

Food Safety

A year in review

2012 issues, challenges, and
forward momentum



Contents

Protecting consumer health and confidence	3
Connecting the dots: Events and issues	4
Issues and a delayed solution	5
A solution, but not without challenges	6
In conclusion	7

Protecting consumer health and confidence

Notable 2012 food industry events

2012 had its share of high profile food recalls.

On April 4, 2012, the Center for Disease Control and Prevention (CDC) concluded its investigation into the multistate outbreak of Shiga toxin-producing *Escherichia coli* serogroup O26 (STEC O26) infections linked to the consumption of raw clover sprouts. The incident affected 29 individuals across 11 states and resulted in seven hospitalizations.

On October 19, 2012, a large retailer announced its decision to no longer sell sprouts due to their potential food safety risk. On October 5, 2012, the CDC released its final report on a multistate cantaloupe outbreak linked to foodborne pathogen, *Salmonella*. The source of the cantaloupes was traced to Owensville, Indiana. The recall affected 24 states, infected 294 people, 94 hospitalizations, and claimed three lives.

On October 11, 2012, the CDC released its final report on the multistate outbreak of *Salmonella* Braenderup infections associated with mangoes that were imported from Sinaloa, Mexico. The case toll for this recall concluded with 127 infections reported across 15 U.S. states and 33 hospitalizations.

One of the biggest meat recalls in 2012 came from Alberta, Canada, and affected 2.5 million pounds of beef that had been shipped to U.S. meat processors and grocery chains. On September 28, 2012, the USDA-Food Safety Inspection Service (FSIS) extended its public health alert for imported Canadian beef due to potential risk of *E. coli* O157:H7 infections.

The year concluded with another massive multistate peanut butter recall outbreak due to *Salmonella* Bredeney infections linked to peanut butter manufactured by a facility in Minnesota, resulting in 42 infections reported across 20 states and 10 hospitalizations. On November 26, 2012, the U.S. FDA suspended the registration of the food facility at Portales, New Mexico.

On June 4, 2012, USDA-FSIS implemented routine verification testing for the six additional Non-O157 STECs (O26, O45, O103, O111, O121, and O145) in raw beef manufacturing trimmings (domestic or imported) derived from cattle designed to safe guard against *E. coli* infections associated with primarily ground beef products.

On December 27, 2012, Food Safety News reported termination of USDA's Microbiological Data Program (MDP). The MDP was initiated in 2001 by USDA's Agricultural Marketing Service (AMS) with a goal to provide monitoring data on targeted pathogens in selected fruits and vegetables. In 2012, MDP was involved in the sampling and testing of alfalfa sprouts, cantaloupe, cilantro, hot peppers, lettuce (bagged), spinach (bagged), and tomatoes (cherry/grape and roma/plum) linked to foodborne illnesses in the United States.

In summary, the recall profiles in 2012 were not very different from 2011 or previous years. Proper execution of critical food safety programs remains an issue for industry and regulators alike as we move into a new year. This involves both buyers and suppliers into the global marketplace.

Protecting consumer health and confidence

Food product recalls and economically adulterated products entering the global marketplace have increased in the past decade and 2012 was no exception to recalls. Risks associated with food pathogens are making national news regularly. Food pathogens have breached their natural reservoirs and are routinely reported in foods where they would not typically be expected. *E. coli* in produce and beef products, *Listeria* in refrigerated products including produce and poultry, and *Salmonella* in produce, meat, and poultry remain a threat in our food supply chain and a significant risk for consumers. U.S. regulatory agencies instituted zero tolerance standards for pathogens such as *Listeria*, *E. coli* O157:H7 and Non-O157 STECs, and of course *Salmonella* in ready-to-eat products. *E. coli* O157:H7 and Non-*E. coli* O157:H7 STEC pathogens in raw beef products destined for ground products is much improved but remains a challenge for the food industry in light of the United States Department of Agriculture (USDA)-mandated zero tolerance. The general public's confidence in its food supply is at an all-time low within the United States.

Protecting consumer health and its confidence in its food supply and maintaining the integrity of the food supply is a responsibility of the government. Consumer risk, brand risk, and economic liability due to poor execution of appropriate food safety measures remain a concern for the nation's food supply. Additionally, the potential for deliberate disruptive acts of terrorism are being addressed by the industry and through sweeping regulatory reform as evidenced by the FDA's Food Safety Modernization Act (FSMA).

Connecting the dots: Events and issues

Food safety and food defense

The United States has witnessed a dramatic increase in food recalls associated with food pathogens. According to the CDC, foodborne illnesses result in about 3,000 deaths per year in the United States, and about 48 million people—or one in six Americans—get sick from food contamination each year. Because of underreporting, the number of sicknesses caused by contaminated food is greatly understated. In 2012, we were alerted to about 10 multistate food recalls. The recent September 2012 peanut butter recall is a classic example that bears testimony to the fact that food safety is an issue that is still at large.

In another report, the CDC tracked imported papayas tainted with Salmonella to a farm in Mexico. Between January 1 and August 21, 2011, this particular recall affected 106 individuals, across 25 states. The U.S. FDA investigation into the source or sources of contamination of *Salmonella* in fresh papayas entering the United States from Mexico reported a *Salmonella* contamination rate of 15.6% in imports between May 12 and August 18, 2011, alone, placing imports of fresh papayas from Mexico into the United States on high alert.

Food safety is concerned with the protection of food products from unintentional contamination by an agent reasonably likely to occur in the food supply. An example of food safety is controls to prevent contamination of ground beef by *E. coli* O157 and non-EHEC (enterohemorrhagic *E. coli*).

Food safety is a key responsibility of the food industry irrespective of whether the food is sourced nationally or from foreign countries. Failure to maintain food safety results in recalls that cost the industry millions of dollars in lost revenues, shatters consumer confidence, destroys brands, and ultimately places unprecedented cost on the economy.

On the other side of the globe in China, 2012 concluded with the municipal government of Shanghai, considering rolling out a mechanism that could blacklist enterprises involved in illegal conduct regarding food safety and imposing harsh punishments on them. The regulation is expected to take effect in 2013.

Food defense is concerned with the protection of food from intentional contamination by biological, chemical, physical, or radiological agents that are not reasonably likely to occur in the food supply.

In 2010, the United States imported 1,350 metric tons of beef, pork, lamb, and poultry meats, 1,411 metric tons of fruits, nuts, and preparations, 10,967 metric tons of vegetables (fresh and frozen), and 42,698 hectoliters of fruit juices among other agricultural products. The total dollar import value for agricultural products for 2012 was \$22.9 billion of which the top five export countries to the United States accounted for: Canada-19.8%, EU-17.5%, Mexico-16.6%, China-4.1%, and Brazil-3.5% of the total imports. A large portion of the U.S food supply is sourced across international borders.

In 2007, the FDA banned imports of wheat gluten from China after it received more than 14,000 reports of pets believed to have been sickened by packaged food. This is an example of premeditated action, wherein the food supply was deliberately adulterated to increase economic gains. The United States imports a significant portion of its food from China as well as from many foreign nations, which may or may not have regulations that govern their food production and processes. Sourcing food from countries, that lack regulatory oversight, poses significant risks. Some of these risks are known and could be managed through intervention, but there are also risks that are of an unknown nature, which are hard to quantify in the immediate future but which may cause serious impacts much later in its life cycle. The United States is particularly vulnerable to these risks since a sizable portion of its food supply is secured from across international borders.

Separate from intentional adulteration of food for economic gains, the attacks of 9/11, and the devastating impacts of terrorism on its citizens and the nation as a whole, presented new challenges to the United States and forced the government to evaluate its preparedness to protect its vital resources from future attacks. The Department of Homeland Security (DHS) defined these resources as “critical infrastructure”, systems and assets, whether physical or virtual. They are so vital that the incapacity or destruction of them may have a debilitating impact on the security, economy, public health or safety, environment, or combination of these matters, across federal, state, regional, territorial, or local jurisdiction. The DHS defined 18 critical infrastructure sectors including food and agriculture, which merits national protection. Food safety defense practices alone are likely inadequate to afford this protection. New regulations are required to protect the integrity and security of the nation’s food supply along the breadth of its supply chain.

Issues and a delayed solution

FSMA

The FSMA (H.R 2751) was signed into law by President Obama on January 4, 2011. FSMA is the first major piece of legislation addressing food safety since 1938. FSMA aims to safeguard the safety of the U.S. food supply, primarily through science- and risk-based preventive controls. FSMA empowers the FDA to regulate how food is grown, harvested, sourced, processed, and labeled. FSMA requires the FDA to undertake more than a dozen rulemakings, issue industry and topic relevant guidance documents, as well as undertake a number of tactical and strategic plans to help with the enactment and enforcement of the new FSMA rules.

Some of the key mandates under FSMA include:

- Federal/state integration that fosters collaboration between local, regional, state, federal, and international inspection agencies critical for transformation of the food safety system. By integrating and expanding the responsibilities of the different overseeing agencies involved with food safety, FSMA aims to build a food safety system with oversight across the breadth of the food supply.
- New import authority and mandates that focus on strengthening the safety and integrity of food imported into the United States through different programs,

such as importer accountability, third-party certification programs for foreign facilities that comply with U.S. food safety standards, import requirements for high-risk foods to comply with U.S. food safety standards, voluntary qualified importer programs for importers to streamline the import process for qualified importers, and authority to deny entry of food from suspect foreign facilities that have restricted FDA access or visibility.

- International capacity building that encourages collaboration between the FDA and international governments to share technical, scientific, and regulatory knowledge that helps to strengthen and build food safety capacities of these foreign nations that import food into the United States.
- Preventive standards that give the FDA legislative mandate to require science-based preventive controls across the food supply. This new mandate places shared responsibility on both the FDA and the food industry for safety of the U.S. food supply. Under these new mandates, food companies have a mandatory obligation to have written risk-based preventive controls and corrective actions plans based on hazard identification. The FDA has a mandatory task to issue revised, risk-based produce safety standards guidelines to decrease microbial hazards of fruits and vegetables.



A solution, but not without challenges

Food safety and regulatory challenges for the food industry

The harsh reality facing the global food industry is increased regulation and inspection frequency, which may increase the cost of compliance. Operational excellence and risk elimination may define the food industry's success in these challenging economic and regulatory environments.

The food industry should expect increased regulatory oversight from U.S. regulatory bodies such as the FDA. In light of pending FSMA regulations, it may benefit companies to reassess food safety risks associated with their products and processes. Taking a proactive food safety and surveillance approach based on a front-end, science-based strategy may benefit commercial companies through increased consumer confidence, increased brand protection, and improved efficiencies.

Current issues that the food industry should be prepared to address can be summarized into the following broad categories.

Preparedness to meet inspection and compliance

Based on their risk profiles, facilities may have to prepare for increased frequency of facility inspections and meet the compliance requirements set forth by new and ever-changing regulations through:

- A compliance strategy to address the facility's high-risk areas, which may typically include standardized operating procedures and controls along the manufacturing chain with special emphasis on identifying and addressing biological, physical, and chemical hazards pertinent to the process, facility, or product.
- Document controls with emphasis on maximal transparency and traceability with respect to deviation reports, corrective actions, change control, audit records, and food safety plans.
- Quality control and quality management systems with special emphasis on meeting specified food testing requirements by accredited testing laboratories.

Preventive standards

- It is expected that facilities will be mandated to have written preventive controls based on an evaluation of their hazards with potential impact on food safety; controls and procedures centered around risk

minimization, mitigation, and risk containment; ongoing inspection and improvement records; and actionable (clear) corrective actions to address deviations should they arise.

Import compliance (establishments with import/export capabilities)

The FSMA regulation when implemented may affect facilities or establishments with export programs to the United States:

- As part of their preparedness plan, such establishments may do well to prepare for importer accountability by verifying that supplier operations have effective food safety systems that meet U.S. regulatory requirements, and requirements including document control and facility registration.
- Adoption of leading industry practices to proactively improve food safety standards may enhance existing food safety programs.

Food safety and regulatory challenges for FDA

The FDA is responsible for the regulatory inspection of about 80% of the U.S. food supply. The passing of FSMA is the first major piece of legislation addressing food safety since 1938. Implemented in its totality, FSMA may increase FDA's regulatory outreach across the food supply chain and grant FDA active powers to intervene and act in the interest of food safety and consumer protection. The success of FSMA depends on the completion and issuance by FDA of a dozen new rules and supporting industry guidance documents designed to facilitate FSMA's adoption and implementation by the industry and FDA. For the FDA, this is no small challenge. January 4, 2013, will mark the 2nd anniversary of FSMA and the first of many proposed regulations are now just being published for public comment in 2013.

Like many new laws, the enforcement of FSMA may take time, but we expect to see the proposals become finalized and require compliance in the next two years. In 2013, we expect to see advancements in the development and implementation of aspects of the preventive action and importer compliance programs. In addition, the issuance of industry guidance documents to help meet regulatory compliance requirements may also see passage in the next 12 months.

In conclusion

There is no doubt that FSMA is a high priority for this administration; however, key questions about the act remain unanswered, namely:

- When will these new rules become finalized?
- How will FDA fund the implementation of the FSMA regulations?
- What will it take for the industry to comply?

While the answers are still at large and industry speculation abounds, there is little doubt that FSMA is critical to securing our nation's food supply today and preparing for a resilient system in the future.

References

Kroger Discontinues Sprouts Due To Potential Food Safety Risk

<http://ir.kroger.com/phoenix.zhtml?c=106409&p=irol-newsArticle&ID=1747789&highlight=>

Investigation Update: Outbreak of Shiga toxin-producing E. coli O104 (STEC O104:H4) Infections Associated with Travel to Germany

<http://www.cdc.gov/ecoli/2011/ecolio104/>

Microbiological Data Program (MDP)

<http://www.ams.usda.gov/mdp>

Multistate Outbreak of Salmonella Braenderup Infections Associated with Mangoes (Final Update)

<http://www.cdc.gov/salmonella/braenderup-08-12/>

FSIS Expands Public Health Alert for Imported Canadian Beef from XL Foods

http://www.fsis.usda.gov/News_&_Events/NR_092812_01/index.asp

Multistate Outbreak of Salmonella Bredeney Infections Linked to Peanut Butter Manufactured By Sunland, Inc.

<http://www.cdc.gov/salmonella/bredeney-09-12/index.html>

Letter to Sunland Inc. Concerning Suspension of Food Facility Registration; Notice of Opportunity for Hearing

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm329370.htm>

Multistate Outbreak of Salmonella Typhimurium and Salmonella Newport Infections Linked to Cantaloupe(Final Update)

<http://www.cdc.gov/salmonella/typhimurium-cantaloupe-08-12/index.html>

Multistate Outbreak of Human Salmonella Agona Infections Linked to Whole, Fresh Imported Papayas

<http://www.cdc.gov/salmonella/agona-papayas/index.html>

Defending America's food supply against terrorism: Who is responsible? Who should pay?

<http://www.choicesmagazine.org/2007-1/grabbag/2007-1-12.pdf>

U.S. Census Bureau, Statistical Abstract of the United States: 2012

Section 17: Agriculture <http://www.census.gov/prod/2011pubs/12statab/agricult.pdf>

Shanghai mulls blacklist mechanism amid food safety concerns

http://big5.xinhuanet.com/gate/big5/news.xinhuanet.com/english/china/2012-12/26/c_132065522.htm

FDA Foods and Veterinary Medicine Program

The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration

Second Annual Report: September 8, 2010 – September 7, 2011

<http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm200958.htm>

Food Safety Modernization Act

<http://www.fda.gov/food/foodsafety/fsma/default.htm>

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm>

FSMA Approaches Two-Year Anniversary as Components Languish

<http://www.foodsafetynews.com/2012/12/fsma-approaches-2-year-anniversary-while-components-languish/>

Contacts

James Cascone

Principal
Deloitte & Touche LLP
+1 213 553 1300
cjcascone@deloitte.com

Debarati Bhattacharya

Manager
Deloitte & Touche LLP
+1 703 251 1277
debbhattacharya@deloitte.com

Kate Ferrara

ERS Principal
Deloitte & Touche LLP
+1 617 437 2030
kferrara@deloitte.com

Elise Gautier

Principal
Deloitte & Touche LLP
+1 214 840 1937
elgautier@deloitte.com

Craig Henry

ERS Director
Deloitte & Touche LLP
+1 601 584 1429
cwhenry@deloitte.com

This document contains general information only and Deloitte is not, by means of this document, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This document is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor.

Deloitte shall not be responsible for any loss sustained by any person who relies on this document.

About Deloitte

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/about for a detailed description of the legal structure of Deloitte Touche Tohmatsu Limited and its member firms. Please see www.deloitte.com/us/about for a detailed description of the legal structure of Deloitte LLP and its subsidiaries. Certain services may not be available to attest clients under the rules and regulations of public accounting.