



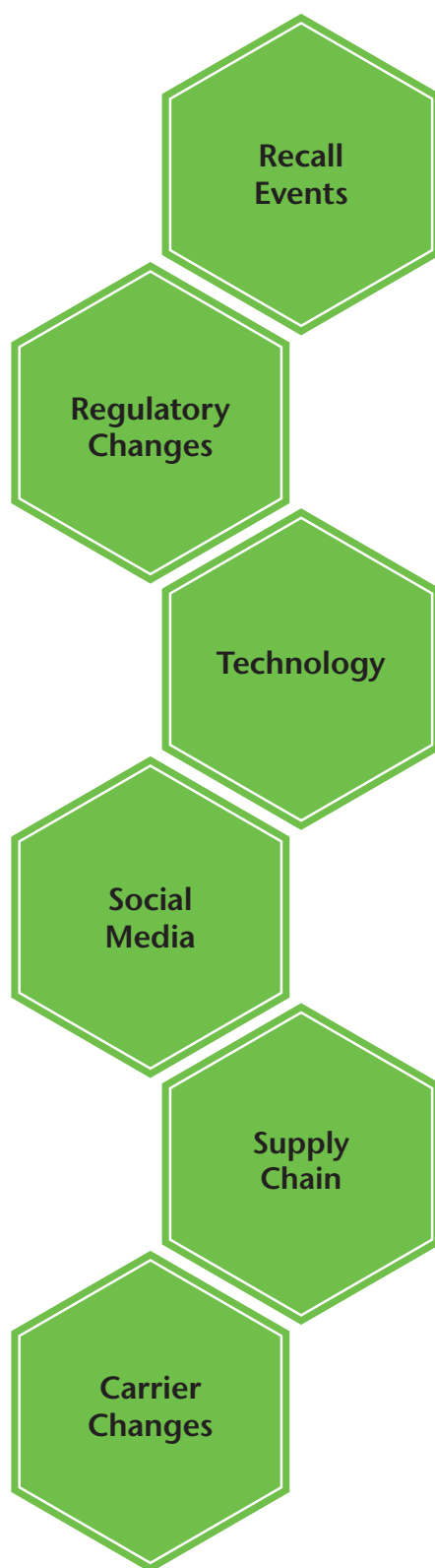
2017 Emerging Trends in Product Recall and Contamination Risk Management

A crisis may be unpredictable,
but it should not be unforeseeable

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2017 Food Safety Risk Management Trends



Significant Product Safety Incidents of 2016

This past year was an interesting year in many respects, with several high-profile events regarding product safety in the news. The media continues to focus on product safety issues, influencing the way in which regulators and the underwriters view and approach risks leading to increased regulatory controls and measures. Technological advancements in product testing can detect and identify problems faster than ever before, and consumers are expecting questionable products be removed from the steam of commerce as quickly as possible.

Product recalls reported by U.S. regulatory agencies are increasing in number across most product categories. The most significant and influential recall of 2016 was arguably the Samsung Note7 smartphone recall, but several food recalls also dominated headlines. In the food sector, the U.S. Food and Drug Administration (FDA) recalled units were up 69% to almost 200 million units in the third quarter of 2016, surpassing the record set in the previous quarter. Many of these events involved ingredient products that significantly added to the spread of the contaminant across numerous companies and products.

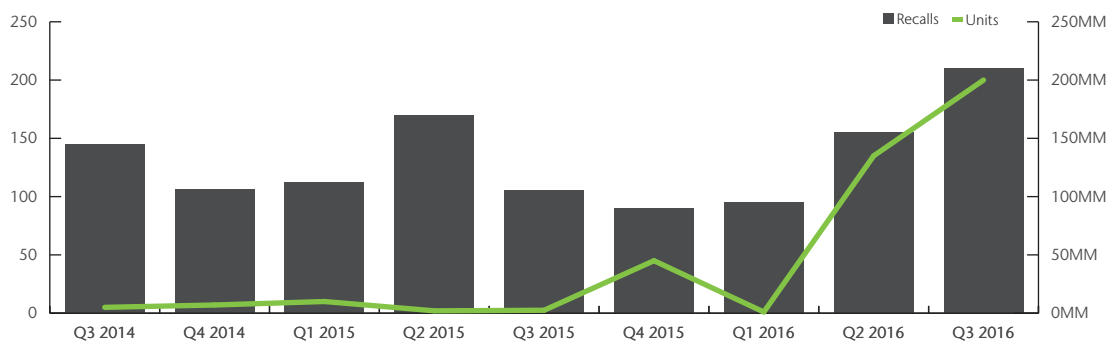
Consumable Product Recalls

Four significant food contamination events and subsequent recalls were of particular note in 2016. Each of these involved ingredient or co-manufacturing exposures in the supply chain, and they affected major brands and a wide variety of end products.

The FDA, the Centers for Disease Control and Prevention (CDC) and state and local officials investigated listeriosis linked to frozen vegetables in the spring of 2016. As part of a routine product sampling program, the Ohio Department of Agriculture collected packages of frozen vegetable products from a retail location and isolated listeria monocytogenes in frozen organic white sweet cut corn and frozen organic petite green peas. Meanwhile, the CDC reported that eight people in three states had been infected with strains of listeria monocytogenes.

Whole genome sequencing showed that the *Listeria monocytogenes* isolate from the frozen corn was closely related genetically to seven bacterial isolates from ill people, and the *Listeria monocytogenes* isolate from the frozen peas was closely related genetically to one isolate from an ill person. This close genetic relationship provided evidence that the people in this outbreak became ill from eating frozen vegetables produced by CRF Frozen Foods. On April 22, 2016, the company recalled 11 frozen

FDA Food Recalls and Units



vegetable products because they might have been contaminated with *listeria monocytogenes*. Subsequently, CRF Frozen Foods expanded its recall to include all of its frozen organic and traditional fruit and vegetable products manufactured or processed in CRF Frozen Foods' Pasco facility since May 1, 2014. Approximately 358 consumer products sold under 42 separate brands were recalled.

In April of 2016, Grain Craft, a supplier of milled wheat to food and baking companies, learned of the intermittent presence of peanut in the wheat flour supplied by one of their flour mills in Georgia. The source was determined to be soft red winter wheat grown in peanut-producing regions of the South. Grain Craft ceased using the wheat in question and recalled numerous products, including snack cakes, cookies, animal crackers, pretzels, cakes and pies for undeclared peanut residue. While peanut allergies are not a problem for the vast majority of the population, exposure to peanut dust can be life threatening for 0.6 to 1 percent of Americans. These recent recalls bring to light the challenge of agricultural cross-contact, which is the result of customary methods of growing, harvesting and shipping of wheat and other agricultural products.

Another ingredient-related recall took place in early 2016 and involved certain sunflower kernel products due to possible *listeria monocytogenes* contamination. SunOpta Inc., a leading global company focused on organic, non-genetically modified and specialty foods, announced it was voluntarily recalling a limited number of sunflower kernel products produced at its Crookston, MN facility. End products recalled included national brands and store-only brands and included spreads, packaged kernels, salad toppings, snack bars and mixes of products containing sunflower seeds.

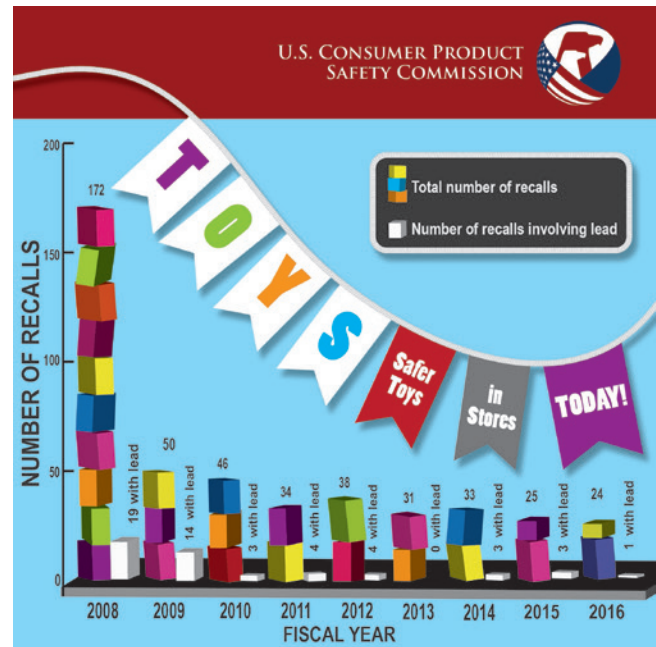
Toward the end of 2016, another recall involved powdered milk products. The U.S. Food and Drug Administration (FDA) announced on November 30th that the U.S. Marshals Service seized more than 4 million pounds of product produced by Valley Milk Products LLC (Valley Milk), alleging that the products were adulterated due to poor sanitary practices and positive results for *Salmonella* in the plant's internal environmental and finished product samples. The seized products, worth nearly \$4 million, include dry nonfat milk powder and buttermilk powder packaged in 40- and 50-pound bags for further manufacturing. Subsequently, Valley Milk Products announced a recall of 50-pound bags of nonfat milk powder and sweet cream buttermilk powder that were produced from December 10, 2015 to July 5, 2016 due to potential salmonella contamination. These products are not sold directly to consumers, but are used as ingredients in a number of foods. Over a dozen different products ranging from baked goods to snacks and candy were recalled as a result.

Non-Food Consumer Product Recalls

Consumer (non-food) product recalls has held fairly steady of the past several years, but recalled units increased 12% in the third quarter of 2016 to nearly 41.3 million. Aside from Q1 2016 when a single propane gas issue caused a spike in recalled units, this is the highest level since Q3 2004.

Much of this spike — though not all of it — can be attributed to the Samsung Galaxy Note 7 smartphone recall announced in September of 2016. The Samsung event was definitely the most widely publicized recall of the year due to the potential for batteries to overheat and result in serious injury or fire. Safety was affected at home, at work, on the road, and in the air for the user and others. About 1.9 million units were recalled, with Samsung receiving 96 reports of batteries in Note7 phones overheating in the U.S. alone. Samsung and the U.S. Consumer Product Safety Commission (CPSC) are seeking 100% response rates for this recall. As CPSC Chairman, Elliot F. Kaye, explains, “The Galaxy Note7 recall has proven to be a real challenge for Samsung. I am very concerned that consumers who exchanged their phones for replacement Galaxy Note7s are now at risk again. We at CPSC have worked diligently under difficult circumstances to protect consumers and bring this matter to an appropriate close. CPSC will continue to hold Samsung and other companies accountable when consumer safety is put at risk.”

A second significant non-food recalled occurred shortly before the year-end holiday season with Cuisinart, in cooperation with the CPSC,

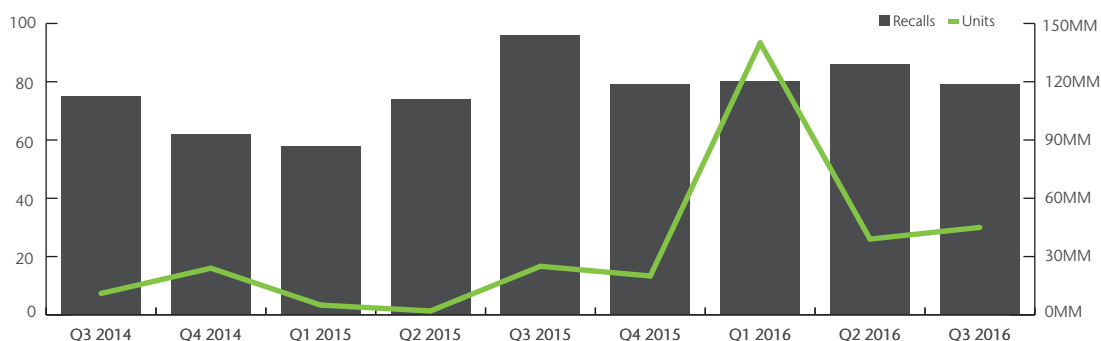


Source: <https://www.cpsc.gov/Newsroom/News-Releases/2017/Safer-Together-CPSC-and-CBP-Collaborate-to-Keep-Unsafe-Toys-Off-Store-Shelves>

announcing the voluntary recall of riveted cutting blades in certain Cuisinart® food processors. This recall affects some 8 million products dating as far back as 1996, making this one of the largest appliance recalls in history, according to the CPSC.

Interestingly, one of the higher risk non-food products has seen a dramatic decrease in the number of recalls. Despite a high profile and safety concern, the actual number of toy recalls has dropped significantly in recent years from 172 in 2008 to 24 in 2016. Riding toys, specifically non-motorized scooters, were the toy category associated with the most injuries and 45 percent of toy-related deaths in 2015.

Consumer Recalls and Units



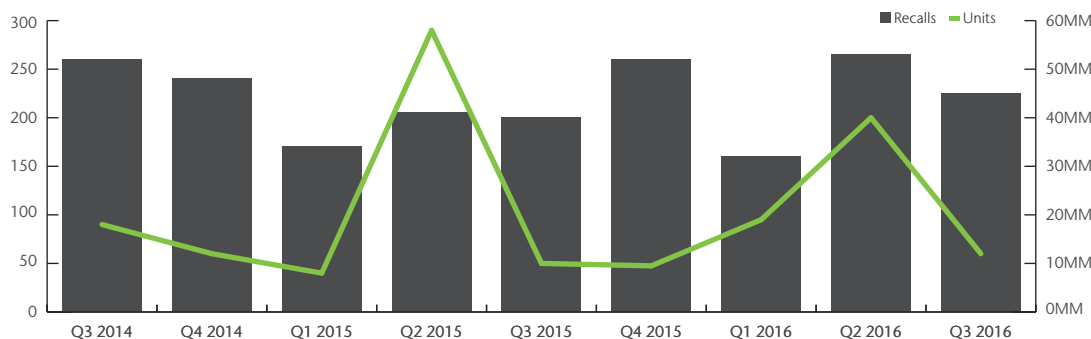
Automotive Recalls

Automotive recalls decreased in both number and units during 2016. This reduction can largely be attributed to the significant number of recalled products related to Takata in 2015, the largest and most complex automotive recall in history. During May 2016, the U.S. Department of Transportation expanded and accelerated the Takata air bag inflators recall to protect American drivers and passengers. This expansion was based on a five recall phase of prioritizing risk which was determined by the age of the inflators and exposure to high humidity and fluctuating high temperatures that accelerated the degradation of the chemical propellant. Ruptures of the Takata inflators have been tied to ten deaths and more than a hundred injuries in the United States. This recall decision follows the agency's confirmation of the root cause behind the inflators' propensity to rupture.

Under the Amended Consent Order issued to Takata, the company is required to make a series of safety defect decisions that will support vehicle manufacturer recall campaigns of an additional estimated 30 to 40 million inflators. This expansion phase from May 2016 to December 2019 will add to the already 28.8 million air bag inflators previously recalled. Also, the expansions mean recalls for all Takata ammonium nitrate-based propellant driver and passenger frontal air bag inflators without a chemical drying agent (also known as a desiccant).

The National Highway Traffic Safety Administration (NHTSA) continues to face scrutiny from the media and regulators who want safety issues to be discovered and resolved as quickly as possible.

NHTSA Recalls and Units



Historically Significant Recall Events of the Past

Historically Significant Recall Events 1982-2016

Product	Company	Year	Country	Recall
Tylenol	McNeil Labs	1982	U.S.	Product Extortion Incident involving over 30,000,000 bottles of pain reliever due to suspected cyanide tampering. Estimated costs in excess of \$100,000,000 with majority of loss due to lost sales and product replacement.
Perrier Water	Perrier Water	1990	U.S./France	Benzene contamination resulting in recall of 160,000,000 bottles. Brand never re-established to pre-recall sales level. Estimated at \$40,000,000 in lost sales plus value of destroyed product.
Pepsi	PepsiCo	1993	U.S.	Alleged tampering of Diet Pepsi products with needles. Loss in excess of \$35,000,000 due to lost sales, rehabilitation and advertising costs.
Jack-in-the-Box	Foodmaker	1993	U.S.	E. coli contamination of ground beef on West Coast. Numerous bodily injury claims and 4 adolescent deaths. Loss in excess of \$100,000,000 primarily due to lost sales and rehabilitating the brand.
Cheerios	General Mills	1994	U.S.	Contamination of grain by grower using improper pesticide. Loss in excess of \$75,000,000.
Ground Beef	Hudson Foods	1997	U.S.	E. coli contamination of ground beef patties. Recall of more than 20,000,000 lbs. of ground beef. The most crippling effect was not direct recall costs, but the loss of Hudson's best customer, fast-food giant Burger King. Company no longer in business.
Hot Dogs	Sara Lee	1998	U.S.	35 million pounds of meat product recall for listeria. The recall itself cost about \$76 million. In addition, an additional \$25 million was spent to renovate the facility.
Coca-Cola	Coca-Cola Company	1999	Belgium/ Europe	Loss in excess of \$100,000,000 as recall of products expands from Belgium to 6 European countries.
Snickers and Mars Bars	Snickers and Mars Bars	2005	Australia	Product extortion in Australia alleging poison contamination forces recall and destruction of over 3,000,000 candy bars. Loss estimated in excess of \$10,000,000.
Cadbury Chocolate	Cadbury Schweppes	2006	United Kingdom	Salmonella contamination resulted in recall of over 1,000,000 chocolate bars. Estimated loss in excess of \$50,000,000.
Spinach	Natural Selection Foods	2006	U.S.	Recall costs and estimated sales losses amounted to \$350 million
Pet Food	Menu Foods	2007	Canada/U.S.	Melamine contamination of wheat gluten used in various pet foods due to Chinese supplier resulted in recall of 60 million containers of pet food. \$42,000,000 in losses attributed to the recall alone, not including lost sales.
Peter Pan Peanut Butter	ConAgra Foods	2007	U.S.	Losses estimated at \$78,000,000 in recall costs plus \$55,000,000 in lost sales. Facility refurbishment estimated at \$15,000,000

Pot Pies	ConAgra Foods	2007	U.S.	The company voluntarily recalled all of its Banquet and private label pot pies out of concern for salmonella. Direct recall costs were approximately \$27 million in the second quarter
Tomatoes / Peppers	Various	2008	U.S.	Salmonella outbreak incorrectly linked to tomatoes by the FDA costs the tomatoes industry more than \$100 million in related losses with one estimate as high as \$350,000,000. Eventually, the contamination is traced to jalapeno and serrano pepper farm in Mexico.
Deli Meat Products	Maple Leaf Foods	2008	Canada	Listeria contamination found in corned beef and roast beef products. Recall expanded to 243 different meat products produced by Maple Leaf Foods. The packaged meats recall significantly affected the business by an estimated \$59 million to \$69 million before taxes, including \$19 million in one-time direct costs.
Peanuts	Peanut Corp. of America	2008	U.S.	Salmonella contaminated peanuts affecting more than 200 companies and 2000 different products. Industry losses estimated at over \$1B. PCA declares bankruptcy. Kellogg had reported losing \$70 million due to the recall.
Cookie Dough	Nestle	2009	U.S.	National outbreak of illness from E. coli 0157 been linked to the product. Company estimated recall would cost between \$30-\$50 million.
Hydrolyzed Vegetable Protein	Basic Food Flavors	2010	U.S./Canada	Salmonella contamination results in recall of 177 different products. Affected bulk, ready-to-eat and ready-to-cook products in the U.S. and Canada.
OTC Children's Medicine	Johnson & Johnson	2010	U.S./Canada	Recall of 43 over-the-counter children's medicines (135 million bottles) by McNeil Consumer Healthcare, a subsidiary of Johnson & Johnson. The recall affected at least 12 countries. Third Qtr. 2012 earnings report listed \$665 million in recall costs.
Eggs	Wright County Egg Farm	2010	U.S.	Recall of over 500 Million shell eggs due to salmonella contamination. GMA estimated loss at \$100 Million to the shell egg industry.
Infant Formula	Abbott Labs	2010	U.S.	5 million containers of top-selling Similac powdered infant formula recalled due to possible contamination by beetles or larvae of the bugs. The company advised that returns of the purchased formula may reduce third-quarter revenue by an estimated \$100 million.
Cantaloupe	Jensen Farms	2011	U.S.	Deadliest foodborne illness outbreak in over 25 years. Listeria contamination results in over 30 deaths and hundreds of illnesses. Dollar volume of sales drops by 55.7% within four weeks. Company declares bankruptcy.

Historically Significant Recall Events 1982-2016

Ground Turkey	Cargill Meat Solutions Corp.	2011	U.S.	Largest meat recall in history with 36 million pounds of ground turkey (representing 6% of annual consumption for the industry) recalled because of potential salmonella contamination. The recall and subsequent plant closure led to 130 employees being laid off and one of the “weakest quarters” ever for their meat division.
Cucumbers/Sprouts	European Farmers	2011	Europe	Cucumbers initially implicated in over 4,000 illness and at least 48 deaths. German Federal Ministry of Food, Agriculture and Consumer Protection, later announced that seeds of fenugreek imported from Egypt were likely the source of the outbreak. EU farmers claimed losses of \$611 million.
Peanut Butter	Sunland, Inc.	2012	U.S.	Over 200 different products recalled. Resulted in first ever facility shutdown by FDA under FSMA authority. Company declares bankruptcy in 2013 with between \$50-\$100 million in liabilities.
Chicken Products	YUM! Brands	2012	China	Accusations of poultry being fed toxic chemicals leads to significant brand damage and China first-quarter loss of 41%. Same store sales down 20% in first qtr 2013.
Whey Protein	Fonterra	2013	New Zealand	False report of botulism-causing bacteria. Fonterra booked loss of NZ\$14 million provision for costs associated with the replacement of recalled products. Customer Danone sued Fonterra in NZ High Court after an estimated loss of \$407 million in free cash flow due to whey protein used as an ingredient in their product.
Frozen Foods	Rich Products Corp.	2013	U.S.	E. coli contamination results in recall of over 10 million pounds of potentially contaminated products. Loss estimated at in excess of \$10 million for recall expense, value of products and lost profit.
Yogurt	Chobani	2013	U.S.	Leading Greek Yogurt manufacturer issues recall due to mold associated with dairy products. The resulting negative publicity, destroyed product and refunds caused significant financial damage. Actual loss costs unknown.
Automobiles	General Motors	2014	U.S.	General Motors announced more than 60 recalls involving 29 million vehicles. Second-quarter profits were down 80% from the prior year and included the impact of \$1.2 billion in recall-related repairs.
Fruit	Wawona	2014	U.S.	Nationwide recall of stone fruits and baked goods containing potentially tainted fruit.
Beer	Constellation Brands	2014	U.S.	Recall of Corona Extra Beer due to glass contamination leads to more than \$10 million in recall-related costs.

Ice Cream	Blue Bell Creameries	2015	U.S.	Blue Bell voluntarily recalled all of its products made at all of its facilities, including ice cream, frozen yogurt, sherbet, and frozen snacks because they had the potential to be contaminated with <i>Listeria monocytogenes</i> . Estimates of the loss of income and recall related expense were estimated in excess of \$100 million
Air Bag Inflators	Takata	2015	U.S.	Largest automotive recall in U.S. history with 34 million units recalled from 12 automakers. NHTSA imposes a \$200 million civil penalty against company.
Frozen Vegetables	CRF Frozen Foods	2016	USA	<i>Listeria monocytogenes</i> genetically linked to frozen vegetables. Approximately 358 consumer products sold under 42 separate brands were recalled.
Galaxy Note7 Smart Phones	Samsung	2016	USA	1.9 million units recalled due to overheating of batteries. Ultimately leads to FAA banning these phones from airplanes. Loss estimates have exceeded \$5 billion.
ConAir (Cuisinart)	Food processors	2016	USA	Cutting blades can break contaminating food products. This recall affected some 8 million products dating as far back as 1996, making it one of the largest appliance recalls in history.

The Regulatory Agencies

New FDA Commissioner and New Rules Enforce Food Safety Moderation Act

Early in 2016, Dr. Robert Califf was confirmed the new commissioner of the FDA after a long search process. Califf succeeds Margaret Hamburg, who left the role in March 2015. As commissioner, Califf has overseen the implementation of the final rules of the bipartisan Food Safety Modernization Act (FSMA), which was passed in 2011.

During 2016 the FDA announced the completion of all seven new food safety rules that implement the core of the FSMA. These historic rules build on the preventive controls rules the FDA finalized in September 2015, which mandate modern preventive practices in food processing and storage facilities. Together, these rules work to systematically strengthen the food safety system.

Seven Final Rules Implementing the Food Safety Modernization Act

1. Preventative Controls for Human Food

requires that facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan.

2. Preventative Rule for Animal Feed

require Current Good Manufacturing Practices (CGMPs) be established for animal food production. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls.

3. The Produce Safety Rule

establishes science-based standards for growing, harvesting, packing, and holding produce that are designed to work effectively for food safety across the wide diversity of produce farms. The main focus is on standards. When followed, the standards are designed to help minimize the risk of serious illness or death from consumption of

contaminated produce. Public comments and input received during farm visits have shaped this rule into one that will reduce the risk of harmful contamination.

4. The Foreign Supplier Verification Program

rule requires food importers to verify that foreign suppliers are producing food in a manner that meets U.S. safety standards and that they are achieving the same level of food safety as domestic farms and food facilities.

5. The Rule on Accredited Third-Party

Certification, which is part of the FSMA's new food import safety system. This rule establishes a program for the accreditation of third-party certification bodies (auditors) to conduct food safety audits and to certify that foreign food facilities and food produced by such facilities meet applicable FDA food safety requirements.

6. The Sanitary Transportation Rule

is designed to help prevent food contamination during transportation. The rule will require those involved in transporting human and animal food by motor or rail vehicle to follow recognized best practices for sanitary transportation, such as properly refrigerating food, adequately cleaning vehicles between loads and properly protecting food during transportation.

7. The Food Defense Rule

is aimed at preventing intentional adulteration including acts of terrorism targeting the food supply. Although such acts are unlikely to occur, the new rule advances mitigation strategies to further protect the food supply. This is the first time that companies are required to create a food defense plan. The FDA has taken an approach similar to the Hazard Analysis Critical Control Point (HACCP) system, an approach adopted by industry for the identification, evaluation and control of food safety hazards. The FSMA rules advance and strengthen those safeguards.

Each covered facility is required to prepare and implement a food defense plan. This written plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification.

In support of the implementation of these rules, the FDA announced their largest allocation of funds yet—\$21.8 million—to help state agencies support implementation of the FSMA. Funding availability will continue for five years, subject to availability of funding from Congress. State governments are full partners with the FDA in implementing the key aspects of produce safety rules under FSMA.

FDA Food Safety Modernization Act (FSMA) Compliance Period

Deadlines for compliance to the rules is dependent upon the business size and run from 2016 through 2021. The Grocery Manufacturers Association (GMA) recently provided a reference sheet for FSMA Compliance Data. The breakdown below shows General Compliance, Small Business Compliance and Very Small Business Compliance Periods.

General Compliance Period

Proposed Rule	Final Rule	Requirement	Deadline
Preventative Controls for Human Food	9-17-15	1 year from final rule	9-19-16**
Preventative Controls for Animal Food	9-17-15	1 year from final rule (cGMP), 2 years for PC	9-19-16
Produce Safety	11-27-15	2 years + 60 days from final rule*	1-26-18
Foreign Supplier Verification Process	11-27-15	18 months from final rule†	5-27-17
3rd Party Accreditation and Certification	11-27-15	After Model Accreditation Standards***	-
Sanitary Transportation	4-06-16	1 year from final rule	4-06-17
Food Defense	4-06-16	3 years from final rule	5-28-19

Small Business Compliance Period

Proposed Rule	Final Rule	Requirement	Deadline
Preventative Controls for Human Food	9-17-15	2 years from final rule	9-18-17**
Preventative Controls for Animal Food	9-17-15	2 years from final rule (cGMP), 3 years for PC	9-18-17
Produce Safety	11-27-15	3 years + 60 days from final rule*	1-26-19
Foreign Supplier Verification Process	N/A§	N/A§	N/A§
3rd Party Accreditation and Certification	N/A§	N/A§	N/A§
Sanitary Transportation	4-06-16	2 years from final rule	4-06-18
Food Defense	5-27-16	4 years from final rule	5-28-20

Very Small Business Compliance Period

Proposed Rule	Limit	Final Rule	Requirement	Deadline
PC Human Food	<\$1M	9-17-15	3 years from final rule	9-17-18
PC Animal Food	<\$2.5M	9-17-15	3 years from final rule (cGMP), 4 years for PC	9-17-18
Produce Safety	<\$250K	11-27-15	4 years + 60 days from final rule*	1-26-20
FSVP	<\$1M†	11-27-15	N/A§	N/A§
3PAC	N/A§	N/A§	N/A§	N/A§
Sanitary Transportation	N/A§	N/A§	N/A§	N/A§
Food Defense	<\$10M	5-27-16	5 years from final rule (modified requirements)	5-28-21

Note: this is for informational purposes and does not constitute legal advice. This helpful tool has been generated by The Association of Food, Beverage, and Consumer Products Companies.

All farms have an additional two years to comply with certain water-related requirements. Separate compliance date applicable to sprouts.

*** Supply Chain Program general compliance: later of (1) March 17, 2017 (September 18, 2017 for small business) OR (2) six months after a supplier is required to comply with the applicable rule.*

† All importers must comply with FSVP requirements 18 months after the final rule OR 6 months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later. "Very small importers" and "importers of food from very small foreign suppliers" are subject to modified requirements.

‡ 3PAC's provisions are effective immediately following the final rule, but can only be implemented after publication of Model Accreditation Standards, which are yet to be released by the FDA.

§ If there is no special compliance period noted, then follow the General Compliance Period rule.

Establishment-Specific Data Release Plan

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) announced in mid-2016 that it will soon begin sharing new levels of food safety data specific to slaughter and processing facilities in the United States. Through the Establishment-Specific Data Release Plan, the agency anticipates this will allow consumers to make more informed choices, motivate individual establishments to improve performance, and lead to industry-wide improvements in food safety by providing better insights into strengths and weaknesses of different practices.

The new datasets will begin to publish on a quarterly basis starting 90 days after publication in the Federal Register. Initially, FSIS will share specific information on the processes used at each facility, as well as a facility specific code that will make it easier to sort and combine future datasets. FSIS then plans to release results for listeria monocytogenes, salmonella, E. coli (STEC) and campylobacter in various products, as well as datasets for chemical residue and meat recovery testing.

The Establishment-Specific Data Release Plan was developed in response to President Obama's call for increased data sharing and greater transparency under the Open Government Plan. The FSIS developed a plan that will not only aid consumers but also make data publicly available that could yield valuable insights exceeding the regulatory uses for which the data was collected.

Earlier in 2016, the FSIS announced new food safety measures to reduce salmonella and campylobacter in poultry. New federal standards were set to reduce salmonella and campylobacter in ground chicken and turkey products, as well as in raw chicken breasts, legs, and wings. The FSIS uses pathogen-reduction performance standards to assess the food safety performance of establishments that prepare meat and poultry products. By making the standards for ground poultry more rigorous, ground poultry products nationwide will have less contamination and therefore result in fewer foodborne illnesses. It is estimated that these new standards will prevent 50,000 illnesses annually.

Food Safety Technology

PulseNet

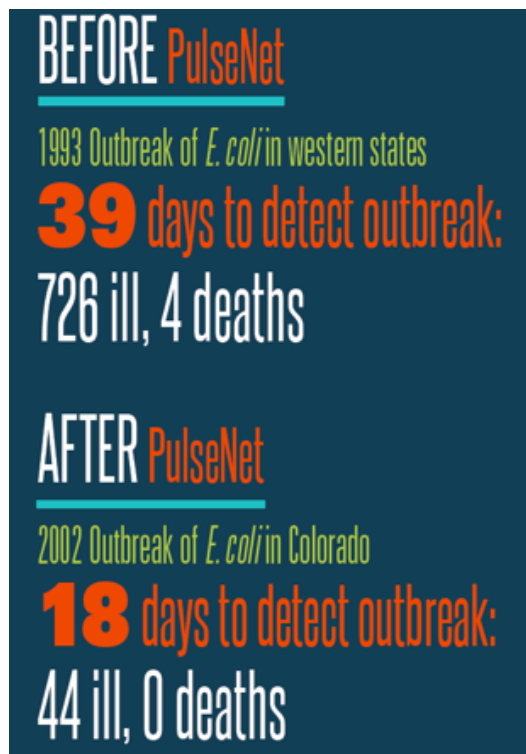
PulseNet, a network run by the CDC which brings together public health and food regulatory agency laboratories throughout the United States, celebrated 20 years of public health achievements in transforming the way we detect and investigate foodborne disease outbreaks.

By connecting cases of foodborne illness and detecting outbreaks, PulseNet, has developed tools including pulsed-field gel electrophoresis and genome sequencing to perform DNA fingerprinting of the bacteria that make people sick. Matching DNA fingerprints indicate an outbreak is occurring and early detection allows scientists to work rapidly to identify the source of the outbreak and prohibit further illnesses.

PulseNet prohibits around 270,000 illnesses every year from the top three causes of foodborne illness (salmonella, *E. coli* 0157 and listeria monocytogenes). Investigations initiated by PulseNet have made many products and food handling practices safer today. Continuous advancements, such as new technology in whole genome sequencing, are making PulseNet a more powerful network by improving its ability to find outbreaks and investigate them more effectively.

Advanced Molecular Detection (AMD)

Industry and regulatory investments in advanced molecular detection (AMD) continue to transform pathogen detection in the U.S. As an example, in 2016, the CDC employed AMD to sequence the DNA of pathogens (i.e., bacteria, viruses, parasites, and fungi) and record data in supercomputers to quickly detect molecular patterns. This ADM process quickly detects molecular patterns that help show the source and spread of disease.



Recent examples of the success of these programs include:

Identifying the source of a Legionnaires' disease outbreak. In fall 2016, the CDC supported a state public health laboratory's investigation of a cooling tower-related outbreak of Legionnaires' disease. The state public health laboratory performed whole genome sequencing analysis on clinical and environmental samples. The CDC quickly compared these genomes using a database comprising hundreds of genomes of legionella. This allowed the state to identify the cooling tower that needed to be remediated to control the outbreak. Legionnaires' disease is on the rise; in recent years about 5,000 people were diagnosed and at least 20 outbreaks were reported in the United States. AMD technologies will improve the ability to quickly identify outbreak sources and prevent more disease.

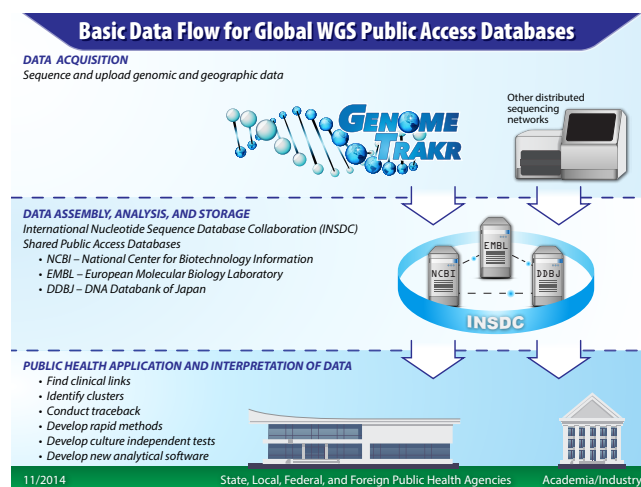
Two Listeria strains linked to facility. In March 2016, the CDC along with public health officials in several states and the U.S. Food and Drug Administration, investigated listeria in environmental and food samples from a Washington State company that produces frozen vegetables. Nine people were infected and three died. Investigators used the PulseNet system, the national subtyping network of public health and food regulatory agency laboratories coordinated by the CDC, to identify illnesses that may have been part of this outbreak. At the end of the investigation 350 consumer products sold under 42 separate brands were recalled, as well as at least 100 other products prepared by other companies that contained recalled ingredients from the company. By expanding advanced molecular detection methods, we can get contaminated products off store shelves sooner.

The GenomeTrakr Network

The FDA is also increasingly using technology to more rapidly identify foodborne pathogens and trace them to their source with unprecedented detail and clarity. The GenomeTrakr Network, consisting of laboratories with whole genome sequencing capabilities, was established to facilitate the sharing of pathogen sequence data between public health agencies, academia, and the food industry, with the goal of preventing large-scale foodborne illness outbreaks. Whole genome sequencing (WGS) lets scientists look at the DNA fingerprint of pathogens, bacteria that cause disease. (WGS) technology can show the relationship among isolates of bacterial pathogens found either in the environment, from a food source or from a person who became ill from consuming contaminated food.

Internationally, we are also seeing increased cooperation between countries on issues of food safety. The FDA, the Canadian Food Inspection Agency and Health Canada have signed a Food Safety Systems Recognition Arrangement. Systems Recognition establishes a framework for regulatory cooperation in a variety of areas that range from scientific collaboration to outbreak response. This arrangement is based on reciprocal food safety systems assessments. The arrangement offers benefits to each country and will consider the oversight of the partner country when prioritizing inspectional activities.

By recognizing each other's systems, the FDA, CFIA, and Health Canada have confidence that they can leverage each other's science-based regulatory systems. This is the second time that the FDA has recognized a foreign food safety system as comparable, the first being New Zealand in 2012. A similar system recognition process is underway between the FDA and Australia and the European Commission.



Source: <https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm403550.htm>

Social Media—Spreading the News—Good and Bad

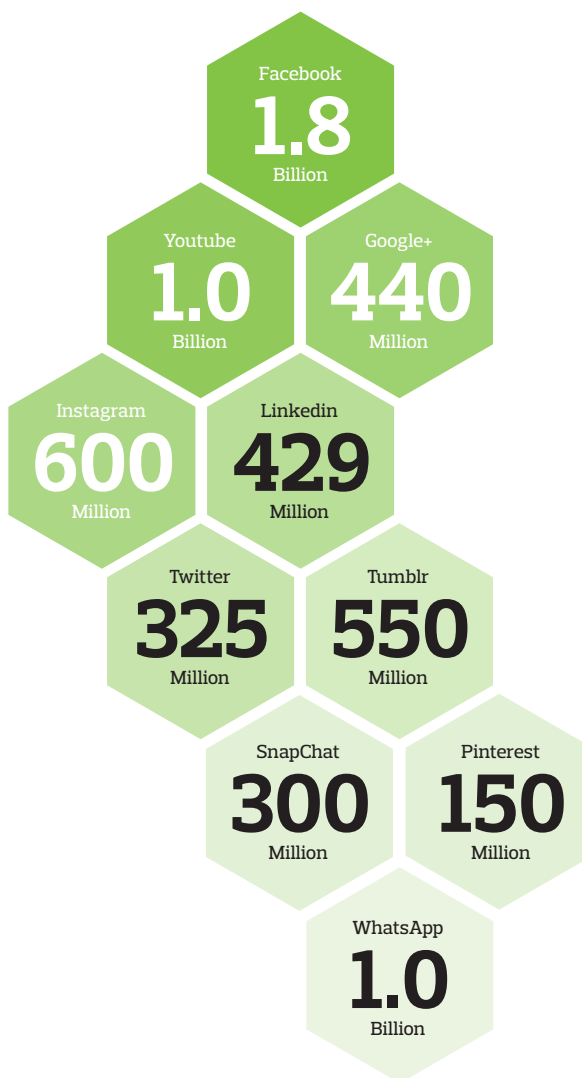
Social Media Monitoring

Estimates show the growth in social media increasing from just under one billion users in 2010 to an estimated three billion users in 2020. Today, the largest media company in the world is Facebook, and everyone is a publisher. YouTube reaches more adults (ages 18--34) than any cable network. Managing this exposure is vital to protecting a company's brand.

Building a proactive social media plan is an essential part of any company's overall food defense strategy. Most companies now recognize the power of social media and how it can be a useful tool in promoting a company's brands. Social media sites are increasingly becoming the way we read and comment on the day's events. It is also an outlet for disgruntled employees, customers and special interest groups looking to cause harm or damage to a brand.

The ability to quickly spot and respond to trends involving your products is crucial in today's world. Increasingly, companies are taking a proactive approach to social media to both mitigate risk and build trust with consumers. An assortment of social listening and monitoring software is now available to assist companies with their social media strategy. Monitoring for certain key words and brands can alert a company to both negative and positive trends involving their brand. Social media not only spreads the news of a dangerous product faster than ever before; it may also be used as a means for revenge, financial gain or other illegal activity. Integrating a company's public relations, consumer affairs and food safety and quality teams can be an effective way to help mitigate risks and recover brand strength after a negative event.

Social Media Statistics—2017/2016



Source: SmartInsights, Digital Sapiens Media

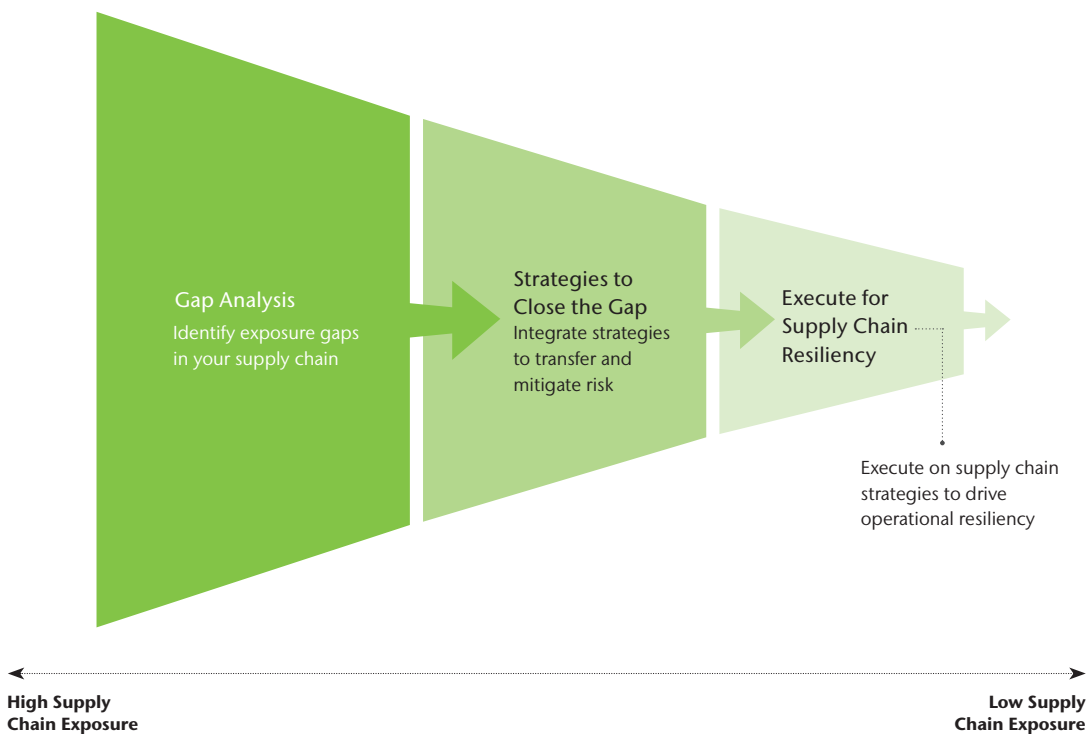
Supply Chain Management

Supply Chain Risk

Product recall or product contamination risk management involves numerous elements working together to properly address the exposure. While risk transfer can be an important element in managing the risk of product contamination, its effectiveness can only be realized with appropriate pre and post loss mitigation strategies to minimize and mitigate the risk. These include quality control and assurance programs, plant security, product traceability and retrieval procedures, as well as recall, crisis management and crisis communication planning. These plans and procedures will form the core of proper risk management of product contamination and should be supplemented by an appropriate risk transfer program. These risks can be either accidental or deliberate (malicious) and despite stringent quality control and assurance procedures, the risk cannot be entirely mitigated.

Further intensifying the exposure is the third-party risk of damage to a customer's brand and reputation due to a contaminated ingredient. The effective management of a company's supply chain, particularly as it relates to the sourcing of ingredients or component parts is a significant factor in evaluating risk. We are increasingly seeing supply contracts request, that at a minimum, a supplier take financial responsibility for damage from a recall caused by ingredients and in many cases are also requiring suppliers to purchase insurance coverage specific to this risk.

Continuum of Supply Chain Exposures



Carrier and Market Update

The insurance marketplace for product contamination and recall capacity remained fairly consistent in 2016. While there has been movement of underwriters and teams between carriers, the carriers themselves have been stable. Policy language has also remained consistent from the prior year, although some nuances and sublimits have been noted amongst carriers. Product specific policies forms have been developed.

As a general statement, underwriters seem to be increasingly wary of food and beverage as a product category. Of particular concern are food processors and distributors of ingredient type products. As noted earlier in this report, several significant recall incidents occurred as a result of an ingredient distributed to multiple firms and used in multiple products. This pyramid effect of a secondary recall has caused many underwriters to look less favorably on ingredient risks or avoid them all together. Underwriters are also scrutinizing supplier audits and supplier contracts more closely as part of their underwriting regime.

While newer detection technologies and methods were expected to increase the number of recalls, it was widely thought that those recalls would be less severe and involve fewer products due to earlier detection. However, the trends we have seen appear to suggest that the trace back technology has resulted in an increase in the time period of product that may potentially be affected with some cases going back years.

With food and beverage products becoming less desirable from a risk transfer standpoint, several carriers are beginning to embrace automotive and non-food consumer products risks. Although the Takata and the Cusinart recalls were certainly severe examples, the frequency of recall is less, particularly for finished consumer goods as the toy recall statistics suggested earlier in this report.

Overall, capacity in the reinsurance market continues to be available and despite difficult loss years for several underwriters, rates are holding steady across most areas and even some reductions for non-food and preferred food risks.

The London market continues, as in past years, to be led by XL Catlin, although there have been recent changes in the global leadership of the recall team. XL Catlin is likely the largest global underwriter of recall risks. XL Catlin announced the repositioning of their U.S. product recall underwriting into London and Bermuda in late 2016. XL Catlin will continue to write U.S. risks out of London and Bermuda. Current XL Catlin U.S. underwritten policies will be submitted through London and/or Bermuda at the policy expiration.

The Hiscox Syndicate, a newer entrant into the recall market, has made significant strides in growing their book of business. Led by former Catlin underwriters, the team has brought significant capacity and innovation to the recall market. New wordings for automotive component recall, as well as retailer/supermarket risks were introduced. Hiscox is also a significant player in the restaurant/food borne illness market.

The Talbot Syndicate also continues to grow across all recall classes for food and non-food business. With \$45 million in capacity, Talbot is a significant carrier for the class.

Unique London capacity to Aon became available on January 1, 2016, with the announcement of the Aon Client Treaty. This facility is an automatic 20% line on orders placed through Aon's Global Broking Centre in London. It follows the pricing, wording, terms and conditions of the lead underwriter for the London order. The capacity behind Aon Client Treaty is 100% Lloyd's, with its A+ S&P Rating, backed by the Lloyd's Chain of Security. Aon Client Treaty's overall leader is XL Catlin with designated leaders for specific classes of business. Aon Client Treaty offers new strategic dedicated capacity from Lloyds exclusively to Aon's clients. The Lloyd's syndicates providing capacity for Aon Client Treaty are committed to Aon Client Treaty for the long term and have subscribed up to a three-year agreement. Aon Underwriting Managers acts as the MGA for Aon Client Treaty and supports the underwriting, reporting, modeling and invoicing for the panel of syndicates.

Domestically, the U.S. market continues to grow and much of the policy innovation is driven by these underwriters. ACE began trading under the Chubb name domestically and while focusing on component-type risks, will also entertain food risks. Chubb is particularly strong in small and mid-sized risks.

Allianz Global Corporate & Specialty (AGCS) announced in early 2016 the launch of its Crisis Management division in North America, with headquarters in Chicago. Allianz has become an important market in the U.S. over the past several years and will entertain all classes of risk and holds significant capacity that can be deployed through most territories of the world.

Houston Casualty Company rebranded itself as Tokio Marine HCC – Specialty Group and remains a major writer in the food and beverage class. Generally, we see Tokio Marine HCC focusing on primary risks with smaller limit requirements. The team, however, has increased capacity up to \$15 million on excess placement. Tokio Marine HCC also has a strong focus on restaurant business where it announced that it has teamed with The Acheson Group to provide crisis response services.

Liberty International underwrites in both the U.S. and London. Liberty has been a steady player for many years and despite some recent changes in team leadership, continues as a strong stable market. Liberty has more recently begun looking at automotive risks and now has the capacity to provide up to \$10 million on a primary basis and up to \$15 million on an excess basis. Liberty announced purchase of Ironshore in December of 2016 has, as of this writing, not had an effect on the Pembroke Syndicate's recall capacity, but will bear watching after the transaction closes.

The Starr Companies are also steady players in the recall and contamination market. With underwriting facilities in the U.S. and London, they will entertain most food and beverage classes including restaurants, as well as non-food consumer products and component parts. Starr will not underwrite automotive recall business.

SwissRe took a new tact in 2016 by hiring an experienced team from Crum & Forster. The team is currently developing new forms and are quoting risks on a primary and excess basis across all product territories including automotive. Prior to this leadership change, SwissRe was primarily an excess or high retention market. SwissRe recently retained the services of red24 as crisis response consultants.

Crum & Forster, Great American, AWAC and Berkley Specialty round out the domestic underwriters for the class with each underwriter having carved a niche within the marketplace. Crum & Forster's announced acquisition of Allied World in December will require monitoring of the companies' combined recall capacity as the transaction closes. AIG also continues as a significant market, though perhaps with more select opportunities, but the company has ample capacity for those select risks.

2017 Global Recall and Contamination Market Capacity

Carrier	Domicile	Food and Beverage		Non-Food	
		Accidental	Malicious	Consumer	Automotive
Aon Client Treaty	London	20%	20%	20%	20%
Ace European Group	Europe / London	\$15m	\$15m	\$15m	\$15m
AIG (Lexington)	US/ Bermuda	\$35m	\$50m	\$25m	n/a
AIG (London)	London	\$25m	\$50m	\$10m	n/a
Allianz	London	€50m	€50m	€50m	€50m
Allianz	US	\$35m	\$35m	\$35m	\$25m
Allied World	US	\$15m	\$15m	\$15m	n/a
Amlin Syndicate 2001	Lloyds	n/a	n/a	GBP1m*	n/a
Apollo Consortium 9398	Lloyds	\$10m	\$10m	\$10m	\$10m
Arch Syndicate 2102	Lloyds	n/a	n/a	n/a	\$15m*
ArgoRe	Bermuda	\$25m	\$25m	\$25m	\$25m
Ascot Syndicate 1414	Lloyds	n/a	n/a	\$25m*	\$25m*
Aspen	Bermuda	\$10m	\$10m	n/a	n/a
Berkley Specialty	US	\$15m	\$15m	\$15m	n/a
Brit Syndicate 2987	Lloyds	n/a	n/a	\$3m	\$3m
CFC	Lloyds	\$10m	\$10m	\$10m	\$10m
Chubb	US	\$15m	\$15m	\$15m	\$15m
Crum & Forster	US	\$10m	\$10m	\$10m	\$10m
C. V. Starr Syndicate 1919	Lloyds	\$15m	\$25m	\$15m	n/a
C. V. Starr	US	\$15m	\$25m	\$15m	n/a
Great American	US	\$10m	\$10m	\$10m	\$10m

Carrier	Domicile	Food and Beverage		Non-Food	
		Accidental	Malicious	Consumer	Automotive
Hardy Syndicate 382	Lloyds	n/a	n/a	\$30m*	\$30m*
HDI Gerling Industrial Insurance Company	London	€15m*	€15m*	€15m*	case by case
Hiscox Syndicate 3624	London	\$50m	\$50m	\$50m	\$50m
Houston Casualty	US	\$10m	\$10m	n/a	n/a
Houston Casualty Excess	US	\$15m	\$15m	\$15m	\$15m
Liberty International	US	\$15m	\$25m	\$15m	\$15m
Liberty Syndicate at Lloyds	London	\$15m	\$25m	\$15m	\$15m
Markel	Bermuda	\$25m	\$25m	\$10m	\$10m
Markel	London	\$25m	\$25m	\$10m	\$10m
Novae Syndicate 2007	Lloyds	\$10m	\$10m	\$10m	n/a
Pembroke Syndicate 4000	Lloyds	\$15m	\$15m	\$15m	\$15m
PLIS	Lloyds	\$25m	\$25m	\$25m	n/a
QBE Syndicate 0386/1886 and QBE Insurance (Europe) Limited	Lloyds / London	n/a	n/a	n/a	€15m*
SwissRe	US	\$25m	\$25m	\$25m	\$25m
SwissRe International	Europe/ London	\$50m*	\$50m*	\$50m*	\$50m*
Talbot Syndicate 1183	Lloyds	\$45m	\$45m	\$45m	\$30m
Tokio Marine Kiln Syndicate 0510	Lloyds	\$20m	\$20m	\$20m	case by case
XL Insurance Syndicate 1209	Lloyds	\$75m	\$75m	\$75m	\$75m
XL Insurance	Bermuda	\$75m	\$75m	\$75m	\$75m
Zurich Insurance plc	London	\$25m*	\$25m*	\$25m*	n/a

*Denotes capacity only available for non-U.S.

Crisis Response and Pre-Incident Services

Most carriers have retained the services of crisis management consultants that are made available to insureds on both a pre-incident and crisis response basis. In fact, policies generally require that these consultants are notified of potential incidents that could give rise to a loss under the policy. These consultants are independent of the insurers, but their fees and expenses are covered under the policy with no retention applying. They can provide valuable advice and assistance in managing a recall crisis.

It is important to note that each of these firms offers various levels of specialization and may utilize and engage outside specialists to assist with aspects of the crisis. This may include other public relations, recall logistics or product testing firms. Underwriters and their partners can assist in developing a successful recall risk management program by bringing valuable expertise to their insureds in the form of crisis communication, quality control and recall logistics.

The company red24 is the consultant retained by many of the carriers. It offers a wide range of services to help clients minimize risks to their personnel, business operations and profitability. With an operational footprint in well over 120 countries, the company provides a range of services to support clients on a 24/7 basis so they can mitigate their risk exposure while also having access to a global network of technical, testing, crisis PR and legal specialists. In December of 2016, iJET International, (iJET) announced the acquisition of red24. Founded in 1999, iJET is a privately held company headquartered in Annapolis, MD, with offices in London, Singapore and Cape Town.

The Acheson Group (TAG) is retained by XL Catlin. Founded by Dr. David Acheson, former Chief Medical Officer for the USDA and FDA, The Acheson Group focuses on assessing and managing operational risk. Dr. Acheson was intimately involved in the development of the 2007 Food Protection Plan, which served as the basis for many of the authorities granted to the FDA by the FSMA. The Acheson Group also responds to Tokio Marine HCC's restaurant contamination program.

Stericycle ExpertSolutions, a division of Stericycle, Inc., is the retained consultant for Tokio Marine HCC. The team provides a comprehensive range of reputation management services and crisis response services across the globe. With over 20 years of experience, the firm has managed approximately 5000 recall events including food, beverage, pharmaceutical, consumer and automotive products. ExpertSolutions also produces an excellent quarterly Recall Index.

Security Exchange is the response firm retained by the Talbot Syndicate. Working primarily in the London insurance market, the firm provides pre-risk consulting to help companies develop contingency plans to reduce exposure in the event of a claim and improve communication between the insurer and the insured for product contamination events. It also provides 24-hour response in the event of an incident. Security Exchange increased their domestic capabilities in 2016 with the hiring of consultants based in the U.S. The firm announced that it would join The Chelsea Group in 2016. Following the acquisition, Security Exchange will form a division of the enlarged Chelsea Group, providing enhanced specialist insurance risk management consultancy services to its clients, including underwriters, brokers and their insureds.

RQA, Inc., formerly retained by the Catlin Syndicate, remains active in recall response and has been approved by several carriers to provide pre-incident services and crisis response for product recall. In order to have fees and expenses paid by carriers, it is important to receive pre-approval from the carrier. RQA serves clients across all products, including restaurant risks, and the company can provide auditing and response services on a global basis.

Cahill Consultants, Inc. is retained exclusively by Chubb and provides product safety and regulatory compliance assistance to companies to help reduce the potential for a product recall or product liability lawsuit. Founded by Katherine Cahill, with over twenty-five years of experience, the firm specializes in product issues related to the CPSC, FDA, USDA, NHTSA and other regulatory agencies.

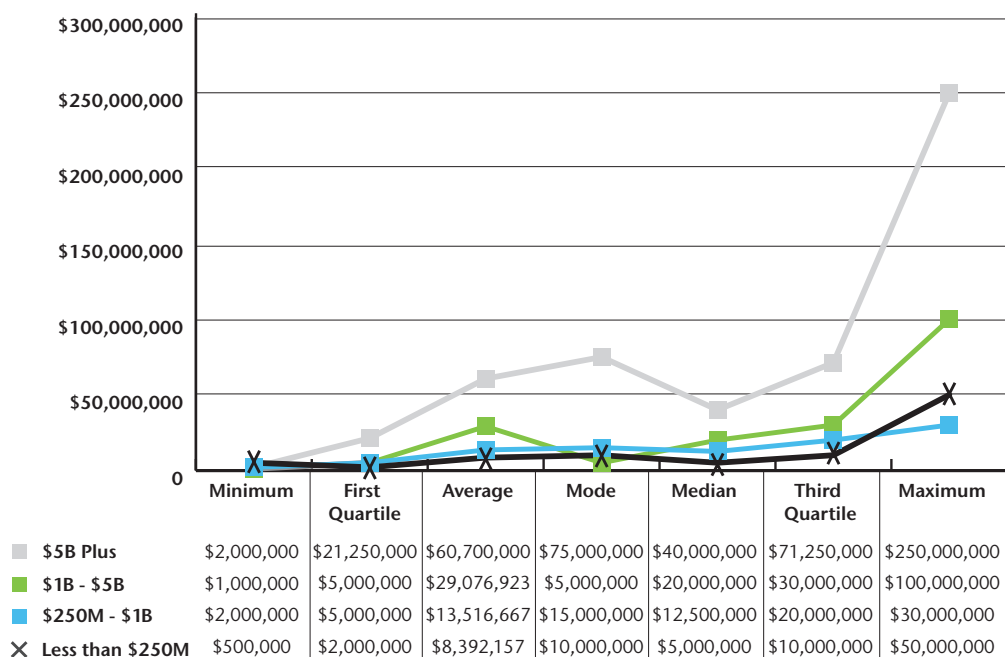
Control Risks is traditionally more thought of as a crisis management extortion consultant in relation to product risks. However, Control Risks has recently expanded into the food safety consulting area and has been expanding their capabilities and network. Control Risk provides services to Hiscox (in addition to red24).

Product Recall and Contamination Benchmarking

Data is critical to making intelligent business decisions. How effectively businesses develop, manage, and utilize data impacts the quality of those decisions. Although recall and contamination events continue to receive a high profile in the media and press, actual damage or loss of vital information is seldom publicized. The size or severity of a loss may very well be more dependent upon the handling of the media and public perception rather than the size of the recall itself. Projecting the exposure to a product recall or contamination can be a difficult task not only for the company at risk but also for underwriters as well.

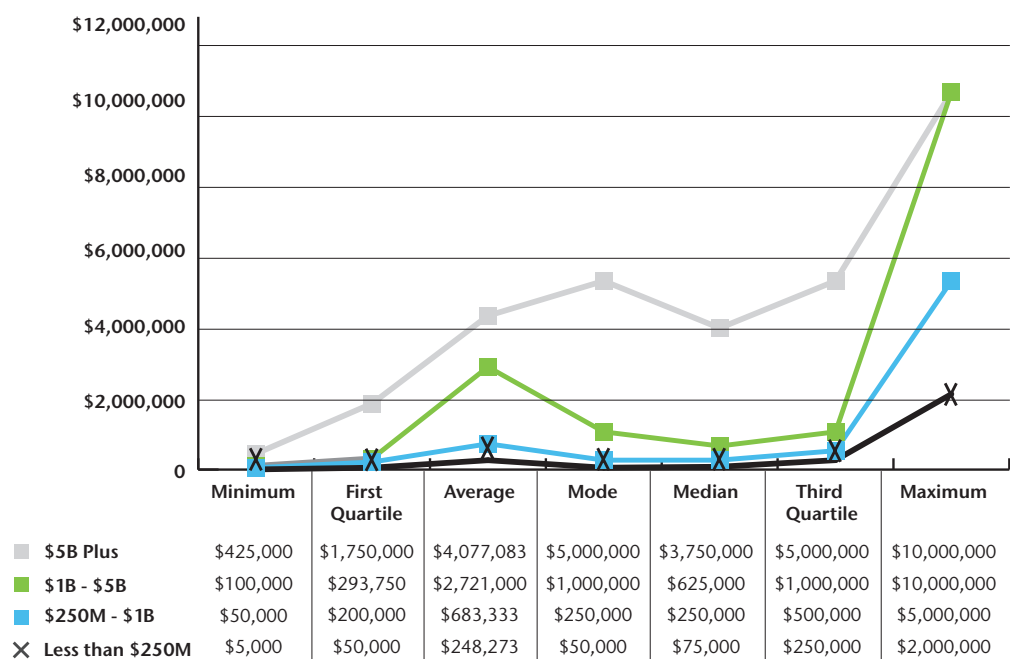
Aon Crisis Management has developed a benchmarking process that enables clients to better understand their potential exposure to product recalls and contaminations. Utilizing a proprietary database of current Aon Crisis Management placements, our benchmarking analysis is able to provide detailed peer group studies on limits, retentions and rates on a global basis. This tool allows us to view data by revenue size, industry or product category providing a valuable tool in helping to determine appropriate limits and retentions. The data provided is in a summary format; however, client-specific reviews based on exposures and products are available.

2017 Limit Profiles—Ingestible/Topical Products



Aon Crisis Management proprietary database

2017 Retention Profiles—Ingestible/Topical Products

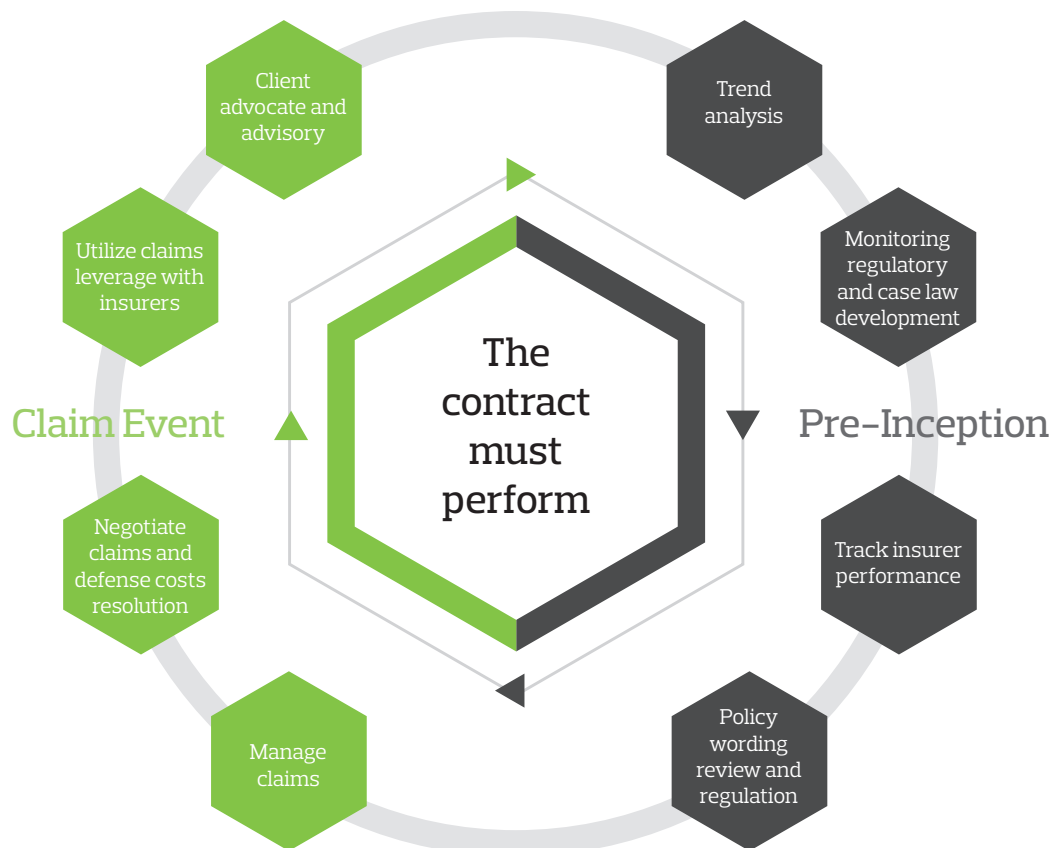


Aon Crisis Management proprietary database

Claims Valuation and Advocacy

Successfully navigating a product recall claim requires numerous moving parts. When a recall or contamination crisis occurs, events move quickly. How a company responds to these challenges may well dictate how quickly and successfully it recovers. Identifying the proper resources can be difficult, particularly for a risk that may have only have happened infrequently in the company's history.

Recovering from a recall efficiently usually requires the involvement of a company's risk management team from start to finish. Outside expertise in the form of claims advocacy, legal support and forensic accounting and claims preparation can be vital. Coordinating this team's efforts can make the process considerably more efficient and results in an accurate and timely reimbursement of losses. Our experience has shown that the longer a company waits to quantify and document costs and make claims to suppliers and insurers, the more difficult it is to recover those costs. The preservation and collection of key data should begin upon notice of a potential claim.



2017 Recap and Outlook

Looking back at our predictions from last year's report, many of our observations seem to have happened. Overall, rates and coverage remained stable through most of 2016 and some risks, particularly those able to demonstrate good product risk management practices, saw rate reductions. While 2015 was fairly quiet from a claim standpoint for most carriers, 2016 appears to have been somewhat more volatile, particularly on the consumable ingredient side. Those losses then spread over multiple different products and brands, compounding the overall effect on the market.

Unlike 2015, we did not see any significant addition to capacity in the product recall or contamination insurance market. We would anticipate that carriers will continue to be cautious with how they deploy their capacity in 2017 and anticipate seeing carriers taking smaller lines or mitigating their capacity risk through layers. XL Catlin's shutting down domestic underwriting facilities has left something of a void in the small and middle market of the U.S. This should be an opportunity for some of the newer carriers to step in and fill the void. Overall, capacity appears stable, and the reinsurance market continues to make capacity available to underwriters.

Most carriers have accepted coverage extensions for government recall and adverse publicity, as well as third-party recall liability. Likewise, a sublimit for claims preparation expense is also becoming more accepted by carriers. The London market may look to sublimit these extensions, whereas domestic carriers seem to be more comfortable with the extensions. We do anticipate many of the carriers seeking to "specialize" in certain classes of product risk with more of an emphasis on non-food consumer and automotive products. This is a significant change from prior years when underwriters sought the relative safety of known food risks. While consumables will continue to make up the vast majority of product recall policies placed, changes in the regulatory landscape is seen as having enhanced the exposure.

It is clear that companies who look to manage the risk of recall in a holistic manner will be best prepared to survive a recall crisis. Transfer of risk through insurance is just one method to prepare for a recall. A successful recall risk management program must include upfront quality control, management of vendors and contracts, and the ability to respond effectively and efficiently to a crisis. This expertise can be the difference in maintaining the safety of your products, and protecting the trust of your customers.

Aon Crisis Management – Global Product Recall Team



Risk/View

Proprietary Recall Benchmarking



Aon Client Treaty

Unique Aon Capacity

Claims

Dedicated Recall Legal, Claims and Forensic Accounting Support



+40

Aon Global Professionals Specializing in Recall

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Crisis Management

Crisis Management is part of Aon Risk Solutions, the risk management and insurance brokerage business of Aon Corporation.

Going beyond traditional risk transfer solutions, our global network of product contamination and recall specialists offers a full range of consultancy services, enabling clients to quantify their risk exposure and make informed decisions on the optimum balance between risk retention, risk management and risk

transfer. Our team of specialist brokers, crisis consultants and in-house claims management combines threat assessment, impact analysis and crisis management, and response with individually structured insurance programs. Our unique, consultative approach enables our clients to implement the most appropriate measures to meet their duty of care and better protect their balance sheet, people, brand and reputation.

About the Author

Bernie Steves is the Managing Director of Aon Risk Services Crisis Management Practice based in Chicago, IL. Bernie is recognized as one of the country's leading product recall, contamination, and food borne illness insurance specialists. With more than twenty-five years' experience in this specialty risk management class, he works with some of the largest companies in the United States and Canada to address product recall, contamination, and food borne illness exposures. Bernie's background includes years of experience from both the underwriting and specialty brokering disciplines having specialized in this field since 1987.

He is a frequent author and speaker on the topics of product contamination and recall insurance. Bernie is a graduate of the University of Arizona and holds a Masters in International Management from the American Graduate School of International Management (Thunderbird). He recently completed his International HACCP Certification from the North Carolina State University. Additionally, Bernie is a licensed insurance producer and a licensed surplus lines insurance producer and a 2016 Risk & Insurance® Power Broker® award recipient.

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About Aon

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