



## 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.