

point of view

January 2011

FDA Food Safety Modernization Act: The President signs the most sweeping over- haul of food-safety legislation since 1938.

pwc

Food Safety Series

Companies at every link in the food chain may need to take additional steps to prevent food-borne illness.

Highlights

- The bill will usher in a new era of food-safety regulation, with increased enforcement, stiffer penalties and broader record-keeping requirements for high risk food.
- The legislation requires food manufacturers and processors to develop and document food-safety plans that identify and prevent hazards at each facility.
- These companies also may need to do more to verify the safety of the ingredients they use.

Food-safety standards aim to reflect today's vastly different food manufacturing and distribution system.

The legislation was prompted by changes in the food supply and outbreaks of food poisoning in recent years involving eggs, tainted peanut butter, cookie dough and fresh bagged spinach that sickened hundreds of people across the country.

The legislation requires risk-based assessments to inform food safety plans.

The planning, testing and documenting controls over food safety could be strongly enforced. Recall procedures and defense from intentional contamination could also be required.

A change in mindset in the food industry will be necessary.

Growers, food manufacturers and processors, importers, restaurants, and food retailers may all face new mandates that could require a change in mindset at the highest level to ensure a culture of food safety.

Background

Responding to the realities of today's food supply chain

The legislation is an important step in updating America's antiquated food-safety laws.

The new legislation was proposed partly in response to high-profile outbreaks of food poisoning in recent years that have undermined public confidence in the nation's food supply. Eggs, peanut butter, cookie dough, spinach, hot peppers and green onions are among the foods that have been found to be tainted with *Salmonella*, *E. coli* or other pathogens.

The Centers for Disease Control estimates that there are 48 million cases of food-borne illnesses in the US each year, resulting in 128,000 hospitalizations and over 3,000 deaths.

Two trends have made the food supply chain more vulnerable to outbreaks of food-borne illnesses in the US and other developed economies: the centralization of food production and distribution and the rapid growth of imports of food and ingredients from countries where safety standards or enforcement is weak. Today, imports account for 15% of the US food supply, including 80% of the seafood Americans consume and 50% to 60% of the fresh produce.

The nature of today's food supply chain means contamination can turn up in more products, more quickly than in the past, causing outbreaks that affect large numbers of people. Tainted milk products from China, for example, wound up in candy sold in the US. And last year's *Salmonella* outbreak linked to Peanut Corporation of America led to the recall of more than 3,900 foods that used its peanut products as ingredients, including peanut butter crackers, cookies, ice cream, granola bars, dog treats and packaged kung pao chicken. This year, more than 100 foods, including salad dressing, dips and snack mixes, were recalled because they had been made with a flavor enhancer called hydrolyzed vegetable protein that might have been contaminated with *Salmonella*.

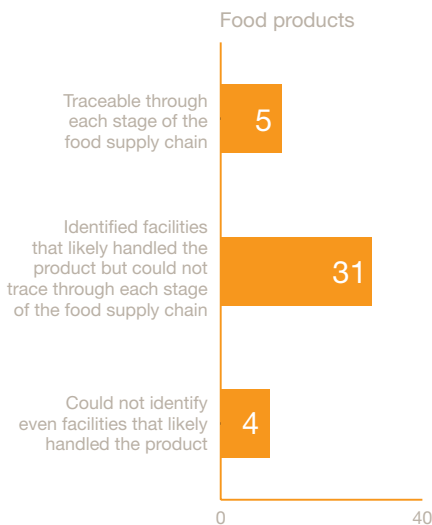
The FDA, which oversees 80% of the food supply, is currently developing new standards for safely growing, harvesting and packing fresh fruit and vegetables. The FDA also is gearing up to propose rules on the sanitary handling of food by companies that transport it in bulk.

Significant features of the legislation include:

1. Companies that now register with the FDA, as required under the Bioterrorism Act of 2002, will be required to perform an analysis of food safety hazards that are reasonably likely to occur in each facility, implement controls to prevent these hazards, monitor the controls to ensure that they are working and correct them if they aren't. The entire plan will have to be documented and updated every two years or sooner if the company changes suppliers, processes or ingredients. Companies will be required to share their food-safety plans with FDA upon request.
2. Registered companies will be required to maintain documents for a minimum of two years and could be subject to expanded record-keeping requirements for higher-risk food.
3. These companies will be required to develop food defense plans aimed at preventing intentional contamination for food determined to be high-risk.
4. Importers will have to ensure that all food coming into the US meets FDA food-safety standards under the Food, Drug, and Cosmetic Act. FDA regulations will likely result in more third-party audits.
5. Entry of imported food products into the US may be expedited based, in part, on the facilities' compliance history, the exporting country's food-safety standards and regulatory capacity, and third-party certifications, among other things. This could ease the burden on importers and food manufacturers.

Tracing food is tough

Results of an effort to trace 40 food products purchased at stores back to the farm or the border:



Source: Office of the Inspector General, Department of Health and Human Services, Traceability In the Food Supply Chain, March 2009.

Analysis

Raising standards to protect your brand

Food companies take safety very seriously, but given the nature of today's supply chains, they may need more stringent controls to avoid unpleasant surprises. The legislation will set minimum standards. Companies rightly aim to meet higher standards and go beyond compliance in order to win the loyalty of consumers and investors and gain a competitive advantage.

Here are the leading practices used by regulators and the private sector.

- 1. Analysis of safety hazards:** Leading companies already employ food safety plans of the type that would be required. The approach, called Hazard Analysis and Critical Control Point (HACCP), is accepted by regulators and trade associations around the world. Restaurants and retailers also have had success with it. In the US, the FDA has used it to reduce outbreaks of food-borne illness associated with juice since 2001. The record is less clear on seafood, where the FDA has required food safety plans since 1998, but the US Department of Agriculture, which regulates meat and poultry, has reduced food-borne illnesses by requiring HACCP plans. Leading companies also conduct internal safety audits that are reviewed by senior executives.
- 2. Training:** Training is widely recognized as a key to food-safety programs, and independent evaluations of both training and the program itself can lead to improvements. In China, where food safety laws were strengthened last year but enforcement gaps remain, the China Chain Store & Franchise Association is working with the UK's Chartered Institute of Environmental Health to adapt food safety courses to meet the new requirements and encourage members to have their managers and workers take these courses.
- 3. Ingredient safety:** Leading companies test high-risk ingredients and require a combination of internal audits and well-executed third-party audits to

check on safety procedures used by suppliers. Some companies limit the number of suppliers so officials can visit them regularly. Some provide training for suppliers and require them to have systems in place to trace ingredients they use. Leading companies realize that having a world-class supply chain can give them a competitive advantage.¹

- 4. Food defense plans:** Measures to prevent intentional contamination include limiting access to key points in production, doing background checks on employees, using tamper-resistant packaging and requiring delivery trucks to be sealed.
- 5. Traceability and recall procedures:** Leading companies have sophisticated electronic systems to track contaminated foods quickly when problems arise. They also conduct mock recalls to test their ability to move quickly. The US produce industry is implementing a traceability initiative that uses bar codes on each case to track the movement of produce electronically. Some companies use radio frequency identification tags. The government of Thailand also is testing an electronic tracking system. But tracing ingredients can be difficult, and companies spend millions of dollars recalling and destroying products that might contain a tainted ingredient.
- 6. Certification of international foods:** Food companies and suppliers around the world may be certified by third-party auditors, who use standards approved by the Global Food Safety Initiative or other groups.

Companies that aspire to be market leaders can start by reviewing their food safety plans, training programs and supply chains, with an eye toward making improvements. External assessments can help.

Test your food traceability practices

Are your records in electronic form rather than paper-based?

Do you track the date and time that a lot was harvested or manufactured?

Can you share data seamlessly with other firms?

Do you track lot numbers and sources of all ingredients used to manufacture a product?

Based on recommendations of the Institute of Food Technologists

¹ From vulnerable to valuable: how integrity can transform a supply chain, <http://www.pwc.com/us/en/supply-chain-management/publications/supply-chain-report-download.jhtml>.

Companies need to act now to avoid putting their brands at risk

Q&A

Q: Why do CEOs and board members pay attention to food-safety rules?

A: Making people sick can literally kill your company. That's what happened to Peanut Corporation of America, which shipped products contaminated with *Salmonella*, leading to one of the largest food recalls in US history. More than 700 people in 46 states got sick, and nine died. The firm filed for bankruptcy, and a criminal investigation was launched. At the very least, selling contaminated food can damage your reputation and hurt your stock price. Recent recalls have cost the food industry tens of millions of dollars. With public scrutiny of food safety on the rise, you could even be called to testify before Congress.

Q: What is the biggest risk companies face?

A: The biggest unknown is the safety of your supply chain, and the risks rise if you use suppliers in countries where food-safety laws or enforcement is weak. Leading companies take steps to prevent problems. CEOs can set the tone by asking what is being done to track suppliers, who may be changing processes or ingredients and putting the brand at risk. Tracking the financial health of suppliers can help you identify potential risks.²

Q: Are there gaps in the legislation?

A: Very small businesses and farms that market directly to consumers are subject to modified requirements for some of the proposed new rules, yet even small farms can be sources of significant national food-safety problems. That was demonstrated by a 2006 *E. coli* outbreak, which was linked to a small lot of spinach from California, and the 2008 hot pepper outbreak that was linked to a small farm in Mexico. It is unclear whether the final rules will give regulators the ability to quickly track tainted foods all the way from the store or restaurant back to the farm.

Q: Why do I need to act now if it will take the FDA a few years to write any new rules?

A: Reviewing your company's food-safety, record-keeping and product-tracking procedures can lead to performance improvements and innovation. By being in the forefront of efforts to improve food safety and providing credible information to regulators and consumers, companies can get a leg up on the competition. They can even influence any new rules.³

Q: If I comply with any new rules, will I stay out of trouble?

A: Not necessarily. The legislation raises the minimum standards for food safety, meaning there could still be outbreaks. Your customers, however, expect the food you produce, sell or serve to be safe. And that expectation is likely to rise. Setting a higher standard will help your company achieve its mission of better serving your customers.

² 10Minutes on Supply Chain Risk Management, <http://www.pwc.com/us/en/10minutes/supply-chain-risk-management.jhtml>.

³ 10Minutes on Trust and Transparency, <http://www.pwc.com/US/en/10minutes/trust-and-transparency.jhtml>.

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