

Operations

Preparing for Recalls Before they Happen

Wed, 10/21/2015 - 9:30am Comments by Alan R. Lyons, Esq., Chair of Herrick, Feinstein LLP's Insurance and Reinsurance Group, and Ronald J. Levine, Esq., Co-Chair of Herrick, Feinstein LLP's Litigation Department



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The Food Safety Modernization Act (FSMA), which became law in 2011, seeks to promote a proactive approach to protecting the public from food adulteration and contamination. At the same time, well-publicized outbreaks involving E. coli and other pathogens have

cost food companies millions of dollars in conducting recalls, and in lost sales and consumer goodwill. Some have even resulted in criminal prosecution.

A recent report by Swiss Re, a leading global reinsurer, of publicly available food recall data in the United States shows that since 2002, the number of food recalls has nearly doubled. In addition, 52 percent of all food recalls cost the affected companies more than \$10 million each, and losses of more than \$100 million are possible. These figures exclude the reputational damage that may take years for a company to recover from.

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Recognizing the importance of an enforceable recall process, Congress provided the FDA with tools to issue a mandatory recall when a company fails to act. As such, any company in the food industry must be prepared before a recall is necessary. As Benjamin Franklin said, "An ounce of prevention is worth a pound of cure."

It is essential that any company plan in advance how it will address an emergency, and not be taken by surprise. No matter how careful a company may be in trying to avoid a recall, there are no guarantees that it may not have to conduct one. It is critical that any company in the food business have a recall plan, and importantly, make sure that it has adequate insurance coverage to address a recall.

Have a Plan

A formal recall plan is not only an essential requirement of manufacturing best practices, it is also addressed in the FSMA. The plan should include, at a minimum, assignments of responsibility for any recall, key contact

information, recall procedures and communication templates. This plan must be more than a document kept in the file drawer.

The company must have a team prepared in advance to implement the recall and be aware of the steps they will take to execute the plan. Those steps will include notification of the parties in the food distribution chain, as well as the public; conducting checks to make sure that the recall is being implemented properly; and the disposal of the recalled food.

It is highly recommended that any plan be tested through a simulation. A mock recall can reveal gaps in the protocols and educate all members of the team about their roles and the procedures to be put into effect in a recall.

Be Ready for the Lawsuit

The recall may not be the end of the story. Well after the recall is over and done, consumers impacted by the adulterated product could file a class action complaint against the company. Both the government and plaintiffs' lawyers may seek access to the company's records. The company must therefore be aware of and maintain thorough documentation of the steps it has taken to address any food safety issues and the recall process. Inadequate compliance with documentation requirements can have serious ramifications for the company. Everyone in the company must be fully engaged and aware of potential pitfalls if they fail to record their actions appropriately.

Get Insurance — CGL Policies

With the potential financial exposure from a recall, the company must assess its insurance coverage. Food companies typically maintain traditional insurance policies such as commercial general liability (CGL) and first-party property insurance policies. A standard CGL

policy will provide a defense and indemnity to the insured for lawsuits brought by consumers alleging physical sickness from the insured's product. In order to trigger coverage, there must be actual physical injury alleged by the plaintiff. However, the mere risk of future bodily injury will generally not trigger coverage under a CGL policy. Moreover, a CGL policy does not cover damage to the insured's own product, and does not cover economic losses sustained by the insured (or by others) associated with a recall of the insured's own product.

First-party property insurance covers the risk of physical damage to the insured's own property and may also cover business interruption losses. However, coverage under property policies for damage to food is often excluded by the "contamination" or "pollution" exclusion. For example, an Ohio federal court found that the contamination exclusion excluded coverage when the insured's meat product was contaminated with listeria bacteria since the policy defined "pollution" to include bacteria.

Added Protection — Recall Insurance

Traditional insurance policies, such as CGL and property insurance, do not fully protect food companies from food contamination and recall losses. In order to fill those coverage gaps, all companies should strongly consider purchasing specialized insurance policies, generally known as recall insurance.

These recall policies typically cover certain defined "insured events," but there is no standard definition of that term. For example, a Liberty Mutual policy defines an "insured event" as follows:

Any inadvertent or unintentional contamination or mislabeling of an insured product that occurs during or as a direct result of its production, preparation, manufacture, packaging or distribution, provided that

the use or consumption of the insured product has resulted in or would result in bodily injury of any person (s), within 365 days following such consumption or use, or has caused or would cause property damage.

In contrast to a traditional CGL policy, most recall policies do not require actual bodily injury to trigger coverage. Rather, depending on the policy wording, it is sufficient if the contamination would likely result in bodily injury within a certain time after consumption (typically 120 to 365 days). This is important because the FDA has the authority to force companies to order recalls in the absence of direct contamination or actual bodily injury.

Prospective insureds should be fully informed as to the scope of the recall insurance policy before purchasing. Slight differences in policy language can determine whether coverage is afforded. For example, in one case, the FDA had issued an advisory not to eat bagged spinach due to an E. coli outbreak. Based on this advisory, the insured recalled its bagged spinach, incurring about \$18.8 million in lost business. The FDA subsequently determined that the source of the outbreak was not the insured's product and retracted the advisory. Based on the policy's definition of an "insured event," the court found that there was no coverage because: (a) the E. coli outbreak was not attributable to an actual contamination of the insured's products; and (b) coverage was limited to those losses "arising out of" and "because of" an error by the insured. Thus, in that case, neither the recall itself nor the insured's belief that the product had been contaminated was sufficient to trigger coverage.





Similarly, in another case, a food manufacturer recalled its product after testing had revealed the presence of listeria. However, after the recall, the listeria was found to be a listeria strain that did not cause bodily injury in humans. The court held that there was no coverage because the contamination did not satisfy the policy's requirement that it "may likely result in bodily injury," even though at the time of the recall the insured may well have acted reasonably in ordering the recall.

Following the passage of the FSMA, many insurers offer "government-mandated recall" endorsements, which cover recalls required (or sometimes recommended) by the government as long as there is a "reasonable probability" that the product would result in bodily injury or property damage. Such endorsements broaden coverage because they often contain no requirement for an actual contamination of the product and no requirement that the potential contamination actually cause, or may likely cause, bodily injury or property damage.

Once an "insured event" is established, most policies cover the following categories of expenses: recall expenses, including pulling the product from store shelves; replacing the product; lost profits; brand rehabilitation expenses; investigative costs; and crisis management expenses. Some policies also include third-party coverage for recall costs.

There is a wide variety of policies and levels of protection available in the marketplace. The policy's terms can often be negotiated with the insurer in order to tailor the policy to meet the needs of a particular company and to avoid potential coverage gaps.

In sum, being prepared, through proper planning and adequate insurance coverage, can be key to survival to any company in the food industry. No matter how careful the company may be in safe manufacturing processes, a contaminated product could slip through the cracks. The ounce of prevention and preparation for the inevitable storm will pay huge dividends down the road.

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