White Paper

Preventing Product Recalls
With Proper Planning and Equipment

Contents

METTLER TOLEDO

1 Introduction

Technological advances in production equipment have made significant contributions to the efficiency of modern production processes. This has occurred in response to a growing demand for products, with manufacturers competing to get their product to market as quickly as possible without sacrificing quality. As production speeds increase, so too has the potential for defective products to reach retailer shelves. In response to this danger, government and industry bodies have created ever-tighter regulations to protect consumers. It is no surprise to see an increase in product recalls as regulations become more strict.

In addition, the movement toward a global market and growing consolidation of suppliers of raw materials has increased the potential scope of product recalls. This danger was demonstrated by a product recall of peanut-contaminated cumin that started in late 2014 and was still ongoing months later in 2015. By the time the source of the contaminated cumin had been traced, nearly fifty manufacturers located in the United States, Canada and the UK were forced to recall massive quantities of products. As manufacturing continues to become more globalized and the supply chain also becomes more unified, recalls of this scale are likely to become more common.

2 What Does a Recall Cost?

The cost of such a product recall to a manufacturer can be immense – surveys of manufacturers conducted by Ernst and Young in 2011 saw 81% of respondents deem the financial risk of a recall as "significant to catastrophic," with an average estimated cost of $9-29 million. These costs primarily are attributed to the cost of disposing the product in question and the subsequent interruption to regular operations. What this survey does not take into account are the less tangible costs of a product recall.

It has become a well-known fact that consumers, upon learning of a product recall, will switch to another product for the duration of the recall. After the recall is over, some of those consumers will switch back, but not all of them. A Harris Interactive poll conducted in April 2007 indicated that 15% of consumers would never return to a product that had been recalled, while 20% said they would avoid any brand linked to the manufacturer as well. This loss of consumer confidence can in turn cause damage to a company's stock, and in a worst case scenario can be the end of a company – a 1997 US recall of contaminated meat sold by Hudson Beef proved so disastrous the company was forced to sell the business. More recently, a 2009 salmonella outbreak caused by the Peanut Corporation of America was one of the largest recalls on record and lead to the permanent closure of the company and has devastated companies which used peanuts supplied by PCA.

3 Reasons for Recalls

These two examples were both caused by the presence of a pathogen in the product, but pathogens are far from the only cause of a product recall. There are numerous reasons a product may be recalled, but they can be broken down into three basic categories:

- Undeclared allergens
- Pathogens
- Physical Contamination

Undeclared Allergens

Nearly a third of all product recalls in the United States are caused by the presence of an undeclared allergen. Allergens have become the focus of recent government regulations, making the addressing of this issue more critical for manufacturers. This is largely in part due to the risk of consumer harm as a result of exposure, which additionally puts manufacturers at risk of litigation. Undeclared allergens are the result of one of two factors:

- Cross-contamination during the production process – which can occur at any number of points in the supply chain.

- Label mistake, such as accidentally shipping packages of peanut butter candies in a box marked as plain chocolate. Allergen recalls are similar to pathogen recalls, with the primary difference being that allergen-based recalls are much easier to prevent.

Pathogens

Viruses and bacteria are the largest danger for consumers, as unlike undeclared allergens a pathogen will have a negative effect on nearly all consumers who encounter it. The food industry in particular suffers from a staggering amount of bacterial outbreaks every year. Salmonella and listeria are the top two causes of pathogen-based recalls, though e.coli and other bacteria are also significant contributors. Controlling bacterial growth is incredibly difficult, and outright impossible to do so with 100% effectiveness. These kinds of recalls are always given the highest priority, as it is in a government's best interest to prevent any outbreaks of illness, and carry the greatest risk to manufacturers—those who fail to demonstrate due diligence[*] when it comes to maintaining a clean environment will find themselves facing enormous fines and legal action.

Physical Contamination

Physical contamination recalls are similar to pathogen-based recalls, but they do not involve living things (i.e. bacteria), but materials. The most common physical contaminants found are metal, glass, stones and plastics. Often this is the result of a breakdown in a piece of production equipment or poor cleaning practices, and unlike a bacterial infection these recalls are much easier to prevent as there are sufficient regulations in most countries to require some kind of detection solution. Much like pathogen recalls, foreign body recalls are given high priority due to the direct danger to a consumer's health.

*See METTLER TOLEDO's white paper "Principles of Due Diligence" for more information

4 Control the Controllable

Any one of the previously-discussed issues is sufficient to trigger a product recall. While some factors, such as bacterial growth, can never be completely controlled, many, if not all, of the other issues can be properly addressed and almost entirely prevented with the right application of equipment and some common-sense policies and procedures.

Modern day technology has advanced to the point where product inspection equipment is able to operate at high speeds without sacrificing accuracy. Controlling the controllable requires the use of multiple pieces of product inspection equipment—some of these pieces of equipment are required by industry and government regulations, and some of them are not. Each of these pieces of equipment exert control over some factor that causes a product recall, and in combination with some other processes can prevent recalls from occurring.

Avoiding Issues with Undeclared Allergens

Undeclared allergens can often be traced to poor production processes. The fact is that products can end up contaminated due to improper cleaning of equipment between production runs. Production equipment should follow hygienic design principles and have smooth edges, rounded corners and avoid having surfaces which might allow the collection of production material, as that can increase the risk of contamination. A strict wash-down policy between production runs and general good hygienic practices can all but eliminate this risk.

Another way to prevent undeclared allergens is through traceability in the supply chain process. It is smart to require knowledge of where raw materials are sourced and what those providers are doing to mitigate the risk of cross contamination. Additionally, knowing the source of a product's raw materials enables a manufacturer to know if they need to execute a recall or not in the event of allergen contamination. Part of the reason the cumin recall mentioned in the introduction was so far-reaching was that some manufacturers did not know for certain whether or not they had used cumin from the source of the contamination.

As mentioned previously, not all undeclared allergen recalls are caused by actual contamination. Sometimes it is simply a matter of putting the wrong label on a product package. This is particularly a danger when it comes to running multiple varieties of product on the same production line, some of which may contain allergens and some of which may not. These label-based errors are easily prevented with the use of a vision inspection system.

Vision inspection systems utilize cameras and software to capture images of a product and look for things such as print and label quality, which are of particular importance when it comes to ensuring the proper label is on a package. A high quality vision inspection system can verify the correct label is present on a given package, and when networked together with other equipment can even automatically change inspection profiles when a product changeover is triggered. In addition, a vision inspection system can be set to look for specific allergen declarations on a package, identifying not just the incorrect label, but any printing errors that may be present. An experienced vision system provider will be able to provide a system utilizing the proper arrangement of cameras and lights to ensure reliable inspection results.

Minimizing Pathogen Risks

The best thing a manufacturer can do to reduce the risk of pathogens appearing in their products is to make it as difficult as possible for bacteria to grow. That means keeping the production environment as clean as possible at all times – it does not take long for bacteria to establish itself. Constant vigilance is the key here, as is being strict about proper hygiene among personnel. Regular wash-downs of production equipment will help contribute to a clean environment, but when executing these wash-downs it is important to ensure that water does not have the opportunity to pool in, on, or around production equipment. That means when purchasing production equipment it pays to seek out equipment with hygienic design. By controlling the production environment as much as possible, the risk of pathogen contamination of products is greatly reduced.

Avoiding Contamination from Physical Contamination

Physical contamination frequently occurs due to a breakdown in the production process such as equipment failure or a damaged package. Metal in particular is enough of a common occurrence that government regulations require the use of in-line metal detection equipment to identify and remove products contaminated with metal. Other types of contamination (glass, mineral stones, dense plastics or rubber, for example) can be identified using x-ray equipment.

In order to find any metal in a wet or dry food product, metal detectors use either single or multiple detection frequencies depending on the particular type of product being inspected. For dry foods such as confectionery and cereals, a single ultra-high tuned frequency detector is good at detecting stainless steel (and other easily detected metal) contaminants. When inspecting a wet or conductive product such as fresh meat, poultry, cheese, fish and metallized film packed products the best results are achieved by using multiple higher and lower frequencies simultaneously. However the wet product itself creates a 'product effect signal' in the detector (limiting its performance) - and this signal needs to be cancelled out before inspection can begin. This new Product Signal Suppression technique attempts to remove or reduce the product signal and by doing so considerably improves the online achievable sensitivity. Metal detectors of this type are referred to as having Multi Simultaneous Frequency (MSF) technology. This new technology can also effectively deal with other product variations which historically have been the cause of high false reject rates or a reason to reduce the metal detectors operating sensitivity.

Like metal detectors, there are different types of x-ray systems which depend on the product type and size. X-ray systems are defined by the geometry of the x-ray beam emitted by the system. A vertical beam system is used on packages which are shorter than they are long and wide, as well as wet or dry free-flowing loose products. Horizontal beam systems are used for packages which are taller than they are wide, often referred to as tall, rigid containers. For other applications, it may be necessary for a system to use multiple x-ray emitters mounted on the top, sides or below; these combination systems are often used to inspect traditionally challenging applications, such as glass contaminants within a glass container.

For both metal detectors and x-ray systems, it is important to know the product being inspected and what particular configuration will deliver the most reliable results. Working with experienced providers in order to ensure the proper system configurations is crucial to implementing a product inspection program that works effectively.

5 Best Practice to Minimize Recalls

While it is certainly true that product inspection equipment contributes significantly to recall prevention, the processes involved are of equal importance. The combination of the two, proper equipment and proper processes, will greatly reduce product recalls.

Food retailers ensure these two concepts are closely observed by requiring manufacturers to comply with industry regulations such as the Global Food Safety Initiative (GFSI), the British Retail Consortium (BRC), Food Safety System Certification 22000 (FSSC22000) and International Featured Standard for Food (IFS). In addition, governments have their own sets of regulations, such as the Food Safety Modernization Act in the United States or the European Union's Regulation 1169/2011. Pharmaceutical manufacturers have their own compliance requirements - the EU's Directive 2001/83/EC and its various amendments, and the United States' Federal Food, Drug and Cosmetic Act, for example. The choice of protection and inspection equipment hugely affects product quality, product safety and consumer confidence.

5.1 Know the Regulations

In the past two years, there have been a number of major updates to industry and government regulations in the food and pharmaceutical industries which have been put into practice. Further updates to product regulations are inevitable as consumers continue to demand more information about the products they consume, governments act to address that demand and technology continues to change the manufacturing landscape. As surprising as it may sound, some product recalls are caused simply because manufacturers didn't comply with a particular regulation. This is particularly a risk for global manufacturers shipping products to multiple countries—each country may have its own particular regulations. For example, a product label that is acceptable in one country may not be acceptable in another.

Keeping on top of country regulations is often made easier by working with a third party regulatory board: industry-run regulatory boards such as the BRC or IFS have guidelines which are meant to comply with most government regulations. Bear in mind, however, that many industry regulations will also add something along the lines of "and whatever local government regulations say" to their list of requirements—meaning manufacturers still need to know what is required by the government of each territory.

It is not enough for only senior personnel to know what the regulations are, all employees should know the particulars of the regulations that will apply to their day-to-day duties, and it would be a benefit to both the employee and the manufacturer if they did have a broader understanding of the rules. The better-educated a workforce is, the more accountable they can be for their own duties.

5.2 **Know Your Suppliers**

Products can be made up of any number of raw materials, and because everything has to come from somewhere it is critical that you know the source of your raw materials. Traceability is gradually becoming a larger concern in some industries, but as a general rule it is a good to know where your raw materials come from and what processes they have been through before arriving at your facility. Some of the largest product recalls in recent years—the previously mentioned cumin recall, for example—were the result of a supplier distributing contaminated product to multiple manufacturers. This was a disastrous event, as the severity of the recall was in part due to uncertainty as to who had been sent the contaminated material. Without the ability to know for certain which production facilities had received the bad cumin, companies had no choice but to enact sweeping recalls which destroyed millions of dollars' worth of product.

It is not a surprise that the latest additions to the FDA's Food Safety Modernization Act include language mandating that suppliers of food ingredients adhere to the same sorts of rigor that food manufacturers operate under. This may not be necessary across every industry, but there is definitely a benefit to knowing the source of your raw materials. Not only that, but knowing how your suppliers operate when processing raw materials makes it far easier to identify potential problems which may arise during the production process.

Part of knowing your suppliers may involve conducting a tour of their facilities, or even performing audits. This can be a costly action, but it is critically important and something worth doing—and depending on the country, it may be required by law. Make sure your suppliers have their own policies which will help prevent problems with their materials, which depending on your particular needs may be as simple as working with suppliers who have particular industry certifications.

5.3 Know Your Production Environment

Even manufacturers who are not at risk of pathogenic contamination have probably heard of HACCP—or Hazard Analysis and Critical Control Points. At its core HACCP involves a thorough investigation of the complete manufacturing process, followed by the identification of critical points at which the possibility of contamination is highest. These critical points then receive a proper control to eliminate, or at the very least mitigate, the potential for contamination. HACCP is so well-regarded among food manufacturers that the FDA used it as the basis for its own Current Good Manufacturing Processes, making it mandatory for food manufacturers in and selling to the United States to have conducted an analysis of their own production processes by September 2018.

While certainly the rigorous nature of HACCP may not be appropriate for other industries, the core concept of HACCP—figure out the points in the manufacturing process at which problems are most likely to happen and then take appropriate steps to minimize the odds of those problems occurring at the aforementioned points—can apply to any manufacturer seeking to reduce the potential for a product recall.

If a manufacturer truly wants to reduce the number of recalls they deal with on a yearly basis, it is worth the time and effort to take a close look at their processes and analyze where problems are occurring. This is basic common sense, but it bears repeating—if a manufacturer knows where problems are likely to occur, they can take the appropriate steps to control those problems or mitigate the risk of them occurring.

It is also worth repeating that no manufacturer will ever manage a 100% success rate in preventing defective products from being manufactured, though sufficient monitoring can at the very least detect most defective products before they are shipped out to customers or retailers.

In short, manufacturers should seek to understand the totality of their production process in as much detail as is possible. Know how products move along the line, know how they come together and know where things could possibly go wrong, and find a way to either mitigate the risk of the problem happening, or monitor for defective products so problems can be swiftly identified and corrected.

5.4 Connectivity

Part of developing a recall-prevention program is going to involve purchasing some product inspection equipment. Some of this equipment is mandatory due to industry or governmental regulations, but other pieces of equipment are optional. The bottom line is that all product inspection equipment will need to be monitored by personnel to ensure proper functionality. In addition, manufacturers should use these systems to refine their production process—runtime data from product inspection equipment can help to spot potential production problems and failing equipment before it becomes a larger issue.

Collecting all this data is recommended and accomplished by connecting product inspection equipment with one another. Each system can send its data and status to a central location where the data is stored. The performance of each system can also be shown, allowing the manufacturer to refine its maintenance scheduled for each system, saving down time and costs. In order to do this, however, all systems must use the same communications framework.

This final step is made easy thanks to the efforts of the Organization for Machine Automation and Control (OMEC). OMEC is an organization of industry end users, developers, and system builders who joined forces to figure out a better way to get systems to talk to one another. Working with a product inspection equipment provider who is part of OMEC, or at the very least willing to utilize the programming standards (PackML™/PackTags) in their software, will make addressing system communication far easier. Other proprietary software systems are also available which are designed to automatically gather and store data from inspection equipment providing robust documentation and supporting compliance with industry standards and regulations.

5.5 Service and Maintenance of Equipment

Product recalls generally occur due to a breakdown somewhere in the production process. This breakdown might be human error or a literal breakdown of a piece of production equipment. Most production lines run at very high line speeds, meaning equipment must be robust enough to stand up to the demands of production. In addition, that equipment requires regular servicing in order to ensure it is functioning properly.

Pay attention to the maintenance recommendations that come with your equipment, and make the effort to create a maintenance schedule in order to ensure everything remains in top condition. Ideally, your equipment provider will most likely offer a service plan that covers regular system checks.

Creating a service plan ties back to knowing your production process. More extreme production environments such as meat and poultry production should plan on performing service inspections more frequently.

6 Do the Research

Setting out to prevent product recalls can seem like an insurmountable task, but there are plenty of resources to reach out to for assistance. Governments and industry regulators alike provide their particular guidelines, usually for free, and make it as easy as possible to get educated as to the best ways to prevent recalls. A large part of recall prevention lies in product inspection, and it is important to gain a firm grasp of what goes into a product inspection program in order to successfully mitigate the risk of a product recall.

Product inspection technology can seem overwhelming at first. While some product inspection technology is capable of impressive results, manufacturers should ensure products are thoroughly tested with the proposed solution before agreeing to buy.

A lot of variables go into product inspection, and it is best to work with a provider who is willing to demonstrate the effectiveness of their equipment before you commit to purchase. It is advisable to have them perform an evaluation of your product beforehand, and use the results of that evaluation to help guide your purchasing process. Many providers offer free product testing, and it is best to take full advantage of this offer. Good product inspection equipment can do a lot to reduce recall risk, but it is vitally important to research your options carefully.

In the end, it takes a not-insignificant amount of time and effort to minimize the risk of a product defect occurring which is severe enough to merit a product recall. Not only that, but a serious monetary investment is required, though when compared to the cost of a product recall it makes perfect financial sense to spend the money. There are numerous organizations which are willing to provide assistance when it comes to developing a comprehensive quality assurance and recall prevention program, with guides from industry bodies such as the BRC and IFS offering best practices to help design effective programs. Additionally, working with a product inspection equipment provider with a proven track record of effective inspection solutions will go a long way toward making the implementation of an effective program both easy and cost-effective.

Further Information about Product Inspection

Free Technical Guide
Make an Informed Decision

METTLER TOLEDO has published a range of authoritative product inspeciton guides covering HI-SPEED and GARVENS Checkweighing, CI-VISION Inspection and SAFELINE Metal Detection and X-ray Inspection.

The guides enable you to select the right product inspection equipment for your production line. They offer support in installing an all-encompassing product inspection program and provide advice to help you in achieving compliance with standards, regulations and legislation.

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The Product Inspection Division of METTLER TOLEDO is a leader in the field of automated inspection technology. Our solutions increase process efficiency for manufacturers while supporting compliance with industry standards and regulations. Our systems also deliver improved product quality which helps to protect the welfare of consumers and reputation of manufacturers.

Metal Detection   X-ray Inspection   Checkweighing   Vision Inspection

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