

point of view

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Exporting food to the US: US regulators take a risk-based approach to imported food.

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Food Safety Series

Stepped-up scrutiny by the US government could trigger higher standards and stronger incentives to ensure food safety.

Highlights

- If the US Congress adopts pending legislation, US regulators will get more power to investigate and prevent food-borne illnesses that arise from imported foods.
- US regulators are already taking a risk-based approach, targeting foods linked to previous outbreaks and those produced in countries linked to exports of tainted foods.
- Food growers around the world could face new mandates under a rule that US regulators plan to propose in October 2010.

The US government is more focused than ever on imported foods.

Heightened US scrutiny is prompted by sharp import growth in recent years and outbreaks of food poisoning linked to imported foods that have sickened hundreds of people and animals in the US.

US regulators are working with counterparts around the world to identify sources of contaminated foods.

Regulators in the US plan to increase inspections of foreign facilities and to collect more import samples.

Growers, food processors and national governments all have an incentive to take additional steps to improve food safety.

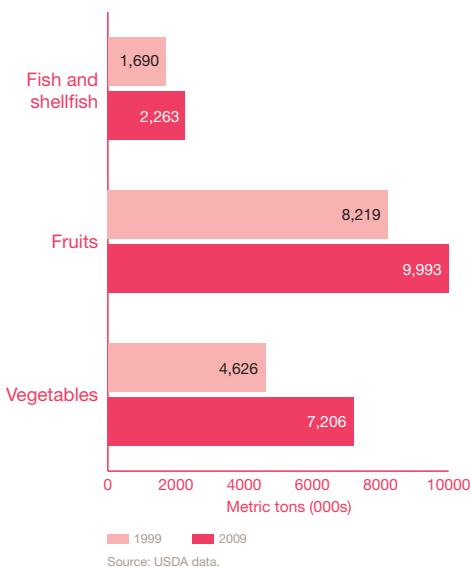
It's a good idea for companies to review their food-safety plans, training programs, supply chains, and traceability programs with an eye towards making improvements. Governments should bolster regulation and enforcement. The consequences of inaction can be serious: exporters could find themselves shut out of the huge US market because of food-safety concerns.

Background

Responding to the realities of today's global food supply chain with a risk-based approach

Import growth

Volume of imported seafood, fruits and vegetables, 1999 vs. 2009:



US regulators are increasing scrutiny of imports as part of a broad effort to prevent food-borne illness. If Congress passes legislation now under consideration, those efforts will accelerate and companies could face stiffer penalties for violating the rules.

These actions follow high-profile outbreaks of food poisoning that have undermined public confidence in the US food supply. Spices, peanut butter, cookie dough, spinach, melons, hot peppers, tomatoes and green onions are among the domestic and imported foods that have been found to be tainted with *Salmonella*, *E. coli* or other pathogens.

US regulators are concerned about imports because they now make up 15% of the US food supply, including 80% of the seafood and approximately 60% of the fresh produce Americans consume. Imports come from more than 150 countries, including many where food-safety standards are weak or enforcement is lax.

The US Food and Drug Administration (FDA), which oversees 80% of the US food supply, is targeting high-risk foods. In October 2010, it plans to propose standards for safely growing, harvesting and packing fresh fruit and vegetables. The rules will apply to growers in the US and those in countries that export produce to the US. The FDA also has told spice producers to do more to prevent contamination.

Under rules already in place, seafood processors and juice manufacturers must develop food-safety plans using an approach called Hazard Analysis and Critical Control Point (HACCP). These groups are required to analyze safety hazards that are reasonably likely to occur in each of their facilities, implement controls to prevent these hazards, monitor the controls to ensure they're working and correct them if they aren't. The US Department of Agriculture (USDA), which oversees meat, poultry and egg products, also uses this approach.

The FDA is taking the following new steps to increase the safety of the imported food it regulates:

1. To improve its ability to identify imports that violate US safety rules, the FDA is developing a computer screening system called Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT). The system, currently used in Los Angeles and New York and set for nationwide release, tracks data about past problems and has the capacity to take into account economic, political and environmental factors that can affect food safety. Heavy rain, for example, can contaminate crops with bacteria carried by mud. In a 2007 test of the system, the FDA found nearly twice as many shipments with violations as it had in the past, while speeding up the entry of foods it considers low risk.¹
2. The FDA has opened offices overseas and is increasing inspections of foreign farms and facilities. At offices in China, Mexico, Costa Rica, Chile, India, Belgium and Italy, FDA officials work with local regulators to learn about manufacturing practices and help exporters understand US rules. In 2010, the FDA plans 600 inspections of foreign facilities, up from 210 in 2009.
3. These actions are expected to result in more "Import Alerts"—holding shipments at the US border until importers can demonstrate that they don't have the problem US regulators suspect. Getting an Import Alert lifted can be time-consuming and expensive—companies usually have to demonstrate through laboratory testing that five consecutive shipments are free of the problem and that steps have been taken to prevent a reoccurrence.

¹ "FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities," US Government Accountability Office (GAO), May 6, 2010.

Analysis

Raising standards can protect the brands of both companies and countries

Leading food companies rightly set high food-safety standards to protect their brands, win the loyalty of customers and gain a competitive edge.

Additionally, governments can raise and enforce standards and in the process enhance their countries' reputations. For example, the Thai government is testing a new "smart sensor" system that will enable officials to track the farm and date on which tainted products were produced.

"As one of the world's largest producers and exporters of agricultural products, we must continue to improve our food-safety standards to meet or even exceed the global market's requirement," Thai Agriculture Minister Theera Wongsamut said in announcing the test.²

Examples of leading food-safety practices:

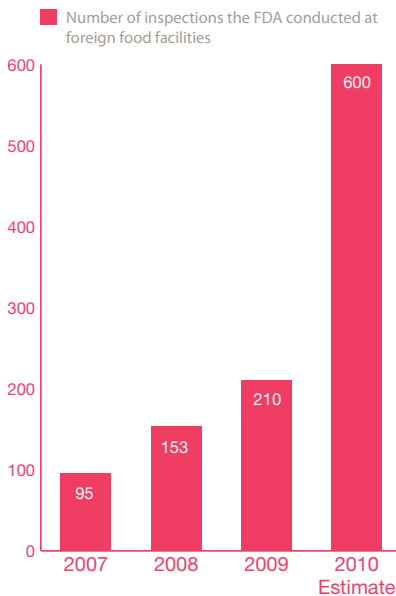
- 1. Analysis of safety hazards:** Leading companies employ food-safety plans using the HACCP approach, which is accepted by regulators and trade associations around the world. They also conduct internal and third-party safety audits.
- 2. Training:** Training is a key to food safety, and independent evaluations of both training and food-safety programs can lead to improvements. In China, where the government strengthened food-safety laws 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 the new requirements.
- 3. Risk-based regulation:** The European Union (EU) is at the forefront of risk-based regulation, requiring certification for high-risk foods such as seafood. In response to past problems, Japan has an arrangement with the Chinese government whereby China must certify Chinese spinach processors who oversee the practices of farmers. Chinese authorities then test the spinach.³

4. Traceability and recalls: The EU has strict traceability requirements for food and animal feed companies, which must document ingredient suppliers and customers that have received shipments. The US produce industry is beginning to implement a system to use bar codes on each case to track the movement of fruit and vegetables. This initiative goes beyond current US traceability rules of "one up and one back," which apply to firms that register with the FDA under the Bioterrorism Act of 2002. Leading companies have sophisticated electronic systems for tracking products, and they conduct mock recalls to test their ability to move quickly.

5. Ingredient testing: Leading companies test high-risk ingredients and require internal audits and well-executed third-party audits to check safety procedures used by suppliers. Major food retailers also set safety standards and conduct audits of companies that produce their private label products. Some companies limit the number of suppliers so officials can visit them regularly. Others provide training for suppliers and require them to have systems in place to trace the ingredients they use. Leading companies realize that having a world-class supply chain can give them a competitive advantage.⁴

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

More foreign inspections



Source: GAO and FDA data.

² "IBM, FXA and Thailand's Ministry of Agriculture Join Forces on Global Food Safety," Webwire, March 26, 2010.

³ "Food Safety: Selected Countries' Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness," US GAO, June 2008.

⁴ PricewaterhouseCoopers, 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>.

Acting now can help companies and countries avoid damage to their brands

Q&A

Q: Why do CEOs, board members and government officials outside the US need to pay attention to US developments and regulations?

A: Companies that export food to the US could find themselves shut out of the huge US market because of food-safety concerns. This could have serious consequences for corporate profits and national economies. Even small problems uncovered in safety audits required by US importers could hurt a company's competitiveness if the importer switches suppliers. And any problem can be magnified by the 24-hour news cycle and large social media presence in the US, tainting the public perception of all foods from that country.

Q: What is the biggest risk food companies face?

A: The biggest unknown is the safety of a company's supply chain. Risks rise if a company uses suppliers in countries where food-safety laws are weak or enforcement is lax. 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 identify potential risks.⁵

Q: Why do I need to act now?

A: With US regulators stepping up their scrutiny of imports, it's a good idea for companies and governments to review their food-safety procedures, the safety procedures of their suppliers and the recall procedures of both. Reviewing these 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 and influence any new rules.⁶ By taking these steps, companies also can win the loyalty of consumers.

Q: What will change if the legislation pending in the US Congress is adopted?

A: Companies that register with the FDA under the Bioterrorism Act would be required to develop HACCP plans and food-defense plans to prevent intentional contamination. High-risk imports would likely face certification requirements and more scrutiny, but imports of low-risk foods could be expedited.

Q: Do I need to hire an auditor to certify that my food is safe?

A: Leading food companies require suppliers to earn and maintain certification by expert third-party auditors, who apply standards approved by groups such as the Global Food-Safety Initiative. Leading companies already go beyond the requirements for certification to meet the demands of consumers and protect their brands.

⁵ 10Minutes on Supply Chain Risk Management, <http://www.pwc.com/us/en/10minutes/supply-chain-risk-management.jhtml>.

⁶ 10Minutes on Trust and Transparency, <http://www.pwc.com/us/en/10minutes/trust-and-transparency.jhtml>.

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