Consumer Products

Consumer product recalls increased 16.9% to 69 - in line with the quarterly average since the start of 2016. Recalled units increased 57.5% to about 5.5 million - despite the increase, this was still lower than 16 of the previous 20 quarters.

**HOME IS WHERE THE RECALL IS**

Home furnishings & décor is back as the top product category based on units, at 36.5%.

**CONNECTING THE DOTS**

1. Fire was the top hazard based on units for the fourth consecutive quarter. Fire was also the top hazard based on recalls.
2. The top product category based on recalls was home furnishings & décor, breaking a two quarter streak for sports & recreation.
3. Incidents increased 272.7% from Q3 2018 to 2,728 - the highest since Q2 2017. Injuries decreased 24.2% to 75 - the second highest since Q3 2017 but lower than 9 of the last 13 quarters.
Automotive

NHTSA recalls increased 12.8% to 220 – the highest quarter since Q4 2016. NHTSA recalled units are down 19.6% to just under 5 million – the lowest since Q1 2013.

**Recalls Fueled Up**

At 27.4%, fuel systems were the top cause of recalled units for the first time in more than 15 years.

**Connecting the Dots**

1. Equipment and electrical systems tied for the top cause for NHTSA recalls at 13.6% each. Equipment has occupied the top spot for seven consecutive quarters.

2. Automobiles accounted for 90.9% of NHTSA recalls and 94.0% of recalled units. In Q3 2018, automobiles made up 80.5% of NHTSA recalls.

3. 64.8% of automobile recalled VINs were issued by just two companies.

**NHTSA Recalls & Units**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Recalls</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 2016</td>
<td>200</td>
<td>18MM</td>
</tr>
<tr>
<td>Q1 2017</td>
<td>15MM</td>
<td></td>
</tr>
<tr>
<td>Q2 2017</td>
<td>12MM</td>
<td></td>
</tr>
<tr>
<td>Q3 2017</td>
<td>9MM</td>
<td></td>
</tr>
<tr>
<td>Q4 2017</td>
<td>6MM</td>
<td></td>
</tr>
</tbody>
</table>

**NHTSA Recalls by Product Type**

- **Automobile** 90.9%
- **Fuel System** 1.36MM
- **Equipment** 8.2%
- **Tire** 0.9%
- **Hybrid Propulsion System** 855K
- **Electrical System** 683K
- **Engine and Engine Cooling** 652K

**Top Causes of Recalled Units by Quarter**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Airbags</th>
<th>Airbags</th>
<th>Airbags</th>
<th>Equipment</th>
<th>Airbags</th>
<th>Electrical System</th>
<th>Seat Belts</th>
<th>Fuel System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2 2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3 2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4 2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

© 2019 Stericycle, Inc. All rights reserved.
Pharmaceuticals

Pharmaceutical recalls increased 11% to 102 - the second highest quarter since Q3 2013. Recalled units increased 641% to just over 52 million - higher than 13 of the last 15 quarters.

CONNECTING THE DOTS

1. For the tenth consecutive quarter, failed specifications were the top reason for pharmaceutical recalls.
2. The average recall size was 510,560 units - the third highest quarter since Q4 2014.
3. 77 individual companies reported recalls in the quarter - the second highest number since at least 2012.

MISERY WITH MISLABELING

At 48.6%, mislabeling was the top cause based on units, breaking a three quarter streak for cGMP Deviations.

TOP PHARMACEUTICAL CAUSES BASED ON RECALLS

- Failed Specs: 22.5%
- cGMP Deviations: 20.6%
- Mislabeled: 12.7%
- Sterility: 10.8%
- Quality: 8.8%

% OF PHARMACEUTICAL UNITS BY CLASS

- Class I: 48.4%
- Class II: 25.6%
- Class III: 25.9%
- Unclassified: 0.2%

OF PHARMACEUTICAL RECALLS WERE NATIONWIDE

82%
Medical Device

Medical device recalls decreased just 1% to 280 – lower than the last three quarters but higher than the three quarters before that. Recalled units increased 449% to just over 161 million – the second highest quarter since at least 2004

MACHINE MISFORTUNE CONTINUES

At 73.5%, machine failure was the top cause based on units, mainly due to one large recall. This is the second consecutive quarter machine failure was the top cause based on units.

CONNECTING THE DOTS

1. The average recall size was 575,449 – the second highest quarter since Q3 2006.
2. At 28.2%, software was the top cause based on recalls for the eleventh consecutive quarter. No other cause was responsible for more than 15.4% of recalls.
3. Five companies reported ten or more recalls in the quarter. This is the highest number since Q3 2016 and the second highest since Q3 2013.

MED DEVICE RECALLS & UNITS

CLASS I UNITS RECALLED PER QUARTER

TOP MEDICAL DEVICE CAUSES BASED ON RECALLS
FDA food recalls increased 21% to 156 – the highest quarter since Q3 2017. Recalled FDA food units increased 457% to 47 million - higher than three of the previous four quarters. USDA recalls increased 62% to 42 – the second highest since Q2 2015. Recalled USDA pounds increased 22 times to 17 million – the highest since Q2 2016.

**ONE BITTERSWEET RECALL**

Candies made up **80.5%** of recalled FDA food units, making it the top product category. This is mainly due to one large recall.

**CONNECTING THE DOTS**

1. At 71.8%, beef was the top category for USDA recalled pounds. Beef was the top category for recalled pounds in three of the four quarters in 2018.
2. Undeclared allergens were the top cause of both FDA food recalls at 46.2% and recalled FDA food units at 81.9%.
3. Bacterial contamination was the top cause of recalled USDA pounds at 97.7%. Salmonella was involved in 98.6% of the bacterial contamination recalled pounds.

**TOP FDA FOOD CATEGORIES BASED ON RECALLS**

- Prepared Foods: **28.8%**
- Flavoring: **10.3%**
- Candies: **9%**
- Produce: **9%**

**TOP USDA REASONS BASED ON RECALLS**

- Bacterial Contamination: **52.4%**
- Undeclared Allergen: **19%**
- Foreign Material: **11.9%**

**TOP USDA CATEGORIES BASED ON RECALLS**

- Poultry: **40.5%**
- Multiple: **26.2%**
- Beef: **16.7%**
- Pork: **14.3%**
Stericycle Expert Solutions & the Recall Index Explained

Stericycle Expert Solutions helps 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. This helps our partners navigate the regulatory environment and identify trends.

How the Stericycle Recall Index is Compiled

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

FDA Data

To track trends in food, pharmaceutical, and medical device recalls, the Stericycle Recall Index uses information publicly available in news releases posted on the FDA website. For additional insight into recalls governed by the FDA, Stericycle 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 analyzes data from CPSC recall announcements. When compiling statistics and analyzing trends for consumer product recalls, the Stericycle Recall 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 Stericycle Recall 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.

NHTSA Data

To understand trends in the automotive industry, the Stericycle Recall Index analyzes data from NHTSA reports on recalls of autos, child seats, equipment, and tires.

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 that are summarized based on the FDA assigned Event ID. 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.