million drink combinations, and friendly service by iconic Carhops.





The Challenge

Prior to selecting <u>CMX's Quality Incident Management Software</u> and <u>CMX's Product Recall Management Software</u>, SONIC had come to a crossroads. Their QA team was stretched thin. They considered their options: should they add more to their headcount, or should they invest in systems improvement? They also questioned the affordability of such an investment. And whether the cost of not investing would end up being greater. One of the biggest challenges they faced was having too many manual processes.

This resulted in inconsistent information, delays in closing product complaints, delays in credit/replacement processing for Drive-Ins, and labor-intensive efforts to execute product withdrawals and recalls.

SONIC quickly reached the conclusion that adding more people was not the most effective way to address their challenges.



"Managing product incidents and recalls effectively is critical to our business and can also be one of the most challenging responsibilities we have as a QA Team. After implementing CMX1's Incidents & Recalls we've experienced measurable improvements in our speed to respond and resolve product-related issues."



David Abney Vice President of Quality Assurance at Sonic



Before selecting the CMX solutions, SONIC evaluated several other options in the market. From outsourced service providers to software options. They found that most lacked important functionality or offered little more than the ability to share documents.

SONIC ultimately selected <u>CMX's Quality Incident Management Software</u> and <u>CMX's Product Recall Management Software</u> because they fit their budget and could be configured to meet their needs now and in the future. They use the solutions to manage and resolve product quality incidents and for conducting investigations, and managing hold/release, withdrawal, and voluntary/mandatory recalls from initiation to resolution. It also gives the team the needed tools to execute mock recall events throughout the year.



The "Crisis in "Crisis Management" has been significantly reduced. The CMX solutions provide SONIC the automation, monitoring, case management, and communication tools to resolve product-related issues, withdrawals, and recalls more effectively and efficiently.





Ready to Digitize Your Product Recall Management?



With an effective <u>Supply Chain Quality Management System (SCQMS)</u> in place, the risk of a product recall event occurring can be significantly reduced. However, the risk can never be entirely removed. That's where <u>CMX's Product Recall Management Software</u> comes into play.

CMX Recalls has you covered from Investigation to Recovery

CMX's Product Recall Management is a comprehensive software solution that many of the <u>world's best brands</u> rely on for end-to-end product recall management.

With <u>CMX's Product Recall Management Software</u>, your team will be able to proactively monitor product complaint trends and immediately jump into action when the time comes. Automated phone, email, and text notifications allow you to contact 1000s of parties simultaneously with product identification information, photos, and detailed instructions on how to proceed. Real-time monitoring and escalations mean you and all your stakeholders will know exactly where you stand during the recall process from recovery to resolution.

When the health and safety of your customers and your brand's reputation are on the line, you can't take risks. You need something you can trust and rely upon. So, if you are ready to up your recall management program, we invite you to visit our website at CMX1.com to learn more and get in touch today to speak with one of our product experts.



Click here to watch CMX Recalls in action



Click here to learn more about CMX Recalls



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CMX is your Product Recall Program Partner

Are you interested in adopting a Product Recall Program specifically suited to your organization?

CMX's cloud-based EQMS platform can empower lasting customer trust for your organization by improving the speed, efficiency, and quality of your Product Recall Program.

To learn more, please visit us at:

www.cmxl.com

858-997-2140

Get In Touch