



RECALL INDEX

Q2  
2018

# Consumer Products

Consumer product recalls decreased by 21% to 57 - the lowest quarter since Q1 2015 and second lowest since Q1 2004. Recalled units decreased 26% to about 6.3 million - below 13 of the last 16 quarters.



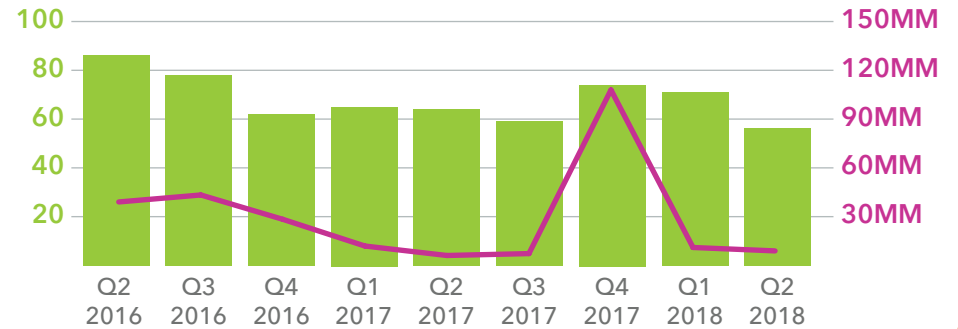
## FUEL TO THE FIRE

For the **second consecutive quarter**, fire was the top hazard for both recalls and recalled units.

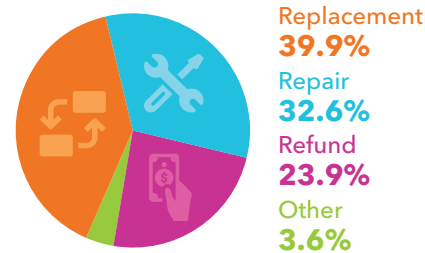
## CONNECTING THE DOTS

1. After two consecutive quarters with no fines, Q2 2018 had the largest single fine in CPSC history and the largest total dollar amount of fines in CPSC history - more than \$10 MM larger than the previous record of Q1 2016.
2. After breaking a four-quarter streak in Q1 2018, sports & recreation was once again the top product category based on recalls, with 26.3%.
3. Incidents decreased 35.5% from the previous quarter to 1,191 - lower than 7 of the last 8 quarters. Injuries decreased 51.6% to 15, tied for the lowest quarter since at least 1998.

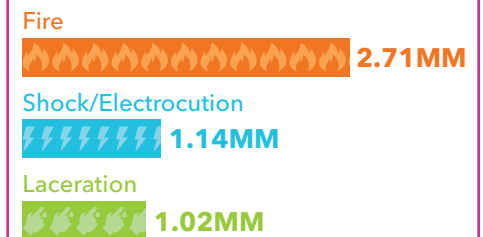
## CONSUMER RECALLS & UNITS



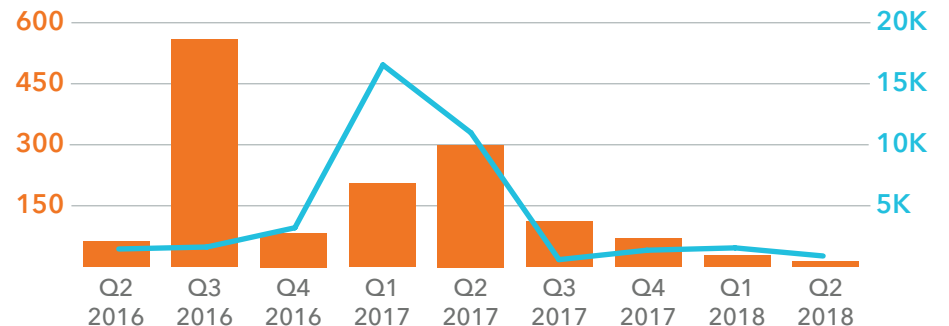
## TOP REMEDIES BASED ON UNITS



## TOP HAZARDS BASED ON UNITS



## CONSUMER INCIDENTS & INJURIES



# Automotive

NHTSA recalls declined 12% to 189 – the lowest quarter since Q2 2017 and below 13 of the last 16 quarters. Recalled NHTSA units decreased 14% to about 8.7 million – lower than 10 of the last 12 quarters.



## SYSTEM FAILURE

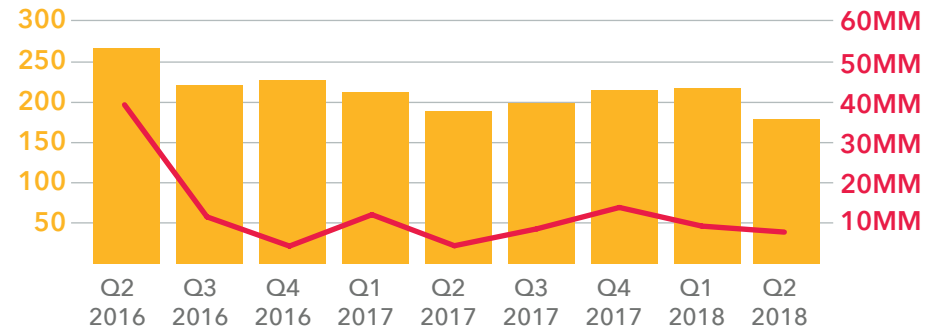
Electrical system issues were the top cause of recalled NHTSA units for the first time since **Q3 2014**.

## CONNECTING THE DOTS

1. Equipment was the top cause for NHTSA recalls for the fifth consecutive quarter, accounting for 15.9%.
2. Automobiles accounted for 89.1% of recalled units, up from 66.9% in the previous quarter.
3. 96.0% of recalled automobile VINs were issued by 5 companies.



## NHTSA RECALLS & UNITS



## NHTSA RECALLS BY PRODUCT TYPE



Automobile  
**88.4%**



Equipment  
**10.1%**



Tire  
**1.1%**



Child Seat  
**0.4%**

## NHTSA RECALL CATEGORIES BASED ON UNITS

### Electrical System



5,004,973

### Airbags



830,679

### Steering



559,705

### Engine & Engine Cooling



467,787

## TOP CAUSES OF RECALLED UNITS BY QUARTER



# Pharmaceuticals

Pharmaceutical recalls declined 27% to 77 - lower than 6 of the last 8 quarters. Recalled units dropped 95% to nearly 15.9 million - lower than 4 of the last 6 quarters, but in line with the average quarter from 2013 to 2016.



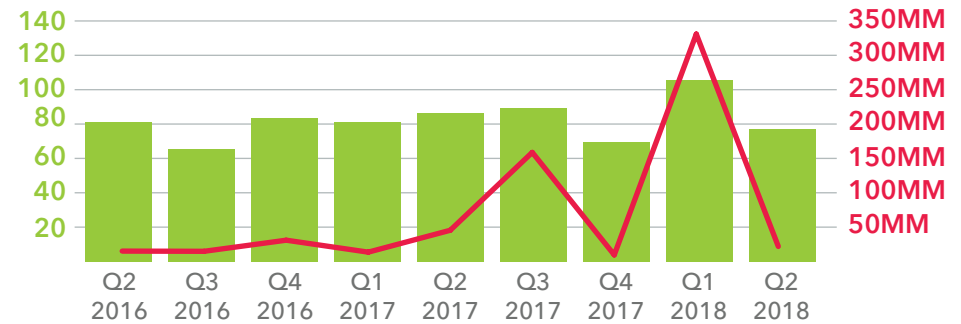
## DRUG DEVIATIONS

For the second quarter in a row, the top recall reason based on units was Current Good Manufacturing Practice (cGMP) deviations.

## CONNECTING THE DOTS

1. The average recall size was 205,804 units - more than 7 of the last 11 quarters.
2. For the eighth quarter in a row, the top cause of recalls was failed specifications.
3. Class I units decreased 42.8% from Q1 2018 - still higher than 6 of the last 10 quarters.

## PHARMACEUTICAL RECALLS & UNITS



## TOP PHARMACEUTICAL CAUSES BASED ON RECALLS



Failed Specs

**23.4%**



cGMP  
Deviations

**20.8%**



Mislabeling

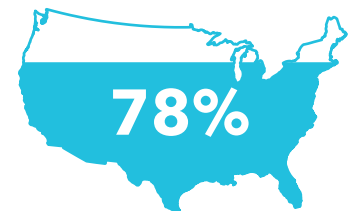
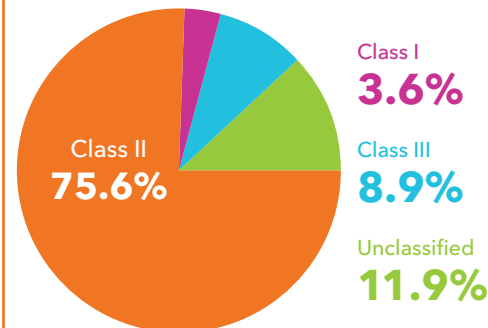
**13%**



Foreign  
Materials

**11.7%**

## % OF PHARMACEUTICAL UNITS BY CLASS



**OF PHARMACEUTICAL RECALLS WERE NATIONWIDE**



# Medical Device



Medical device recalls increased 5% to 360 - making it the largest quarter since at least 2005 and surpassing last quarter's record by 17 recalls. Recalled units decreased 80% to about 42.4 million - lower than 8 of the previous 13 quarters.



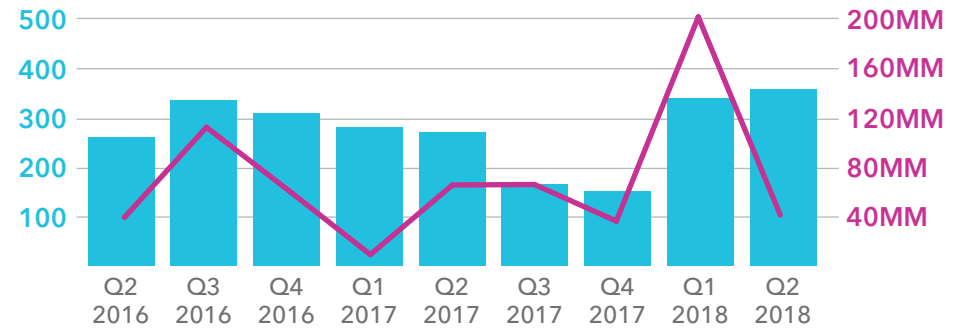
## STERILITY STRUGGLES

Sterility was the top cause for recalled units, at **33.7%**. This breaks a two-quarter run for manufacturing defects.

## CONNECTING THE DOTS

1. The average recall size was 117,774, the lowest since Q1 2017 and down considerably from last quarter's 607,512.
2. At 22.8%, software issues were the top cause of recalls for the ninth quarter in a row.
3. After dropping to 36% last quarter, recalls of products distributed both domestically and globally bounced back to 48%, in line with the average from 2016-2017.
4. 16 companies reported at least 5 recalls - the largest since Q3 2013.

## MED DEVICE RECALLS & UNITS



## AVERAGE CLASS I UNITS RECALLED PER QUARTER

2017 AVG.

**511,017**

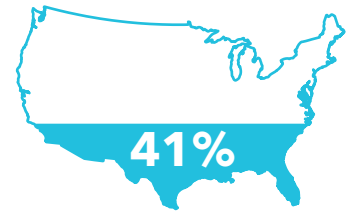
Q1 2018



**186,580,917**

Q2 2018

**599,165**



**41%**  
OF MEDICAL DEVICE  
RECALLS WERE  
NATIONWIDE

## TOP MEDICAL DEVICE CAUSES BASED ON RECALLS



Software  
Issue  
**82**



Mislabeling  
Issue  
**73**



Quality  
Issue  
**57**



Manufacturing  
Defect  
**38**

# Food & Beverage



FDA food recalls increased 7% to 147 – although an increase from Q1, that's still the second lowest quarter since Q1 2016. Recalled FDA food units increased more than 20 times to about 212.8 million, mostly due to one large recall. USDA recalls increased by 1 to 29, while recalled USDA pounds increased 74% to more than 1.75 million – still lower than 11 of the last 17 quarters.



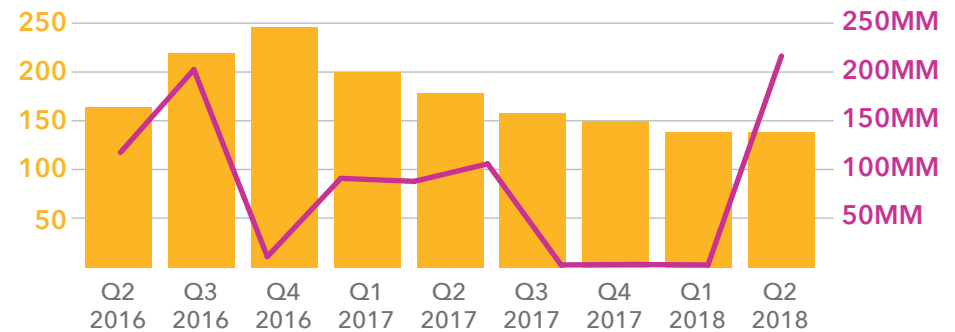
## FRIED BY RECALLS

Due to one large recall, eggs accounted for **97.2%** of recalled FDA food units.

## CONNECTING THE DOTS

1. Beef was the top category for recalled USDA pounds for the second consecutive quarter at 44.2%. Before Q1 2018, beef had not been a top category for two years.
2. The top FDA recall cause was undeclared allergen at 42.2%. Bacterial contamination was second at 32%. No other reason topped 9%.
3. At 18.4%, prepared foods made up the top FDA product category based on recalls for the sixth quarter in a row.

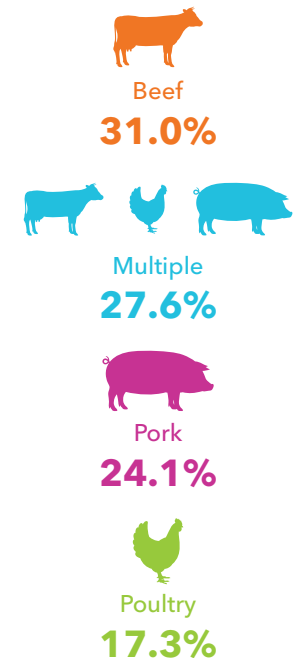
## FDA FOOD RECALLS & UNITS



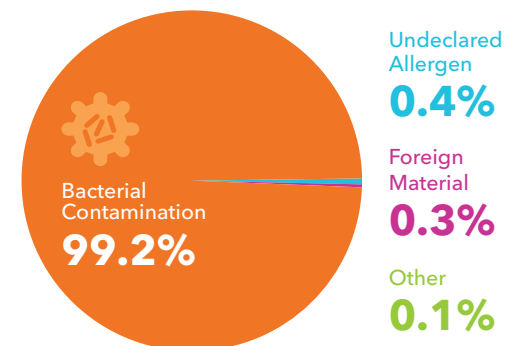
## TOP USDA REASONS BASED ON RECALLS



## TOP USDA CATEGORIES BASED ON RECALLS



## TOP FDA FOOD CAUSES BASED ON UNITS



# 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.