

**FOURTH QUARTER 2011**

**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 fourth quarter of 2011 included:

**63**

percent

decrease in medical device recalls quarter-over-quarter, reaching a five-quarter low.

**35**

percent

decrease in pharmaceutical recalls quarter-over-quarter.

**80**

percent

increase in units affected by fourth quarter food recalls, reaching a four-quarter high.

**63**

recalls

of consumer products were announced in the fourth quarter, representing a five-quarter low.

**45**

percent

of all children's and infant product recalls were initiated out of a concern for the choking risk associated with small parts.

## Recall Index - Fourth Quarter 2011

### 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

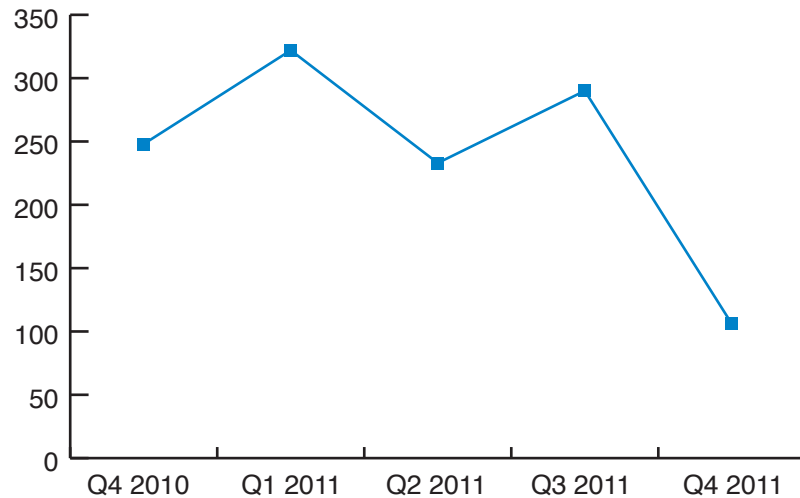
Announced recalls represent events documented in news releases published on agency websites. Enforced recalls refer to events documented in weekly FDA enforcement reports. Their documentation can lag behind announced recalls by weeks or even months because a recall process may take time to complete.

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.

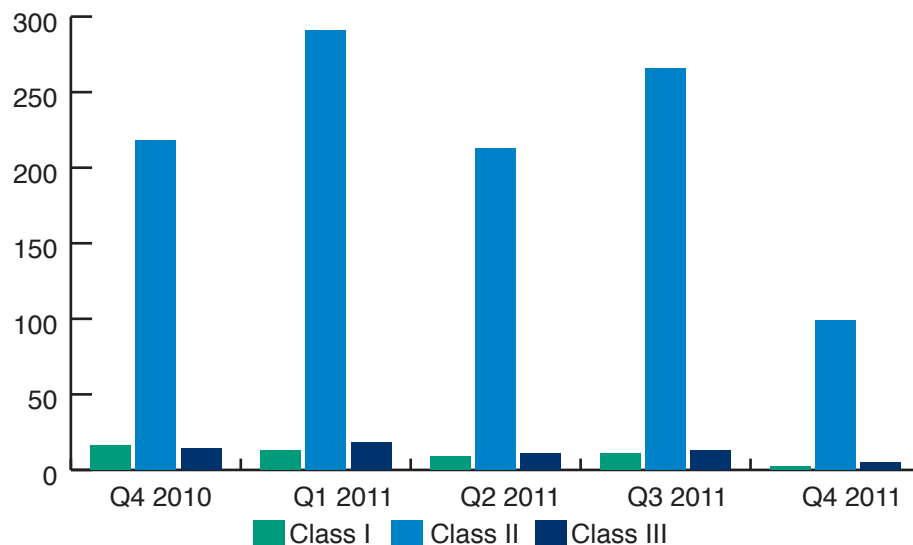
# Recall Index - Fourth Quarter 2011

## Medical Devices

Medical Device Recalls  
According to FDA Enforcement Reports



Medical Device Recalls by Class  
According to FDA Enforcement Reports



During the fourth quarter of 2011, FDA Enforcement Reports documented 106 medical device recalls involving more than 13 million units. This reflects a more than 63 percent decrease in recalls over the previous quarter, and a more than 57 percent decrease in the number of recalls over the same quarter last year.

Medical device recalls in the fourth quarter affected consumers both in the U.S. and overseas. Of the 106 recalls documented in FDA enforcement reports, 98 affected customers nationwide. Seventy-three recalls affected customers in both the U.S. and at least one other territory or country. Three recalls affected only customers outside the U.S.

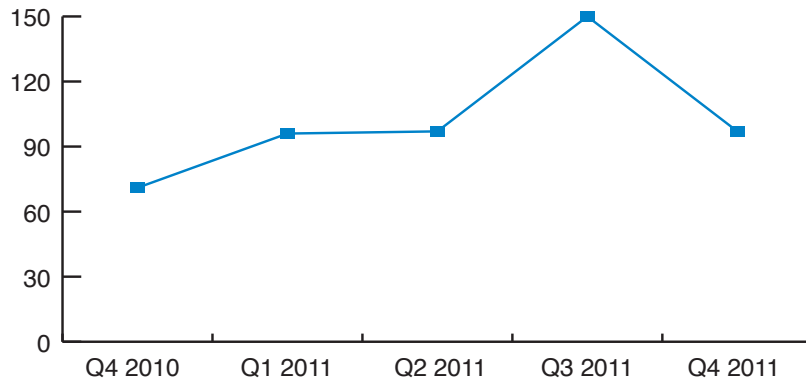
The ExpertRECALL Index also revealed the following:

- Medical device recalls decreased in the fourth quarter of 2011; fourth-quarter recalls reached the lowest number of recalls documented in the last five quarters.
- Fourth-quarter recalls affected less than half the number of units as recalls documented in the third quarter of 2011.
- Four recalls in the fourth quarter affected more than 1 million units.
- Less than 2 percent of recalls in the fourth quarter of 2011 were classified as Class I; these recalls affected less than 1 percent of all units recalled in the quarter.
- More than 93 percent of medical device recalls in the fourth quarter were classified as Class II recalls, accounting for more than 99 percent of all units recalled.
- More than 60 companies initiated at least one recall in the fourth quarter; more than a dozen companies issued more than one recall.

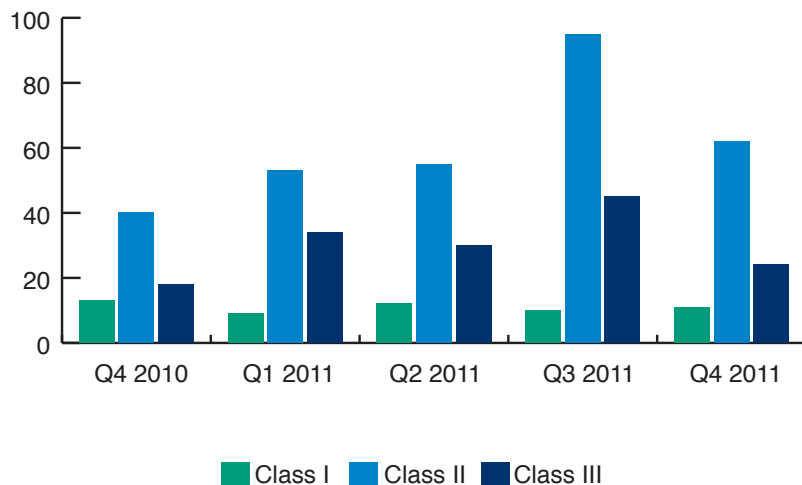
# Recall Index - Fourth Quarter 2011

## Pharmaceuticals

Pharmaceutical Recalls  
According to FDA Enforcement Reports



Pharmaceutical Recalls by Class  
According to FDA Enforcement Reports



FDA enforcement reports documented 97 pharmaceutical recalls in the fourth quarter of 2011, affecting more than 92 million units. While the number of recalls in the fourth quarter of 2011 decreased more than 35 percent over the previous quarter, fourth-quarter recalls affected 200 percent more units than recalls documented in the third quarter of 2011.

Pharmaceutical recalls in the fourth quarter of 2011 affected consumers in the U.S. and overseas. Of fourth-quarter pharmaceutical recalls in the U.S., 12 affected customers in only certain states, including one that also affected international customers. More than 85 percent of recalls affected customers nationwide, including 27 recalls that also affected international customers.

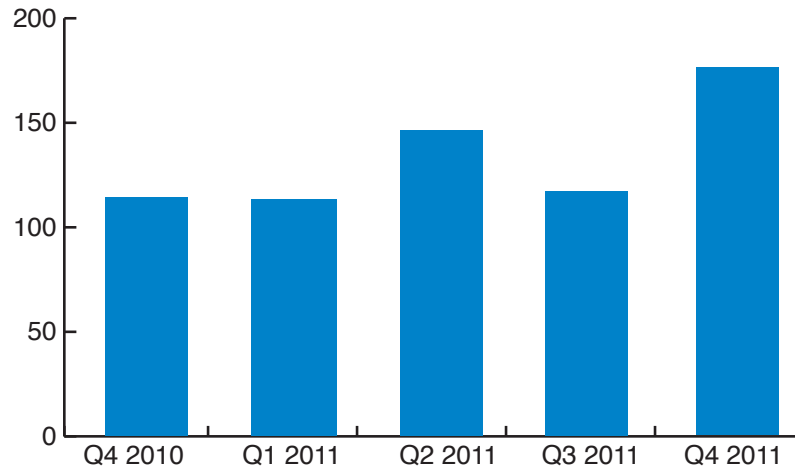
The ExpertRECALL Index also revealed the following:

- Pharmaceutical recalls documented in enforcement reports in the fourth quarter decreased more than 35 percent compared to the previous quarter.
- Pharmaceutical recalls in the fourth quarter increased by more than 36 percent compared with the same quarter last year.
- More than 65 companies initiated at least one recall in the fourth quarter; more than 20 companies issued more than one recall.
- About 11 percent of fourth-quarter pharmaceutical recalls were Class I recalls; more than 63 percent of recalls were Class II; the remainder of recalls were Class III.
- Class I recalls in the fourth quarter affected less than 4 percent of all pharmaceutical units recalled.
- Eleven recalls affected more than 1 million units, including two recalls that affected more than 10 million units.

# Recall Index - Fourth Quarter 2011

## Food

Food Recalls by Quarter

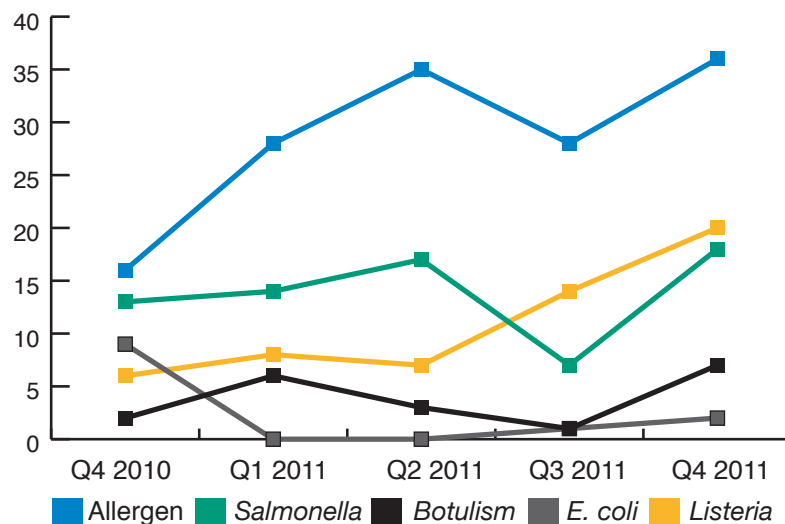


In the fourth quarter of 2011, FDA enforcement reports documented 176 food recalls initiated by more than 150 companies and affecting nearly 70 million units. The number of recalled units documented in enforcement reports during the fourth quarter was the highest in the past four quarters, affecting 80 percent more units than recalls documented in the third quarter of 2011.

Of fourth-quarter recalls, 42 affected customers nationwide. Twenty-eight recalls affected domestic and international customers. Two recalls affected only customers outside the U.S.

FDA enforcement reports documented over 50 percent more recalls in the fourth quarter of 2011 compared to the previous quarter, and almost 55 percent more recalls than the same quarter last year.

Leading Causes of Food Recalls



Of recalls documented in FDA enforcement reports during the fourth quarter, 50 percent were listed as Class I. About 40 percent were listed as Class II and the remainder were listed as Class III.

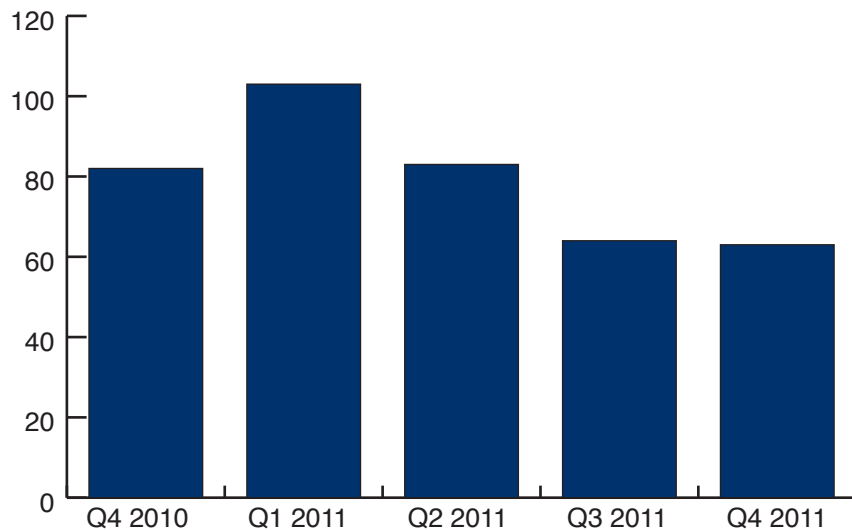
The ExpertRECALL Index also reviewed FDA recall announcements which revealed the following:

- Undeclared allergens or other allergen concerns remained the primary cause of recalls during the fourth quarter, accounting for more than one-third of food recalls initiated in the quarter.
- Recalls due to undeclared allergens reached a new high in the fourth quarter, surpassing levels recorded in at least five quarters.
- Potential *Listeria* contamination was the second leading cause of the more than 100 food recalls announced on the FDA website during the fourth quarter, representing 20 recalls throughout the quarter. The third leading cause of food recalls was potential *Salmonella* contamination, representing 18 recalls.

CPSC Recalls by Product Category in Q4 2011



Consumer Product Recalls by Quarter



# Recall Index - Fourth Quarter 2011

## Consumer Products

Consumer product recalls initiated at the recommendation of the CPSC in the fourth quarter reached a new five-quarter low with 63 recalls. Fourth-quarter recalls affected more than 4.6 million units that were responsible for more than 500 reported product safety incidents. There were more than 100 injuries related to 22 of the recalls announced during the fourth quarter. No deaths were reported.

During the fourth quarter, the CPSC announced more recalls than the previous quarter in the child nursery equipment & supplies; sports/recreational activities & equipment; home communication, entertainment & hobby; personal use items; home workshop apparatus; and housewares categories. The CPSC announced fewer recalls in the toys; yard & garden equipment; home furnishings & fixtures; and miscellaneous products categories.

The ExpertRECALL Index also revealed the following:

- Laceration hazards were the leading cause of CPSC recalls during the fourth quarter, triggering eight recalls. Risks of structural collapse and entrapment/strangulation hazards were the second-leading causes, each triggering seven recalls.
- Recalls of products in the sports/recreational activities & equipment category accounted for more than 20 percent of fourth-quarter recalls, representing the leading category of products recalled.
- During the fourth quarter, 58 companies initiated recalls, with five manufacturers being involved in more than one recall.
- In the fourth quarter, there were no recalls initiated at the recommendation of the CPSC in the product packaging; yard & garden equipment; and home & family maintenance products categories.

# Recall Index - Fourth Quarter 2011

## Children's Products

Nursery equipment & supplies and toys accounted for 11 CPSC recalls during the fourth quarter. Of the 15 product categories recognized by the CPSC, these two accounted for about 17 percent of all recalls in the quarter and affected less than 1 million units.

The total number of children's and infant product recalls decreased 8 percent compared to the previous quarter, recording a new five-quarter low. Recalls in the toy category decreased more than 50 percent compared to the previous quarter, while nursery equipment & supply recalls more than doubled compared to the third quarter of 2011.

The primary cause of children's and infant product recalls was the choking risk associated with small parts. This risk prompted five recalls within these product categories, representing more than 45 percent of children's and infant product recalls. Fall hazards and entrapment and strangulation risks were the second leading causes, each triggering two recalls.

The ExpertRECALL Index also revealed the following:

- Of fourth-quarter recalls, about 37 percent were in the toy category, while about 63 percent were nursery equipment & supplies.
- Children's and infant products recalled in the fourth quarter were responsible for 56 reported incidents.
- Four injuries were associated with three nursery equipment & supply recalls. Toy recalls were associated with only one injury.
- Ten companies initiated recalls in the fourth quarter.

