

THIRD QUARTER 2012

ExpertRECALL

QUARTERLY RECALL INDEX





Overview

The ExpertRECALL Index tracks recall activity and trends in five product categories: medical devices, pharmaceuticals, food, consumer products and children's and infant products. Highlights of recall activity in the third quarter of 2012 included:

70
percent

increase in medical device recalls in the third quarter of 2012—the most number of recalls documented in at least nine quarters.

140
percent

increase in the number of pharmaceutical recalls in the third quarter—the most number of recalls documented in at least nine quarters.

414
recalls

of food at the initiation of FDA which represents a rate of more than 4 FDA food recalls each day in the last quarter.

12.4
million

units affected by consumer product recalls across all 15 product categories in the third quarter of 2012.

6.9
million

units affected by children's and infant product recalls initiated by the CPSC during the third quarter of 2012.

Recall Index – Third Quarter 2012

How the ExpertRECALL Index is Compiled

The ExpertRECALL Index gathers and tracks cumulative data from the two primary federal agencies that oversee recalls in the United States: the Consumer Product Safety Commission (CPSC) and the Food and Drug Administration (FDA). Recall trends are calculated from FDA enforcement reports and news releases published on agency websites.

FDA Data

To track trends in food, pharmaceutical, and medical device recalls, the ExpertRECALL Index uses information publicly available in news releases posted on the FDA website. For additional insight into recalls governed by the FDA, Stericycle ExpertRECALL collects and analyzes data from the agency's weekly enforcement reports, which provide additional details, including recall class, quantity of units affected, and number of reported incidents.

CPSC Data

For further insight into consumer product recall trends, Stericycle ExpertRECALL analyzes information data from CPSC recall announcements. When compiling statistics and analyzing trends for consumer product recalls, the ExpertRECALL Index uses standard product categories and hazards recognized by the CPSC.

Terminology

Announced recalls represent events documented in news releases published on agency websites. Enforced recalls refer to events documented in weekly FDA enforcement reports. Their documentation can lag behind announced recalls by weeks or even months because a recall process may take time to complete.

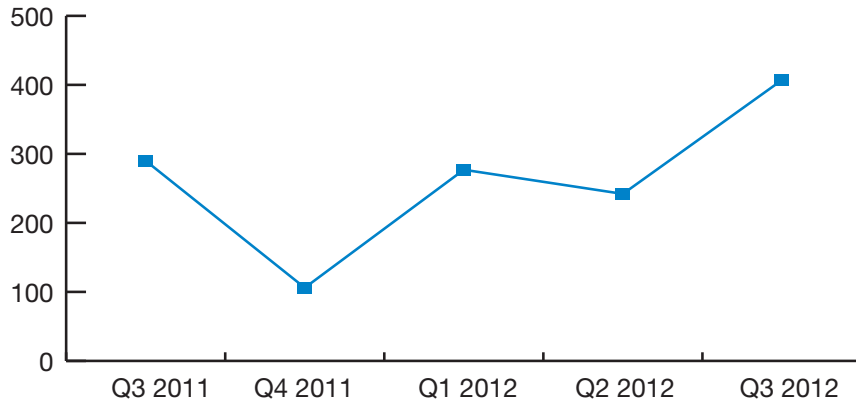
A Class I recall, according to the FDA, is a situation in which there is a reasonable probability that the product will cause serious adverse health consequences or death. A Class II recall is a situation in which the product could cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. The FDA defines a Class III recall as a situation in which the product is not likely to cause adverse health consequences.



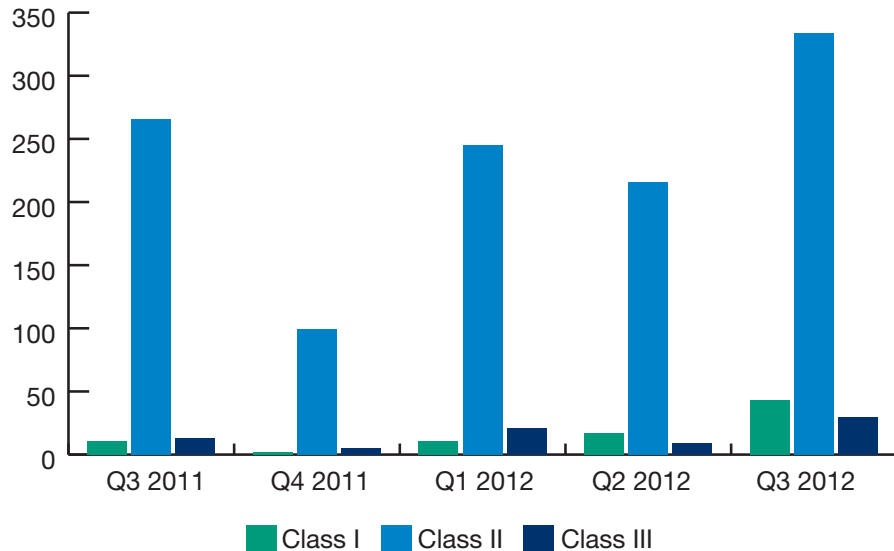
Recall Index – Third Quarter 2012

Medical Device Recalls

**Medical Device Recalls
According to FDA Enforcement Reports**



**Medical Device Recalls by Class
According to FDA Enforcement Reports**



FDA Enforcement Reports for the third quarter of 2012 documented 407 medical device recalls, reflecting the highest number of recalls in at least the last nine quarters. This reflects a nearly 70 percent increase compared with 242 recalls in the second quarter, and a 40 percent increase in recalls compared with the same quarter last year.

The 407 medical device recalls affected nearly more than 26.5 million units, compared with nearly 123.5 million recalled units affected in the second quarter. The number of recalled units is at its lowest level since the fourth quarter of 2011. Two of these recalls affected more than 5 million units. Third quarter recalls affected about one-fifth the number of units as the previous quarter, despite the dramatic increase in recall events.

Medical device recalls documented during the third quarter of 2012 affected customers in the U.S. and overseas. Of the documented recalls, 132 affected customers nationwide. Of third quarter recalls, 258 affected customers in the United States and at least one other country or territory. Thirteen recalls affected U.S. customers in limited geographic regions. Two recalls affected only customers outside of the United States. Geographic distribution was not documented for two recalls.

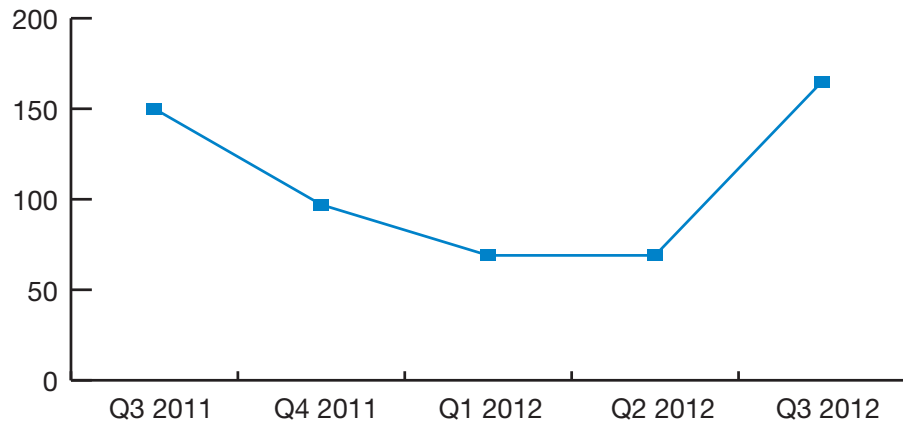
The ExpertRECALL Index analysis also revealed the following:

- 40 percent of companies named in FDA Enforcement Reports in the third quarter of 2012 were involved in more than one recall.
- Forty-three recalls were classified as Class I, more than doubling the number of Class I recalls in the second quarter of 2012 and reaching the highest level of recalls for that category in at least the last nine quarters.
- Class I recalls in the third quarter affected 5 percent of recalled units.

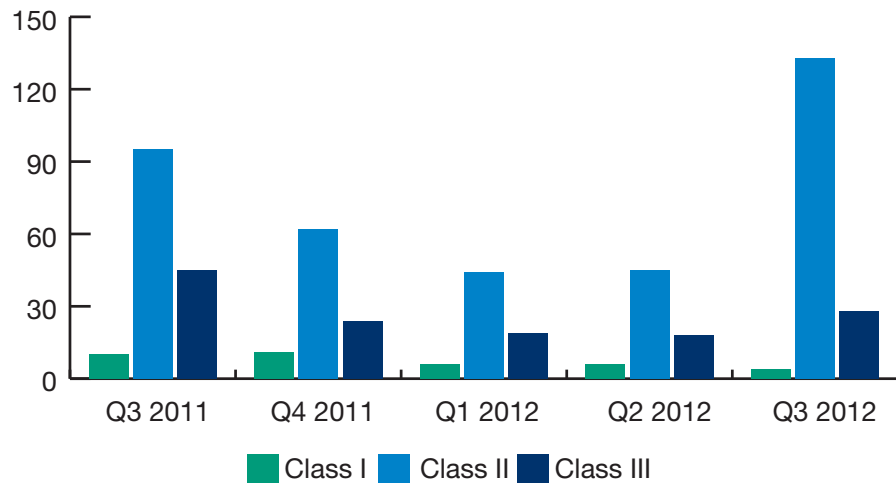
Recall Index – Third Quarter 2012

Pharmaceutical Recalls

**Pharmaceutical Recalls
According to FDA Enforcement Reports**



**Pharmaceutical Recalls by Class
According to FDA Enforcement Reports**



FDA Enforcement Reports documented 165 recalls of drugs and pharmaceutical products during the third quarter of 2012, more than doubling the number of recalls documented in the second quarter and reaching the highest level seen in at least the last nine quarters. While the number of recalls documented significantly increased in the third quarter, these recalls affected about 16.2 million units, just 1 million more units than second quarter recalls.

Four recalls were classified as Class I recalls, 133 were designated as Class II recalls and 28 were assigned Class III status. Two recalls of the 165 documented affected over-the-counter (OTC) products. Both recalls were designated as Class III and affected just 1 percent of all units recalled. The remainder of recalls affected prescription medications.

Pharmaceutical recalls in the third quarter affected customers both in the U.S. and overseas. Of recalls documented in the third quarter, 50 affected customers nationwide and 102 recalls affected customers in the United States and at least one other country or territory. Thirteen recalls affected U.S. customers, but only in limited geographic areas.

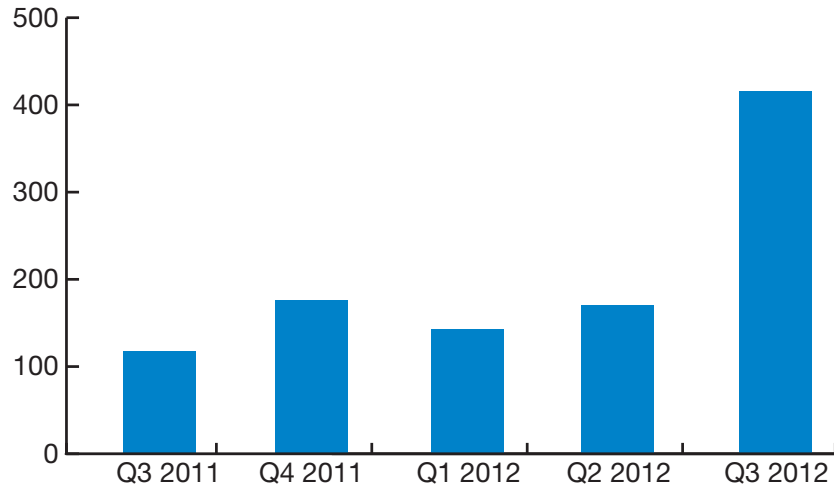
The ExpertRECALL Index analysis also revealed the following:

- According to FDA Enforcement Reports, five recalls affected between 1 million and 5 million units; five recalls affected between 500,000 and 1 million units while the remaining recalls affected fewer than 500,000 units.
- Recalls documented in the third quarter affected 52 companies, with 18 companies facing more than one recall. In other words, more than one-third of companies named in third quarter Enforcement Reports were affected by more than one recall. This is the highest percentage of repeat violations by companies in at least the last nine quarters.
- 80 percent of recalls were designated as Class II recalls. These recalls affected more than 76 percent of units recalled.

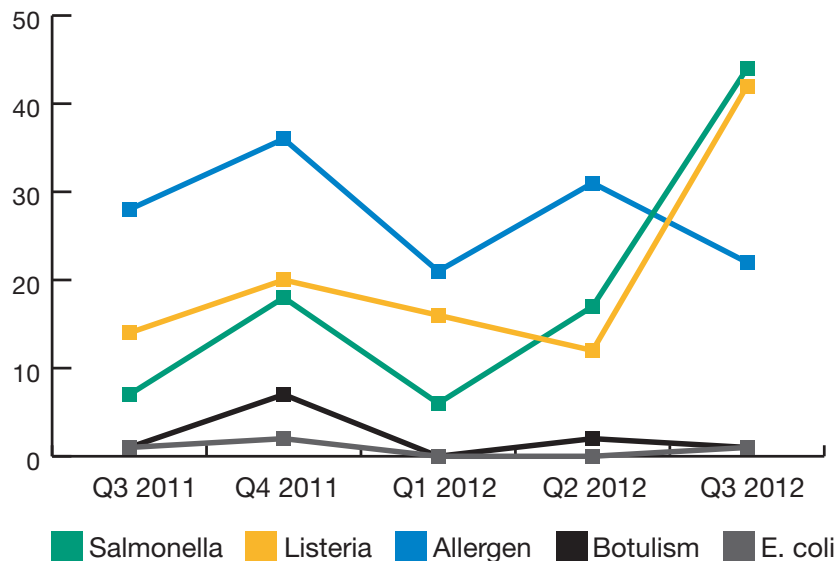
Recall Index – Third Quarter 2012

Food Recalls

Food Recalls by Quarter
According to FDA Enforcement Reports



Leading Causes of Food Recalls
According to Recall Announcements on FDA Website



FDA Enforcement Reports documented 414 food recalls in the third quarter of 2012, 2.5 times the number of recalls documented in the second quarter. Recall activity in the third quarter of 2012 reached the highest level in at least eight quarters.

Recalls documented in the third quarter were initiated by 189 companies. Of these companies, 44 faced more than one recall. Nine of these companies were linked to 10 or more recalls during the third quarter.

Third quarter recalls affected nearly 8.5 million units. This reflects a 57 percent increase in units affected compared with the previous quarter, but a 78 percent decrease compared with the same quarter in 2011. According to the documentation, two recalls affected between 1 million and 5 million units and 1 recall affected between 500,000 and 1 million units.

Of recalls documented in FDA enforcement reports during the third quarter, 58 percent were listed as Class I, 38 percent were listed as Class II and just 4 percent were listed as Class III. More than 55 percent of all units recalled were part of Class I recalls, which put consumers at the highest risk.

Of the 414 recalls documented in the third quarter, 359 recalls affected U.S. customers in only certain states; while 30 affected customers nationwide. Nineteen recalls affected customers in the United States and at least one other country or territory. Six recalls affected only international customers.

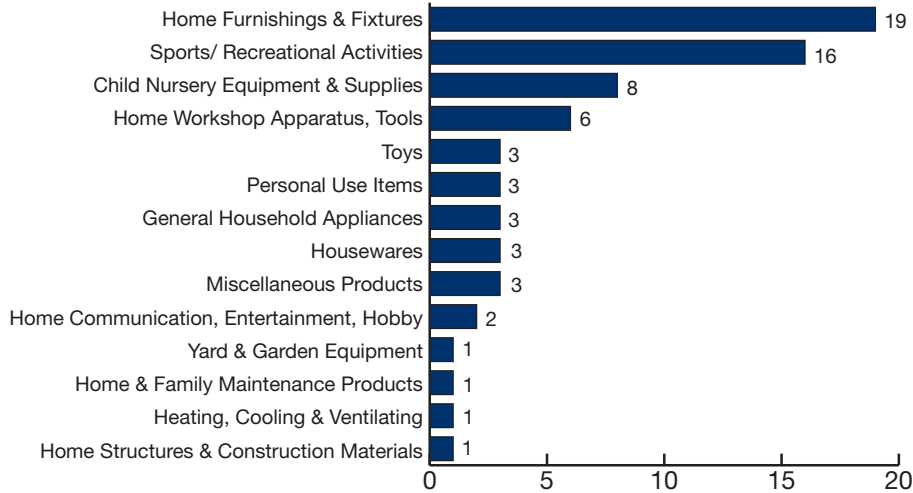
The ExpertRECALL Index analysis also revealed the following:

- The number of recalls announced in the third quarter as published on the FDA website reached the highest level recorded in the last ten quarters.
- Foodborne illness concerns, specifically *Salmonella*, *Listeria*, *E. coli* and *Botulism*, accounted for 74 percent of recalls initiated during the third quarter. *Salmonella* concerns were the number one cause of recalls, followed closely by *Listeria*.
- Undeclared allergens or other allergen concerns were responsible for 18 percent of food recalls, falling to the third most common cause for recalls in the third quarter, after spending more than eight quarters as the leading cause of recalls.
- Improper processes to control pathogens, the lack of key ingredients, foreign material, elevated levels of lead and *Staphylococcus aureus* concerns were also among the reasons for recalls announced during the quarter.

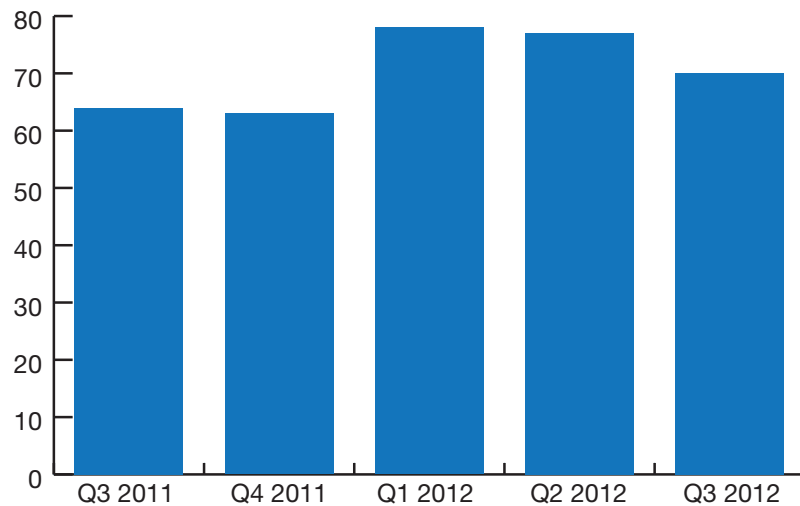
Recall Index – Third Quarter 2012

Consumer Product Recalls

CPSC Recalls by Product Category In the Third Quarter of 2012



Consumer Product Recalls by Quarter



Seventy recalls of consumer products were initiated at the request of the CPSC during the third quarter of 2012, down slightly from 77 recalls announced the previous quarter. Third quarter recalls affected approximately 12.4 million units compared with 7.5 million units in the second quarter.

Third quarter recalls were connected with 2,609 product safety incidents, down from 3,202 incidents reported in the second quarter. One recall was linked to 1,232 of these product safety incidents. Of the reported incidents, 190 resulted in injury and 3 resulted in death.

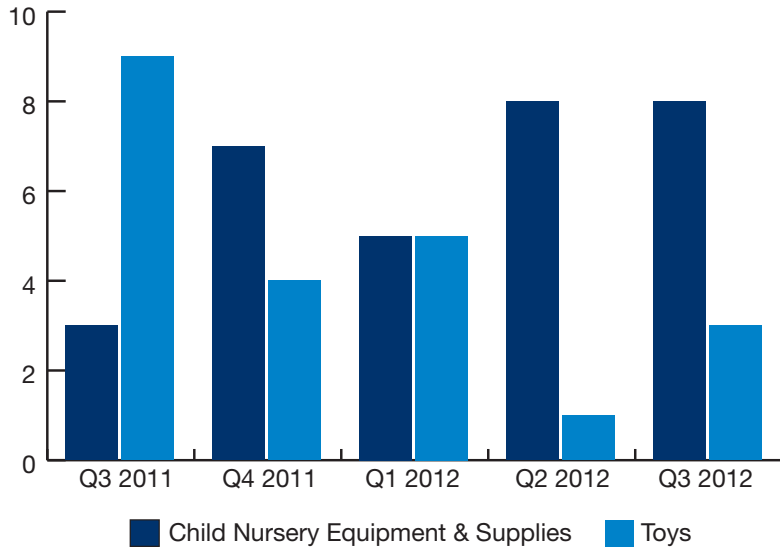
During the third quarter, the CPSC initiated more recalls than the previous quarter in the toys; home communication, entertainment, and hobby; home workshop apparatus and tools; home and family maintenance products; general household appliance; home furnishings and fixtures; home structures and construction materials; and miscellaneous products categories.

The ExpertRECALL Index analysis also revealed the following:

- More than one-quarter of third quarter recalls affected products in the home furnishings and fixtures category.
- Concerns related to structural collapse were the leading cause of recalls during the third quarter. Laceration and over-heating risks were the second-leading causes.
- During the third quarter, 66 companies initiated recalls. Three companies initiated more than one recall at the request of the CPSC.
- The CPSC did not recall any products in the product packaging and containers category.
- Recalls of tools and home workshop apparatus products reached an eight-quarter high.

Children’s and Infant Product Recalls

Children’s and Infant Product Recalls

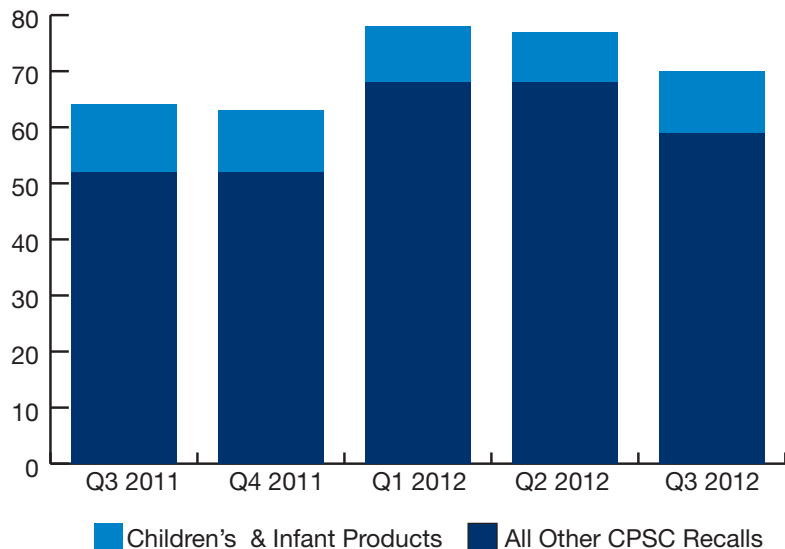


Eleven recalls of nursery equipment and supplies and toys were initiated at the request of the CPSC during the third quarter of 2012. Recalls of child nursery equipment and supplies remained steady at eight recalls when compared with last quarter, while recalls of toys increased to three recalls from just one recall announced during the second quarter.

Of the fifteen product categories recognized by the CPSC, two accounted for just 16 percent of all recalls in the quarter and affected approximately 6.8 million units – more than half of all units recalled by the CPSC during the third quarter.

The primary cause of children’s and infant product recalls were risks that a child could fall out of the product, which led to three recalls. Other major hazards included entrapment and strangulation risks and concerns related to choking and small parts; each of which caused two recalls. Laceration risks, hazardous materials, overheating concerns and risks of structural collapse each led to one recall.

Children’s and Infant Products Recalls Within the Consumer Product Recall Category



The ExpertRECALL Index analysis also revealed the following:

- Eleven companies initiated recalls in the third quarter. None experienced more than one recall.
- Recalled children’s and infant products were responsible for 122 reported product safety incidents, which resulted in 27 injuries and 1 death.
- Two recalls affected more than 1 million units. Each of the remaining nine recalls affected fewer than 500,000 units.
- The number of third quarter recalls increased 22 percent compared to the second quarter and decreased 8 percent compared with the third quarter of last year.