



## Ready for a Recall


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IN 1906, UPTON SINCLAIR'S NOVEL *THE JUNGLE* EXPOSED POOR WORK AND unsanitary conditions in the U.S. meat packing industry. The book prompted social outrage and eventually led to the passage of landmark legislation including the U.S.'s Meat Inspection Act and the Food and Drug Act, which led the way for the creation of the Food and Drug Administration (FDA). More than a century later, stories of food safety and contamination are not central to any novel's plot, but are making news headlines and are likely to prompt more government intervention in food safety issues.

The interesting aspect of the pending legislation this time is the shift in emphasis on the government's view of its responsibilities for ensuring food safety. In his weekly address of March 14, 2009, President Obama commented about his appointment of Dr. Mary Hamburg to the position of Commissioner of the Food and Drug Administration: "There are certain things only a government can do. And one of those things is ensuring that the foods we eat, and the medicines we take, are safe and don't cause us harm."

The price of contamination outbreaks in food can be costly both monetarily and in the loss of human lives. For instance, consider the estimated \$1 billion loss to the U.S. peanut industry as a result of a salmonella outbreak last year. It led to the biggest food recall in U.S. history. The U.S. Center for Disease Control and Prevention (CDC) reported that 714 people were sickened and nine deaths resulted in the outbreak linked to foods using peanut ingredients made by the now-bankrupt Peanut Corp. of America. According to the CDC, 76 million cases of food-related illnesses are reported every year with over 300,000 hospitalizations and 5,000 deaths.



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### CONGRESSIONAL ATTENTION

As a result of these high profile and deadly cases, food safety has Congress' attention. In March 2009, President Obama established the President's Food Safety Working Group. On July 7, the Working Group issued its key findings on how to upgrade the food safety system based around three core principles of prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

Last November, the Senate unanimously passed the FDA Food Safety Modernization Act (Senate Bill 510). The bill, originally introduced in the Senate in March, is very similar to the Food Safety Enhancement Act of 2009 (HR 2749), which passed the House in July. In testimony to Congress, Dr. Hamburg noted how this legislation would transform the U.S.'s approach to food safety from responding to outbreaks to preventing them.

According to FDA Commissioner, Dr. Hamburg, the new regulations under Congressional discussion would require and hold companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination. The legislation seeks enhanced ability for the FDA to:

- Require sanitation and preventive controls at food facilities (based on a scientific hazard analysis);

- Access basic food safety records at facilities;
- Establish basic standards for preventive controls;
- Require facilities to conduct hazard analyses;
- Implement preventive controls; and
- Require companies to have a comprehensive food safety plan.

Perhaps of most significance is that the bill also aims to grant the FDA the ability to require mandatory food recalls in certain situations. Currently, other than a few exceptions, recalls are carried out on a voluntary basis. This proposal would take the ultimate decision for a recall away from food companies.

### INCREASING EXPOSURES

In addition to potential regulatory changes, food companies also need to look at the improved methods of linking food borne illness outbreaks to particular producers. In the past, linking illnesses across multiple states to a common cause was like finding a needle in a haystack. The CDC however is now increasingly able to trace and link these outbreaks through improved data passed on by hospitals and health practitioners. A few years ago, companies may have not realized that their products were making consumers sick — due to the lack of scientific evidence — and therefore would not initiate a recall. Today, there is a greater likelihood that outbreaks will be traced back to the company or com-

panies responsible for the contaminated product causing the illness.

Going forward, recalls will not only be about linking actual illnesses to culprit products. They will also hinge upon how a company implement's FDA's new preventive measures. Rather than waiting for either consumer complaints or finished product positive test results to determine a recall, a company may be required to recall if the FDA determines that the company's product was manufactured in unsanitary conditions in breach of food regulations. It may be determined that those conditions created the potential for products to be adulterated, even if there may be no evidence in consumers or the end product itself.

Already this year, there have been several cases along these lines including the FDA's announcement in the first week of January about its intentions to ask a federal court to shut down a New Jersey cheese manufacturer. The company had an alleged history of operating under unsanitary conditions and producing cheese contaminated with *Listeria monocytogenes*.

How the practicalities of implementing the FDA's requirements end up will depend on the outcome of the Food Safety Enhancement Act once it comes before the Senate this year. However, should mandatory recalls become part of legislation, it will be critical for food

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companies to be on top of their game when it comes to food safety and recall preparedness.

### IMPROVING QUALITY AND READINESS

Most companies in the food industry have solid systems in place and make these activities part of their day-to-day risk management efforts. For those that don't however, these efforts to update out-of-date food safety regulations should be more than enough impetus. Businesses involved in the growth, production or preparation of food will need to reinforce their quality and risk management strategies to not only avoid food safety issues but also to financially prepare themselves to respond quickly in the event of a product recall.

For food producers, having proactive quality systems in place is a key risk management strategy in preventing contamination from happening. It can also help minimize reputation damage. Well risk-managed food companies will no longer view food safety as seeking compliance to a regulatory minimum standard but will instead be looking to get ahead of the game. Correctly implemented HACCP (Hazard Analysis Critical Control Points) plans that focus on the most relevant food safety and brand equity risks to the business and risk-based supplier management systems are two effective and proactive tools in



mitigating risk to food companies' recall exposure and brand.

In today's global market, the supply chain presents significant risk management challenges. Having an appropriate traceability and recall plan in place is critical to managing supply chain risks. At a minimum, companies are required by the Bioterrorism Act to have a traceability plan that adheres to the "one step up, one step down" principle so that the company can immediately know both the person from whom the product (or its ingredients) came and the next person to whom it has gone.

For years food companies have relied on certificates of analysis as a confirmation of food safety for their supplied goods. Companies can, however, go even further to improve that risk by building in testing programs for supplied ingredients and products as well as carrying out

appropriate due diligence of suppliers such as site risk reviews, obtaining critical performance data as well as food safety and GMP audits. The Peanut Corp of America recall is a salutary reminder of the importance of knowing how safe supplied ingredients are.

Even companies with excellent food safety may need to review their risk management efforts. With the likelihood of the FDA having access to company recordkeeping, it will be increasingly important to be able to demonstrate that a company has a good handle on the scope and severity of a recall should one be necessary. This means implementing an effective sanitation, testing, lot coding and batch management program in order to minimize the potential size of a recall. Given the potential for incurring enormous costs in recalling a product, it is vital that a food company can quickly provide the right data to the FDA to be able to isolate

**Food Recall Information/Web Resources:**

In the US: <http://www.fsis.usda.gov/recalls/>

In Canada: <http://www.inspection.gc.ca>

In Australia/New Zealand: <http://www.foodstandards.gov.au/consumerinformation/foodrecalls/>

and segregate contaminations and to ensure that the FDA will agree with the company's data. If a company cannot demonstrate to the FDA where a contamination began and ended, there is a much higher chance that the recall's scope can effectively be left open-ended. Recalling a few weeks worth of product may be manageable for some companies. Recalling a year's worth of product, which has been seen over the last few years in a number of cases in the U.S., could be financially devastating not to mention ruinous from a reputation standpoint.


**A PLAN OF ACTION**

A sound food safety program, traceability system, recall and crisis plan and business continuity plan should be part of a food company's risk management strategy. Prioritizing prevention is critical and is one of the three core principles of the President's Food Safety Working Group. Being prepared to handle the crisis is of huge importance also because a company will be judged by the regulators, the media and consumers on its ability to manage a recall well. Ultimately a company's reputation lies in the hands of these three groups in a time of crisis.

While Product Contamination insurance is available to address the direct and indirect costs involved in the recall of food products, it is important to look at how coverage responds to addressing the expense and implementation of crisis management. For insurance providers, the question is not only how they can help prepare their clients to handle a recall but also how to assist them in addressing the changing regulatory requirements to ensure the implementation of best practices for managing a crisis. This is why Product Contamination insurers see value in not only providing their clients with coverage to help pay for a range of specialist recall and crisis consultants but often offer upfront guidance to develop an appropriate plan of action to handle a recall.

While Product Contamination insurance is available from a growing number of insurers, it is estimated that only a small percentage of food companies are carrying the coverage. That might change given the current regulatory atmosphere. In fact, some industry leaders believe that, as a result of possible mandatory recalls, recall insurance or other financial

protection may become a regulatory requirement itself in due course.

While traditional Product Contamination insurance will be more of a necessity in the food industry's risk management plans, greater attention to quality control and advance crisis management planning is of equal and growing importance. Being prepared for a product recall in advance of it happening could be the difference between disaster and a client's survival. 

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