To Recall or Not to Recall?
How to Answer the Question
It’s one of the most difficult situations a company faces: when a potential defect or other health hazard is reported by a customer or consumer.

In the consumer product industry, it may be a battery that overheats. In the food and beverage sector, it may be a report of an illness or an object discovered in the product. Across industries and individual companies the scenarios are different, but the dilemma is the same. How do you know when it is time to issue a recall?

There are many factors to consider, including the expectations of regulatory agencies and the public. To the layperson, it may sound simple enough: recall at the first sign of trouble. But reports don’t always indicate a systemic issue with the product. It could be a case of user error. An illness after eating a certain product may indicate correlation, not causation. Even in cases where there is reason to believe the product is faulty, it is difficult to determine whether other products are also affected and, if so, how many.

While no document can foresee each unique situation, this white paper serves as a guide on the factors companies should consider when facing this question.
To Recall or Not to Recall: How to Answer the Question

The Consumer Product Safety Commission (CPSC) says companies must inform them of a product safety issue within 24 hours of obtaining “reportable information” – even while their internal investigation is still underway¹.

They do clarify that “if a company is truly uncertain whether information is reportable, the firm may spend a reasonable time investigating the matter.” It is important to note that the product must be reported whether or not any injuries have occurred.

Some executives may be hesitant, assuming notification will automatically trigger a costly recall. However, many disclosures result in a form of corrective action that helps avoid a recall. Many others require no action at all. In fact, a recent analysis by the CPSC found that, on average, 46 percent of cases reported to the agency lead to a recall or recall alert.². If there is any ambiguity, the CPSC will allow time for both parties to investigate.

In some situations, there is a clear pattern. One report can be a fluke, but when multiple consumers report the same incident, there is likely an issue with the product that must be addressed.

Even in the event that reporting a hazard does lead to a recall, it is important for companies to understand that the price of delaying or failing to report can far exceed the cost of compliance. This hefty price tag comes in the form of significant fines. From 2015 to 2016, the average quarterly fine issued by the CPSC nearly doubled from $4.7 million to $9.3 million. In the first half of 2017, that figure dropped slightly, but remains higher than previous years³.

¹ cpsc.gov
² slideshare.net
³ stericycleexpertsolutions.com

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The other financial consequence comes in consumer loyalty and trust.

Nothing will damage hard-earned brand reputation faster than knowingly leaving an unsafe product in the market. This number can be more difficult to quantify, but the consequences of such damage can be felt long after the recall has been closed out.

Another consideration is the increasingly global marketplace. Consumer products in particular are commonly sold in multiple countries, or they may be sent as gifts across borders.

Companies must take differing regulations into account, being careful not to be perceived as inconsistent and unconcerned with consumer safety. In some cases, companies have declined to issue recalls in countries with more lenient standards and faced swift blowback in both traditional and social media.

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The question of whether Food and Drug Administration (FDA) regulated products must be reported to the agency comes down to the type of product and the hazard it poses.

While nearly all recalls are voluntary, the FDA has the authority to order recalls of medical devices and, since the passage of the Food Safety Modernization Act (FSMA), food products when there is a “reasonable probability” that the issue with the product will cause “serious, adverse health consequences or death.” Food products that meet this definition must be reported to the FDA within 24 hours.

Certain biologics, such as vaccines and blood or blood components also fall under its recall enforcement power, but unlike other FDA regulated industries, the agency does not have the authority to mandate a recall on pharmaceutical products. But that doesn’t mean the FDA has no regulatory muscle to flex. It has the power to issue public warning letters, withhold approval of pending drug applications, and even shut down facilities.

But regulatory requirements are only one factor companies should consider when determining whether a recall is necessary – and how quickly they should act. Customer reaction is a crucial component.

A recent survey by Stericycle Expert Solutions found that approximately 70 percent of consumers ranked food and pharmaceutical recalls as most important to them – far higher than electronics or even children’s products. While those results may sound surprising given the sensitivity of children’s products and the high profile nature of electronics recalls, it makes sense that a product meant to be ingested provokes a stronger reaction. While few companies fail to issue a recall entirely, too many delay the inevitable, which can result in serious repercussions when it comes to not only public health and safety, but also consumer trust and loyalty.

It is important to note that not every change to a product’s functionality requires a product recall. For example, if an update is meant to improve quality but is not remedying a risk or regulatory violation, it may be considered an enhancement. Similarly, if an issue is discovered prior to the distribution of the product, it is typically considered a stock recovery, rather than a recall.

4 fda.gov
5 stericycleexpertsolutions.com
6 fda.gov
Bottom line: if a company knows that one of its products is likely to cause a serious hazard to people or animals, it should be recalled quickly and effectively. Regulators require it. The public expects it. Most of all, it is simply the right thing to do.

But what about when you’re not sure if that is the case? Each regulatory body provides detailed guidance online, but with so many rules and considerations at play, it may be necessary to consult with an experienced recall management partner, a law firm that specializes in regulatory affairs and product liability, the regulators themselves – or some combination of all those.

The price for failing to issue a recall in a timely fashion can include consumer illness and injury, regulatory fines and legal liability, and long-term brand damage – all of which are too high for companies to bear.