

SECOND QUARTER 2013

# ExpertRECALL

QUARTERLY RECALL INDEX



## Recall Index – Second Quarter 2013

ExpertRECALL™ helps our partners minimize risk to the public and to their company brand by executing and planning for product recalls efficiently, effectively and compliantly. Each quarter, we analyze cumulative recall data across five product categories to help our partners stay abreast of the latest trends in product recalls and the regulatory environment.

Our clients include some of the world's leading pharmaceutical, medical device, food and beverage, consumer goods, and juvenile product companies that have relied on us to manage more than 3,000 recalls, from the largest withdrawal in U.S. history to smaller consumer product and medical device recalls.

ExpertRECALL service offerings include the following:

- » **Consulting**
- » **Affected Party Identification**
- » **Notification/Communication**
- » **Response, Product Processing**
- » **Remedy Management**
- » **Resolution Management**
- » **Retrieval**
- » **Technology**



## 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 second quarter of 2013 included:

**48**  
percent

48 percent of reported medical device recalls had international and U.S. components.

**104**  
recalls

104 recalls of drug and pharmaceutical products were issued by compounding pharmacies. Overall, the number of pharmaceutical companies facing recalls was up 20 percent over the prior quarter.

**70**  
percent

70 percent of affected food units were classified as Class I recalls, the FDA's most serious classification. Year-over-year food recalls are up 73 percent.

**65**  
percent

65 percent of USDA recalls were the result of undeclared allergens.

**71**  
recalls

71 recalls were initiated by the CPSC this quarter, the second-lowest number in the past six quarters.

**52**  
percent

52 percent of all CPSC recalled units came from one recall in the children's and infant category.

## Recall Index – Second Quarter 2013

### How the ExpertRECALL Index is Compiled

The ExpertRECALL Index gathers and tracks cumulative data from the three primary federal agencies that oversee recalls in the United States: the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). 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.

#### USDA Data

For additional insight into food recall trends involving meat, poultry, and egg products, the ExpertRECALL Index collects and analyzes data from recall announcements posted on the USDA's FSIS website. Statistics and trends are compiled using standard product categories, classifications, and reasons for recalls as recognized by the USDA.

#### Terminology

Announced recalls represent those recalls documented in news releases published on agency websites. Enforced recalls refer to those recalls documented in weekly FDA enforcement reports. Their documentation can lag behind announced recalls by weeks or even months because the 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 – Second Quarter 2013

## Medical Device Recalls

FDA Enforcement Reports documented 411 medical device recalls in the second quarter of 2013, an increase of 30 percent from the previous quarter.

There were 9.2 million units affected by recalls in the second quarter, a dramatic decrease of over 50 percent from the previous quarter, resulting in the lowest level of units affected in six quarters. No recalls affected more than one million units, with four recalls affecting between 500,000 and one million units, and 407 recalls affected less than 500,000 units.

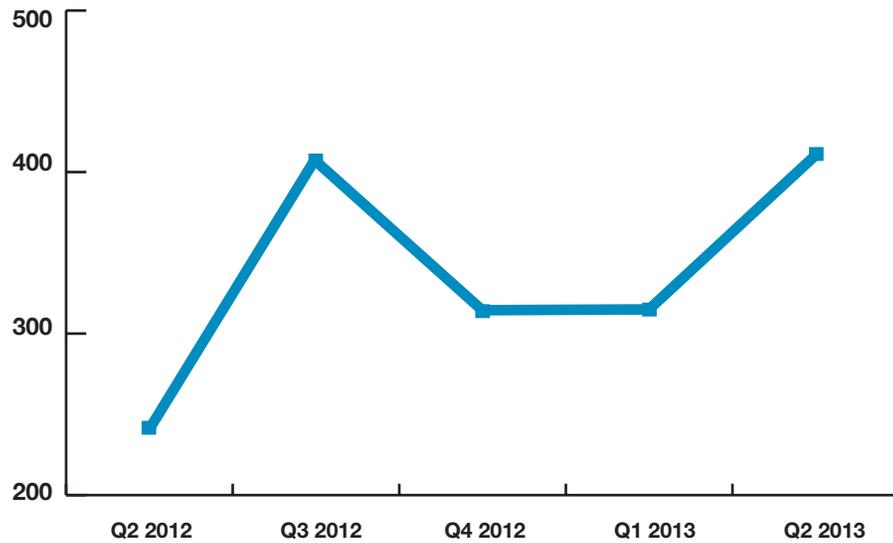
Recalls were issued by 174 companies in the second quarter. Of these companies, 38 percent issued more than one recall, a trend that continues from the previous four quarters. One company announced 17 recalls, and six companies announced 10 or more recalls each.

Medical device recalls documented during the second quarter of 2013 affected both domestic and international customers. The majority of recalls (335) impacted customers nationwide. There were also 197 recalls that affected customers in the United States and at least one other country or territory.

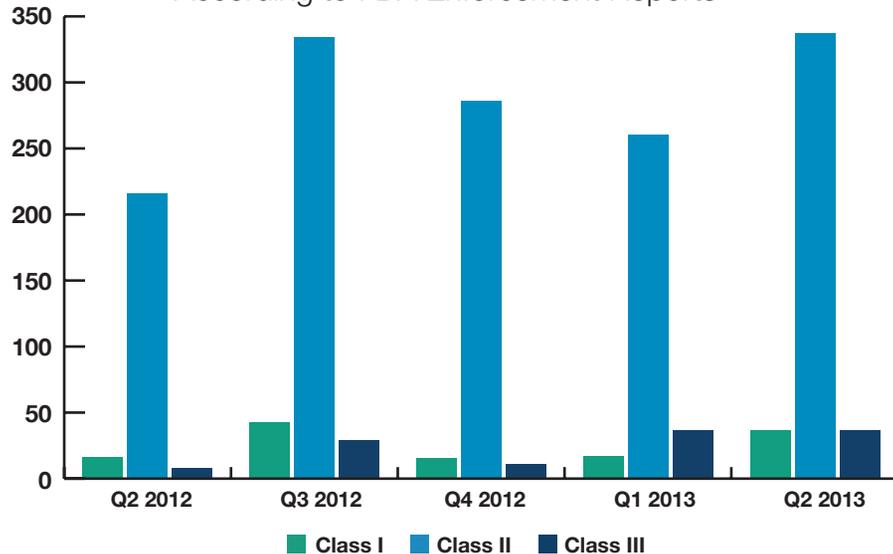
The ExpertRECALL Index analysis also revealed the following:

- Overall, the number of recalls increased 30 percent from the last quarter, with 80 percent of recalls classified as Class II.
- Approximately 38 percent of companies announced more than one recall. This is a trend that has continued from the previous four quarters, during which 40 percent of companies announced more than one recall.
- Recalled units decreased over 50 percent this quarter compared with the previous quarter, representing the lowest level of recalled units in six quarters.

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



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



### Global Spotlight

Nearly one out of every two medical device recalls this quarter occurred on a global scale. Additionally, recall activity reached a five-quarter high. With the significant number of recalls combined with the global nature of the recall environment, medical device manufacturers must be well-versed in the regulatory environments within countries they operate in as well as capable of managing the logistical complexities of a global recall.

# Recall Index – Second Quarter 2013

## Pharmaceutical Recalls

FDA Enforcement Reports in the second quarter of 2013 documented 241 drug and pharmaceutical recalls, an increase of 127 percent from the previous quarter.

Units affected by recalls also increased in the second quarter, affecting 17,354,390 units, compared with 13,102,606 in the first quarter. According to FDA Enforcement Reports, one recall affected more than one million units but less than 5 million units; 11 recalls affected between 500,000 and 1 million units; and 229 recalls affected fewer than 500,000 units.

Twenty-two recalls were documented as Class I recalls, 175 were documented as Class II, and 44 were Class III – all increases over the previous quarter. Twelve recalls of the 241 affected over-the-counter (OTC) products. The remaining 229 recalls affected prescription medications, of which 22 were Class I, 164 were Class II, and 43 were Class III recalls.

Pharmaceutical recalls in the second quarter affected domestic and international customers. Of recalls documented in the second quarter, 118 recalls affected customers nationwide, while nine recalls affected customers in the United States and at least one other country or territory.

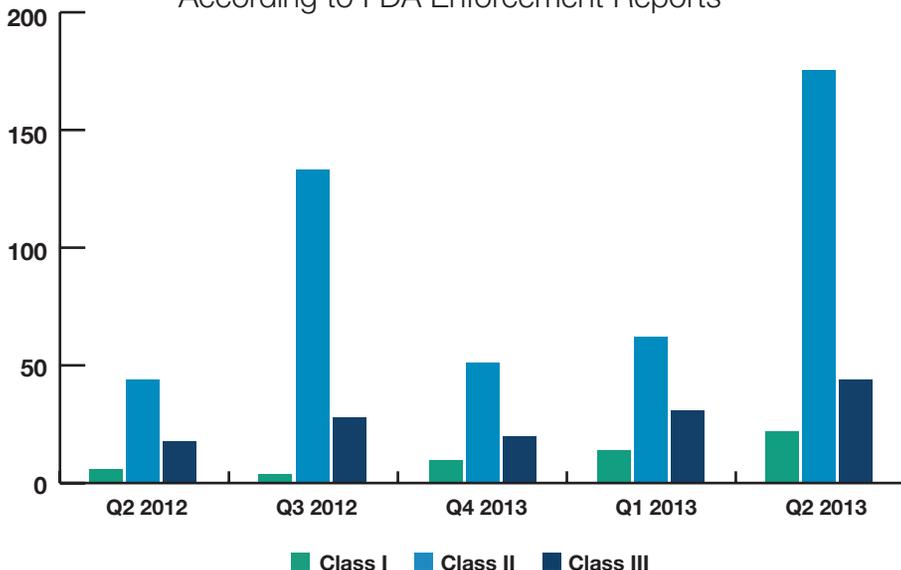
The ExpertRECALL Index analysis also revealed the following:

- Recalled units increased approximately 32 percent, representing the highest number of recalled units in six quarters. Most notably, five companies represented 65 percent of recalled units in the second quarter.
- In the second quarter, less than five percent of recalls affected the international community, representing a significant decrease from the first quarter with 29 percent.
- Two compounding pharmacies accounted for 104 recalls, more than 43 percent of all recalls for the second quarter.

**Pharmaceutical Recalls**  
According to FDA Enforcement Reports



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



### New Development

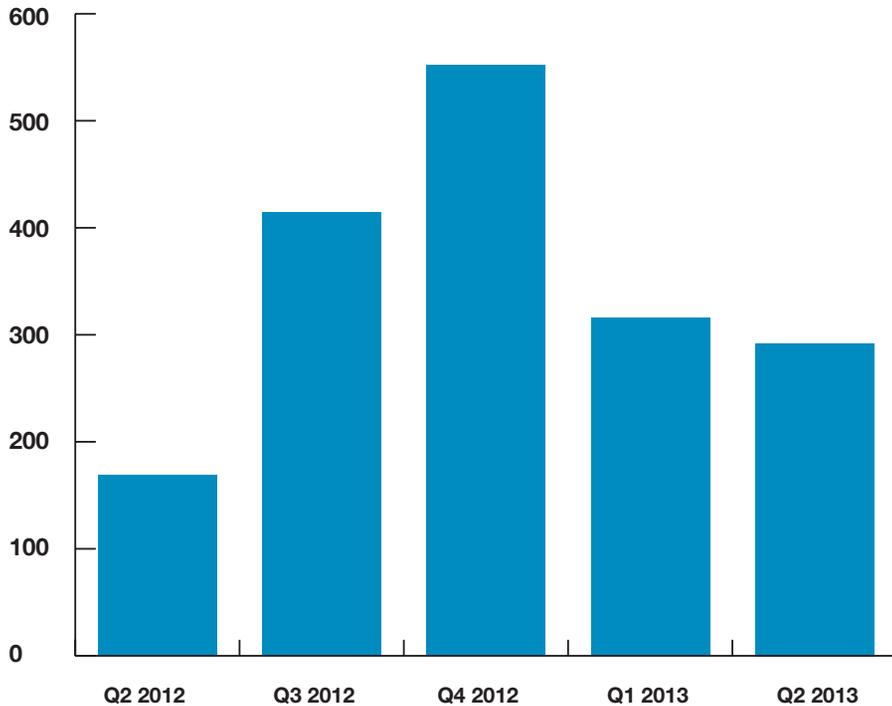
There have been several major recalls involving compounding pharmacies that have received significant media attention in recent months. As a result of these significant recalls and the resulting media attention, the FDA has increased its inspections of compounding pharmacies<sup>2</sup>. Additionally, the Government Accountability Office (GAO) just announced a recommendation for the FDA to be granted greater oversight of compounding pharmacies<sup>2</sup>. As Congress debates the GAO's recommendation, compounding pharmacies need to pay close attention to their current safety compliance because the FDA will continue to increase inspections and enforce its authority.

<sup>2</sup> <http://www.gao.gov/products/GAO-13-702>

# Recall Index – Second Quarter 2013

## Food Recalls

**Food Recalls by Quarter**  
According to FDA Enforcement Reports



### Best Practice

Although the number of recalls has remained constant, 36 percent of food recalls were classified as Class I this quarter, comprising over 70 percent of the total affected units. With the surge of Class I recalls and the scale of units affected, it is critical for food manufacturers to ensure traceability of their supply chains. Companies can minimize the damage of a recall outbreak by having a good, well-documented traceability program.

FDA Enforcement Reports documented 292 food recalls in the second quarter of 2013, representing an eight percent decline over the previous quarter. Second quarter recalls affected about 3.5 million units, nearly a third of the about 9.7 million units affected in the previous quarter. According to FDA documentation, one recall affected between 500,000 and one million units and seven recalls affected between 100,000 and 500,000 units. The remaining recalls affected less than 100,000 units.

Of recalls documented in FDA Enforcement Reports during the second quarter, 36 percent were classified as Class I recalls, 54 percent were categorized as Class II recalls, and 10 percent as Class III.

Recalls documented in the first quarter were initiated by 116 companies. Of these companies, 45 faced more than one recall. One company faced 26 recalls this quarter, followed by another company with 18 recalls and another with 13 recalls.

Of the recalls documented by the FDA in the second quarter, there were 91 recalls that affected customers nationwide, as well as nine that affected customers in the U.S. and at least one other country or U.S. territory.

The ExpertRECALL Index also analyzed second quarter FDA recall announcements, which revealed the following:

- Allergens were the single largest cause of food recalls, composing approximately 60 percent of recalls initiated in the second quarter, up from 34 percent in the first quarter. Allergens have been the first or second largest cause of food recalls in the past six quarters.
- Foodborne illness remains a top concern, as *Salmonella*, *Listeria* and *E. coli* accounted for nearly one in every four recalls initiated during the second quarter. However this is down from 65 percent in the first quarter of 2013.
- Foreign material in food products caused 13 recalls, which is higher than the historical average.

# Recall Index – Second Quarter 2013

## USDA

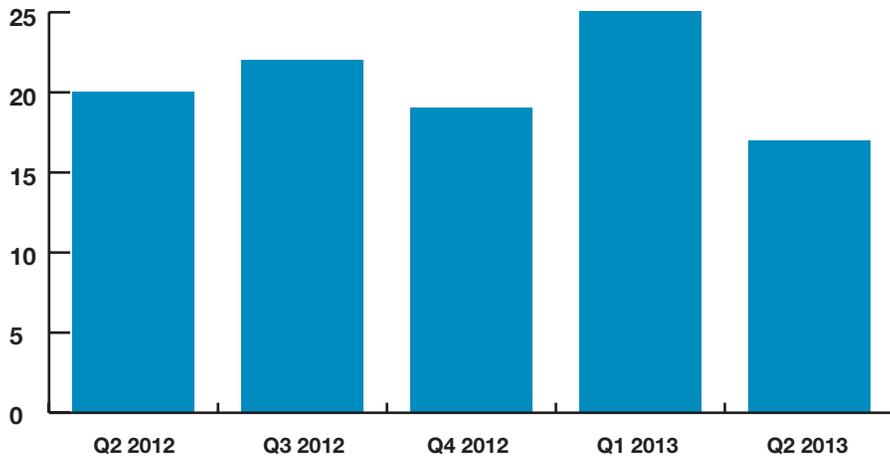
There were 17 recalls of meat, poultry, or processed egg products in the second quarter according to USDA reports. Second quarter recalls impacted 250,829 lbs. of product, which is down approximately 40 percent from the previous quarter with 450,415 lbs. of product.

Twelve recalls were documented as Class I recalls, five were classified as Class II and none were designated as Class III recalls. No company faced multiple recalls this quarter.

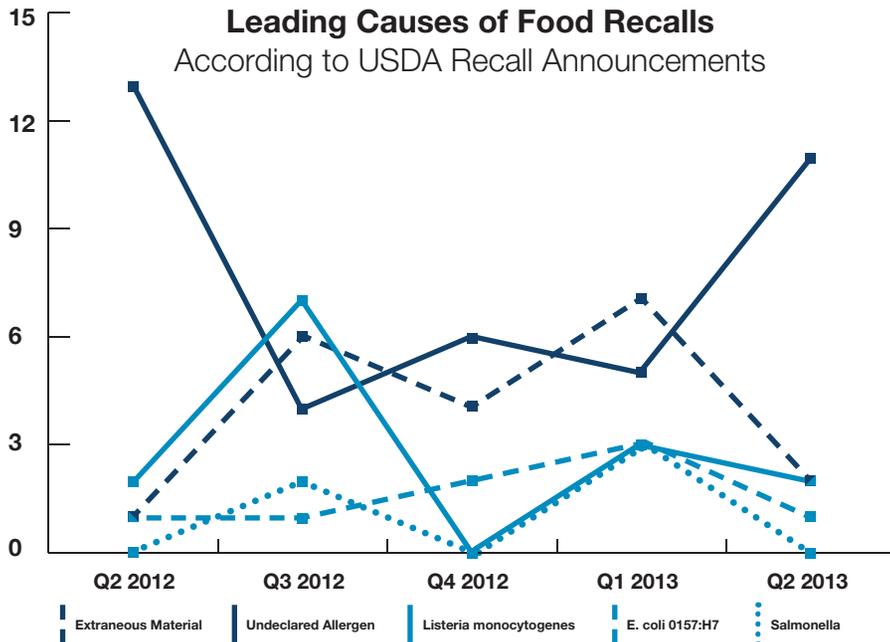
The ExpertRECALL Index analysis also revealed the following:

- Undeclared allergens were the single largest cause of recalls this quarter with 11 recalls, followed by extraneous materials and listeria, with two recalls each.
- The number of recalls is down nearly 30 percent since the previous quarter, resulting in the lowest number of recalls in the last six quarters.
- Foodborne pathogens decreased significantly from nine recalls last quarter to three recalls this quarter, down approximately 66 percent.

**USDA Food Recalls by Quarter**  
According to USDA Recall Announcements



**Leading Causes of Food Recalls**  
According to USDA Recall Announcements



### Trend Report

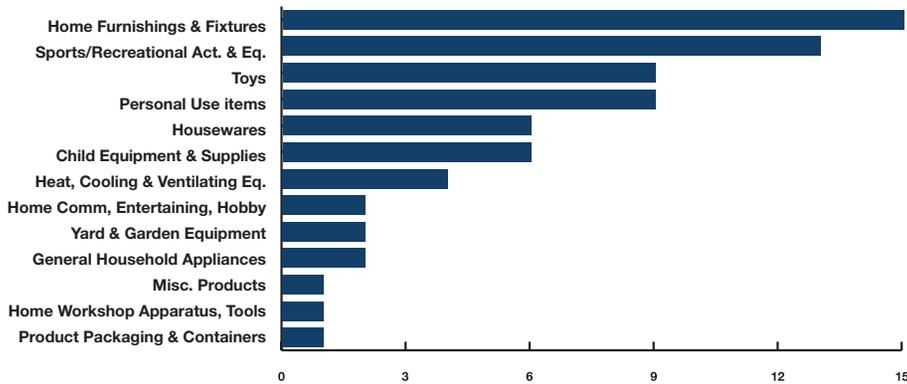
Undeclared food allergens continue to be one of the top trends for USDA recalls. The Food Safety and Inspection Service (FSIS) is now explicitly directing USDA inspectors to review labels and formulations related to a company's Allergen Control Program. Food manufacturers can expect to have their records audited and their production processes observed with increased frequency. As such, manufacturers must ensure that they are in compliance with these verification processes before an inspector arrives onsite<sup>1</sup>.

<sup>1</sup> FSIS Notice, "Targeted Verification of Product Formulation and Labeling for the Eight Most Common ("Big 8") Food Allergens," April 30, 2013. Available at: <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/29-13.pdf>

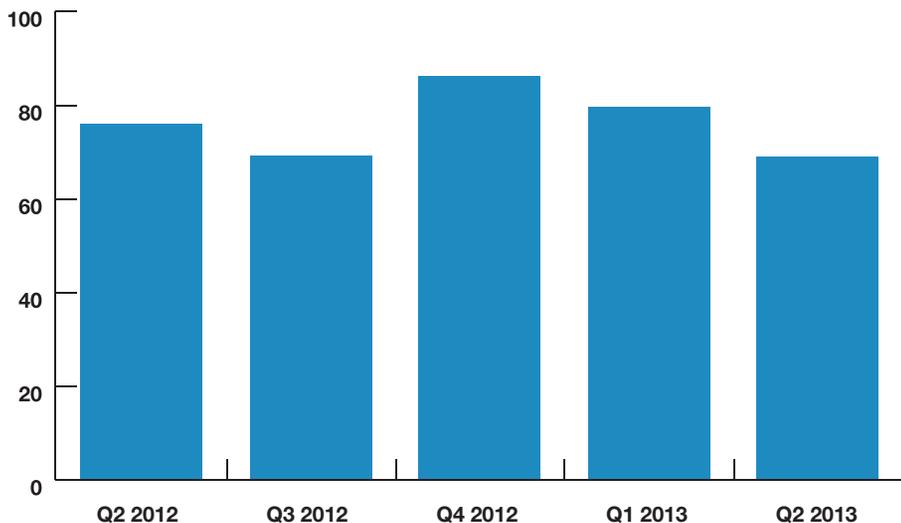
# Recall Index – Second Quarter 2013

## Consumer Product Recalls

CPSC Recalls by Product Category



Consumer Product Recalls by Quarter



Consumer product recalls initiated at the request of the CPSC decreased to 71 recalls during the second quarter of 2013, down from 80 recalls in the previous quarter. The number of affected units also decreased by approximately six percent compared to the first quarter.

Products recalled in the second quarter were responsible for 917 product safety incidents, down from 1,333 in the first quarter of 2013. Of the reported incidents, 109 resulted in injury. No product recalls this quarter resulted in death.

The CPSC initiated more recalls than the previous quarter for personal use items, toys, housewares, and heating, cooling, and ventilating equipment. In particular, recalls of sports and recreational activity equipment decreased by 50 percent compared to the first quarter, which was a six-quarter high. All other categories, including home furnishings and fixtures, child nursery equipment and supplies, miscellaneous products, general household appliances, home communication, entertainment and hobby products, yard and garden equipment, product packaging and containers, and home workshop tools were either flat or saw minor declines.

The ExpertRECALL Index analysis also revealed the following:

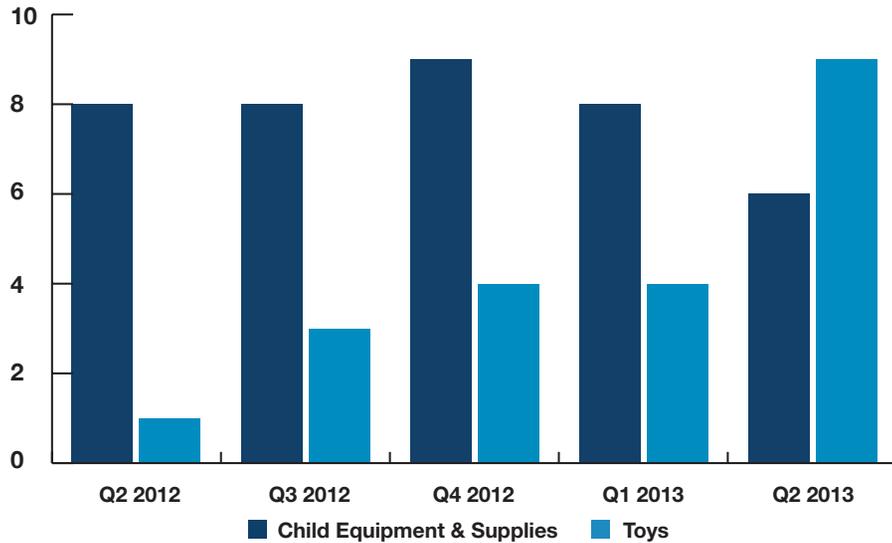
- Recalls of heating, cooling, and ventilating equipment were up this quarter from two recalls in the first quarter of 2013 to four in the second quarter of 2013.
- The total number of units affected in the second quarter decreased six percent.
- Only one company announced more than one recall, down from six in the first quarter.

### Best Practice

**Companies should continue to monitor complaints on the Consumer Product Safety Information Database and listening to social media chatter. Recall and quality control managers can use this data to better identify potential problems and begin preparing for a recall before the CSPC even begins an investigation.**

## Children’s and Infant Product Recalls

Infant and Children’s Product Recalls



The CPSC initiated 15 recalls of children’s and infant products in the second quarter of 2013, an increase of three recalls compared with 12 in the previous quarter. Recalls of child nursery equipment and supplies decreased by two compared to the previous quarter, while the toys category more than doubled from the previous quarter with nine recalls. Recall volume of children’s and infant products was up significantly in the second quarter, from 199,410 units in the first quarter to 3,223,949 units this quarter.

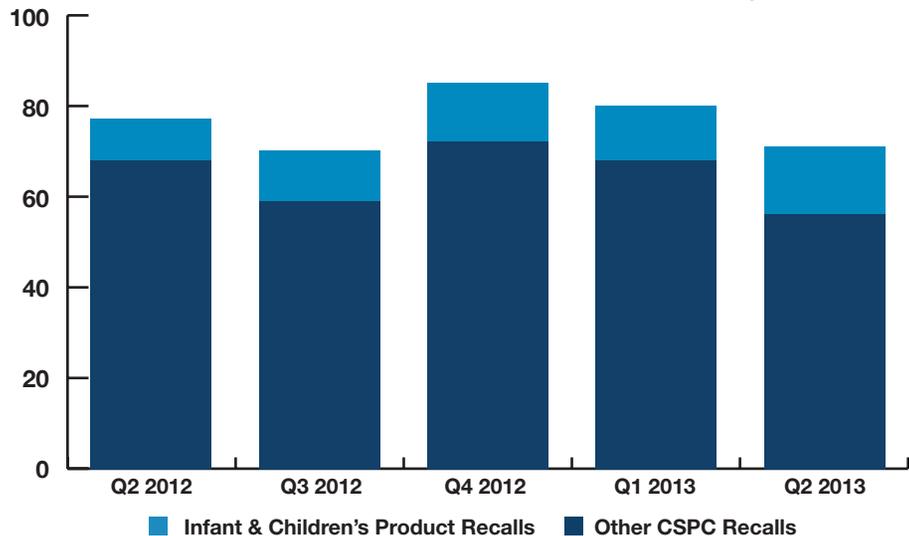
Of the 15 product categories recognized by the CSPC, child nursery equipment and toys accounted for approximately 21 percent of the total recalls, and more than half of units affected.

The primary cause of children’s and infant product recalls was hazardous materials, which led to four recalls, compared with two in the previous quarter. Choking and small parts risks or the risk that a child could fall out of a product were each documented as the primary hazard for two recalls. The risk of explosion led to two recalls, and machine failure and entrapment or strangulation each led to one recall.

The ExpertRECALL Index analysis also revealed the following:

- Fifteen companies faced recalls in the first quarter, up by four from the previous quarter. No company faced more than one recall.
- Children’s and infant recalled products were responsible for 69 product safety incidents in the second quarter, down from 86 in the previous quarter. There were 53 injuries and no deaths as a result of these incidents.

Infant and Children’s Product Recalls  
Within the Consumer Product Recall Industry



### Trend Report

**This quarter, the CSPC issued a mandatory recall of a children’s toy product – a relatively rare measure that has only happened four times in the past 11 years. This caused the number of toy recalls to outpace the number of children’s equipment and supply recalls for the first time in six quarters.**