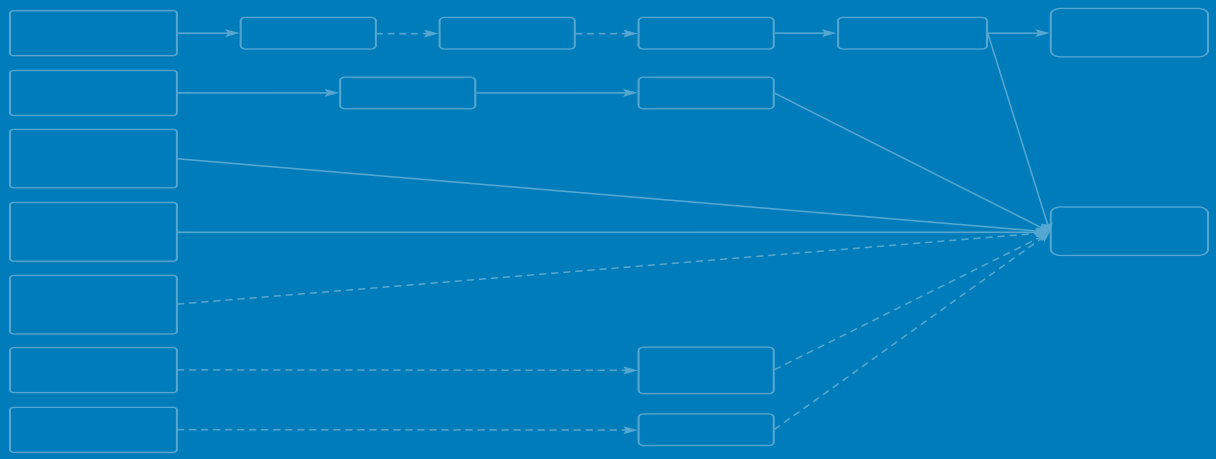
U.S. FOOD & DRUG ADMINISTRATION

Center for Food Safety and Applied Nutrition

Investigations of Foodborne Outbreaks and Adverse Events in FDA-Regulated Foods

Coordinated Outbreak Response and Evaluation (CORE) Network 2022 Annual Report



Coordinated Outbreak Response and Evaluation Network

2022 Annual Report

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Coordinated Outbreak Response and Evaluation Network
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Introduction

This report includes information on incidents investigated by the United States Food and Drug Administration's (FDA) Coordinated Outbreak Response & Evaluation (CORE) Network that were linked to FDA-regulated human food in 2022. CORE's mission is to find, stop, and aid in the prevention of foodborne illness outbreaks. These investigations were conducted in partnership with the Centers for Disease Control and Prevention (CDC) and state and local partners.

The CORE Network has a publicly available Investigation Table that is updated weekly and provides information about foodborne illness outbreak and adverse event investigations that are occurring across the United States. This tool shares information on outbreak investigations, even in their early stages, and increases transparency, giving consumers early awareness of developing multistate outbreaks of foodborne illnesses. This table is limited to information about incidents managed by FDA's CORE Network and does not include seafood-related illnesses and outbreaks or incidents related to animal or pet food. The FDA Division of Seafood Safety investigates, tracks, and monitors seafood-related illnesses and outbreaks, and illnesses or adverse events related to animal/pet food and feed are monitored and investigated by FDA's Center for Veterinary Medicine (CVM).

Information on outbreaks linked to products regulated by the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) can be found on their website.

CDC also publishes annual summaries, which include information on both FDA- and USDA-regulated products linked to outbreaks.

"CORE provides the critical service of protecting public health. Foodborne illness and adverse events linked to FDA-regulated products take a very real toll on American lives. This report provides an overview of some of the work done by CORE in 2022. While illnesses that are reported are easier to quantify, the work done by the CORE Network that leads to prevention is less often captured and reported. CORE continues its work to stop outbreaks and prevent them from happening in the future. I just can't credit my staff enough for how hard they work to keep people safe."

Dr. Stic Harris
CORE Network Director

CORE 2022 Activities

65 Incidents Evaluated:

Incidents evaluated includes potential outbreaks, confirmed outbreaks, and adverse events that were evaluated by the CORE Signals and Surveillance Team. Not all incidents evaluated by Signals are transferred to Response for follow up.

28 Responses Initiated:

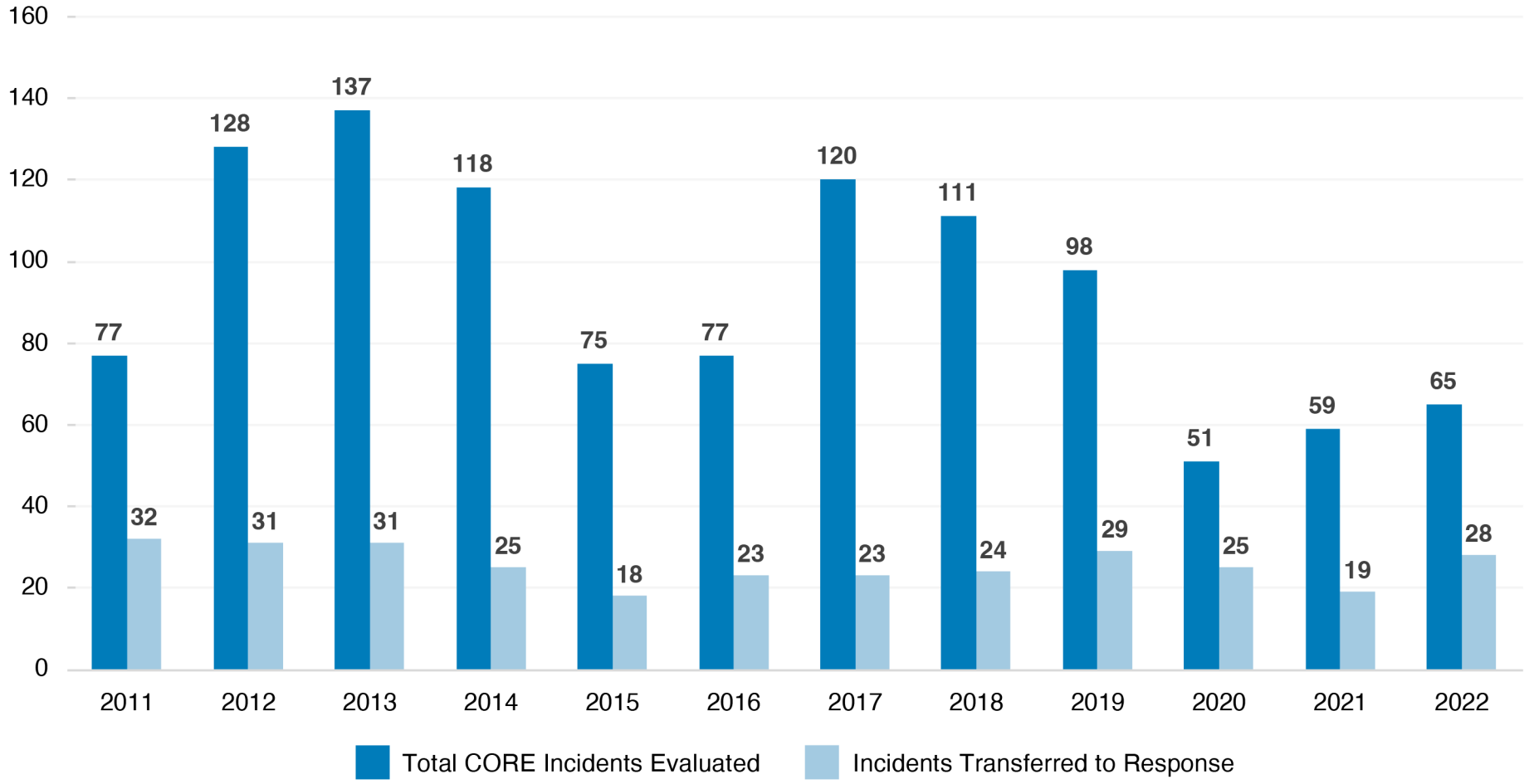
When an outbreak appears to be caused by an FDA-regulated food, this information is passed to a Response Team to coordinate FDA's response efforts.

11 Advisories Issued:

Public health advisories are issued to provide consumers with actionable advice about an FDA-regulated food linked to an outbreak.

*Note: These categories represent the number of activities in each category that occurred during 2022. The lifespan of a single incident may include activities spanning multiple years.

Total CORE Incidents Evaluated and Number Transferred to a CORE Response Team, by Year, 2011 – 2022

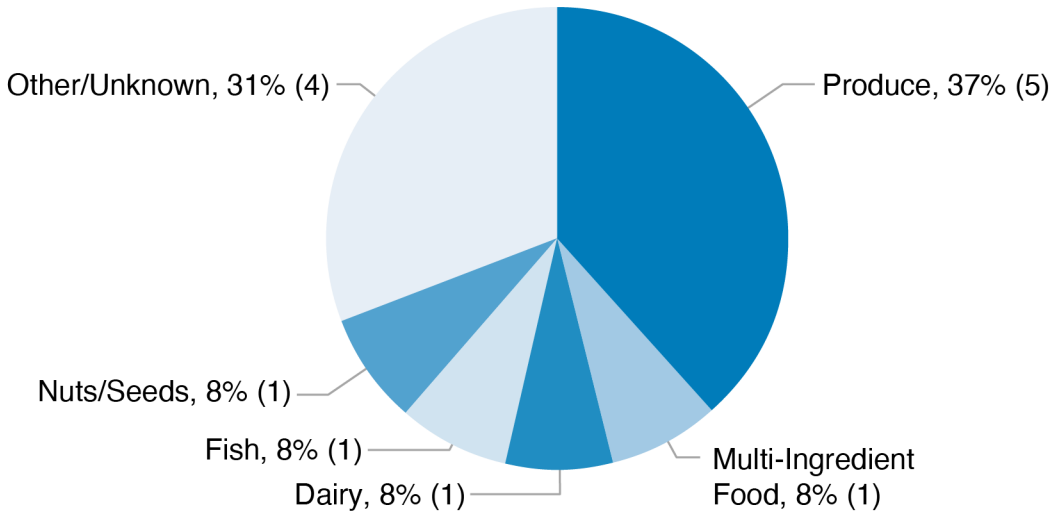


*Note: These categories are not direct subsets of each other, but rather represent the number of activities in each category that occurred during 2022. The lifespan of a single incident may include activities spanning multiple years

The CORE Signals and Surveillance Team evaluates emerging outbreaks and disease surveillance trends, working in collaboration with CDC, FDA field offices, and state agencies. The team reviews data from food firms, including past inspections, sampling results, product distribution, and sourcing information. It also considers previous incidents involving similar pathogen and food pairs. This information can provide clues to understand emerging outbreaks. When an outbreak appears to be caused by an FDA-regulated human food, this information is passed to a CORE Response Team to coordinate FDA's response efforts.

Not all evaluations conducted by the Signals and Surveillance Team result in a transfer, for example, outbreaks that have already ended or are linked to non-FDA regulated products, such as those regulated by USDA, are not transferred to a Response Team for further coordination.

Responses with Identified Product(s) Linked to Illnesses, by Associated Food Category, 2022



Identified Product(s) Linked to Illnesses

Produce
- Enoki Mushrooms
- Alfalfa Sprouts
- Cantaloupe
- Strawberries
- Romaine Lettuce

Multi-Ingredient*
- Ice Cream

Dairy
- Brie and Camembert Cheese

Fish
- Fish (Multiple Types)**

Nuts/Seeds
- Peanut Butter

Other/Unknown
- Plant-based Crumble product
- Meal Replacement Drink
- Powdered Infant Formula
- Falafel

* This list excludes the adverse event investigation of Dry Cereal because there was no evidence to establish a link between the reported food and illnesses.

** While most foodborne outbreaks are tracked through the FDA's Coordinated Outbreak Response & Evaluation (CORE) Network, seafood-related illnesses caused by natural toxins have a unique reporting mechanism. The FDA Division of Seafood Safety works with first responders, physicians, and state and local health departments to investigate illnesses and outbreaks, manage them, and learn how to lessen future occurrences.

Public Health Actions

When investigators find the food source of a multistate foodborne illness outbreak they can take actions, such as issuing a public health advisory or requesting companies to recall products associated with these outbreaks. FDA also can pursue compliance actions as needed (for example, a mandatory recall). The work conducted by the CORE Network during and following investigations of foodborne illness outbreaks or adverse events culminates in actions to drive the prevention of additional illnesses and future outbreaks.

In 2022, FDA issued public health advisories for 11 multistate outbreaks of foodborne illnesses or adverse events, associated with nine product recalls. As a result of these investigations, FDA CFSAN Office of Compliance also issued Import Alerts, entered into consent decrees, and issued warning letters to firms.

Investigations coordinated by CORE also inform follow-up activities carried out by other offices and divisions of FDA. These include but are not limited to follow-up inspections, continued risk assessments, and the development of comprehensive prevention strategies.

FDA Actions Related to Outbreaks in 2022*

Pathogen or Cause of Illness	Product(s) Linked to Illnesses	FDA Advisories	Recalls	Legal and Other Action
E. coli O157:H7	Packaged Salad	Outbreak Advisory		
Cronobacter	Powdered Infant Formula	Adverse Event Advisory	U.S. Recall Announcement	Consent Decree; FDA Prevention Strategy
Salmonella Senftenberg	Peanut Butter	Outbreak Advisory	Recall Announcement	FDA Warning Letter
Hepatitis A Virus	Strawberries	Outbreak Advisory		
Unknown	French Lentil and Leek Crumbles (Frozen Food)	Adverse Event Advisory	Recall Announcement	
Listeria monocytogenes	Ice Cream	Outbreak Advisory	Recall Announcement	FDA Warning Letter
Listeria monocytogenes	Brie and Camembert Soft Cheese Products	Outbreak Advisory	Recall Announcement; Expanded Recall Announcement	FDA Warning Letter
E. coli O121	Frozen Falafel	Outbreak Advisory	Recall Announcement	
Salmonella Litchfield	Seafood	Outbreak Advisory	Recall (Announcement in Advisory)	FDA Warning Letter
Listeria monocytogenes	Enoki Mushrooms	Outbreak Advisory	Recall Announcement; Expanded Recall Announcement	Country-wide Import Alert (IA #25-21); FDA Prevention Strategy
Salmonella Typhimurium	Sprouts	Outbreak Advisory	Recall Announcement; Expanded Recall Announcement	FDA Warning Letter

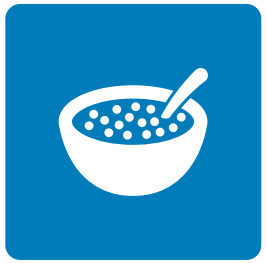
*Note: Some investigations listed in this table may have been initiated in 2021, but an advisory was not issued until 2022. This is not an exhaustive list of all FDA activities related to these incidents and additional activities may be ongoing.

New Trends in 2022 – Adverse Event Investigation

In 2022, CORE investigated four incidents of adverse events reported for the following FDA-regulated products: infant formula, a meal replacement drink, dry cereal, and a frozen food product. These adverse event report investigations rely on self-reported complaints submitted by consumers and health care practitioners and data voluntarily reported by industry to FDA consumer complaint coordinators and the CFSAN Adverse Event Reporting System (CAERS).

Powdered Infant Formula

Meal Replacement Drink



Dry Cereal

Frozen Food Product

Generally, these types of complaint driven investigations present unique challenges. One of these challenges is that investigators often must rely on consumer's self-reported data, which may not always include all the necessary information to fully investigate the product or event. Another common challenge is that the laboratory testing information available during typical outbreak investigations is often lacking or unavailable for these types of adverse event investigations.

What's New

To handle the increasing workload of investigating outbreaks and adverse events, in 2022, CORE established a permanent fourth Response Team with experts dedicated to solving and stopping outbreaks.

Noteworthy Outbreaks

Enoki Mushrooms

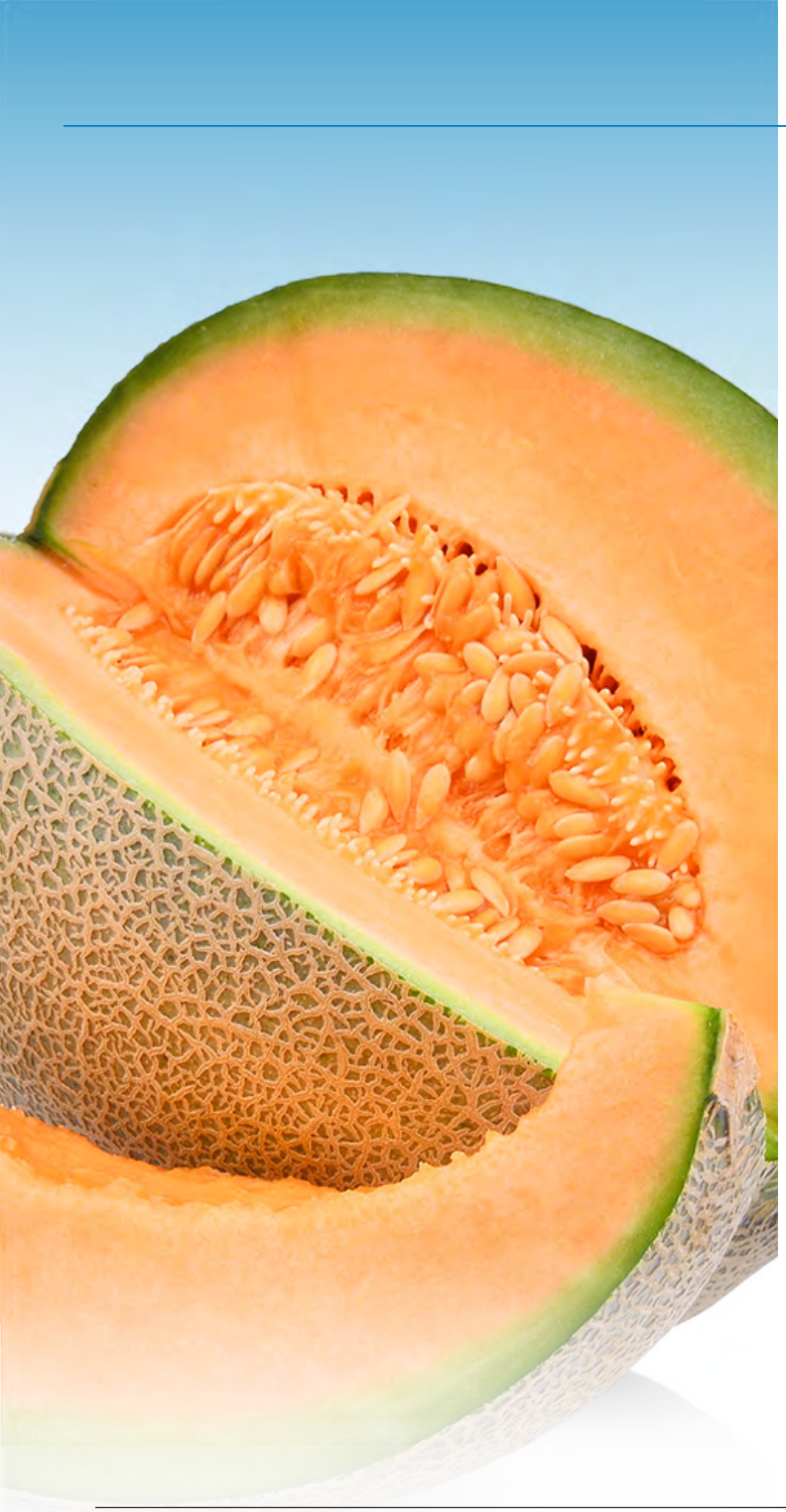
Enoki mushrooms (also known as enokitake, seafood, golden, golden needle, futu, and lily mushrooms) have been linked to two recent multistate *Listeria* outbreaks. The first known *Listeria* outbreak in the U. S. was linked to enoki mushrooms from the Republic of Korea in 2020 and another outbreak was linked to enoki mushrooms imported from China in 2022.

The 2020 outbreak and subsequent increase in surveillance also prompted the development of a Strategy to Help Prevent Listeriosis and Salmonellosis Outbreaks Associated with Imported Enoki and Imported Wood Ear Mushrooms, to protect public health.

As of August 9, 2023, more than 25 recalls of enoki mushrooms due to potential *Listeria* contamination have been conducted since 2020.

Further, after the 2022 outbreak, FDA added enoki mushrooms from China to an import alert (Import Alert (IA) #25-21) that was originally established for enoki mushrooms imported from the Republic of Korea based on information gathered during and following the 2020 outbreak.

These outbreaks demonstrate the importance of fast international data sharing and collaboration during foodborne outbreaks and the importance of food sampling, testing, and international genomic data sharing. In May 2023, an article was published in the Journal of Food Protection, discussing this international collaboration.



Cantaloupe

In August 2022, the FDA, CDC, and state partners conducted an outbreak investigation into a multistate outbreak of *Salmonella* Typhimurium infections linked to cantaloupe.

The isolates in this cluster of illnesses were within seven alleles / 11 single-nucleotide polymorphisms (SNPs) of two FDA soil swab samples collected from a 2020 outbreak investigation in Indiana.

Based on traceback information from the 2022 outbreak, FDA conducted investigations in Indiana at three farms, their common packinghouse, and nearby public lands. *Salmonella* positive environmental samples were found at each location, but none of the resulting *Salmonella* isolates conclusively matched the outbreak strain by whole genome sequencing (WGS). The outbreak vehicle was confirmed after the outbreak ended. No cantaloupes were recalled, and no public warning was issued as the implicated products were no longer on the market.

An Outbreak Investigation Report for this incident was published on April 2, 2023: Factors Potentially Contributing to the Contamination of Cantaloupe Implicated in the Outbreak of Salmonella Typhimurium During the Summer of 2022.

Peanut Butter

The FDA, along with CDC and state and local partners, investigated a multistate outbreak of *Salmonella* Senftenberg infections linked to certain peanut butter products.

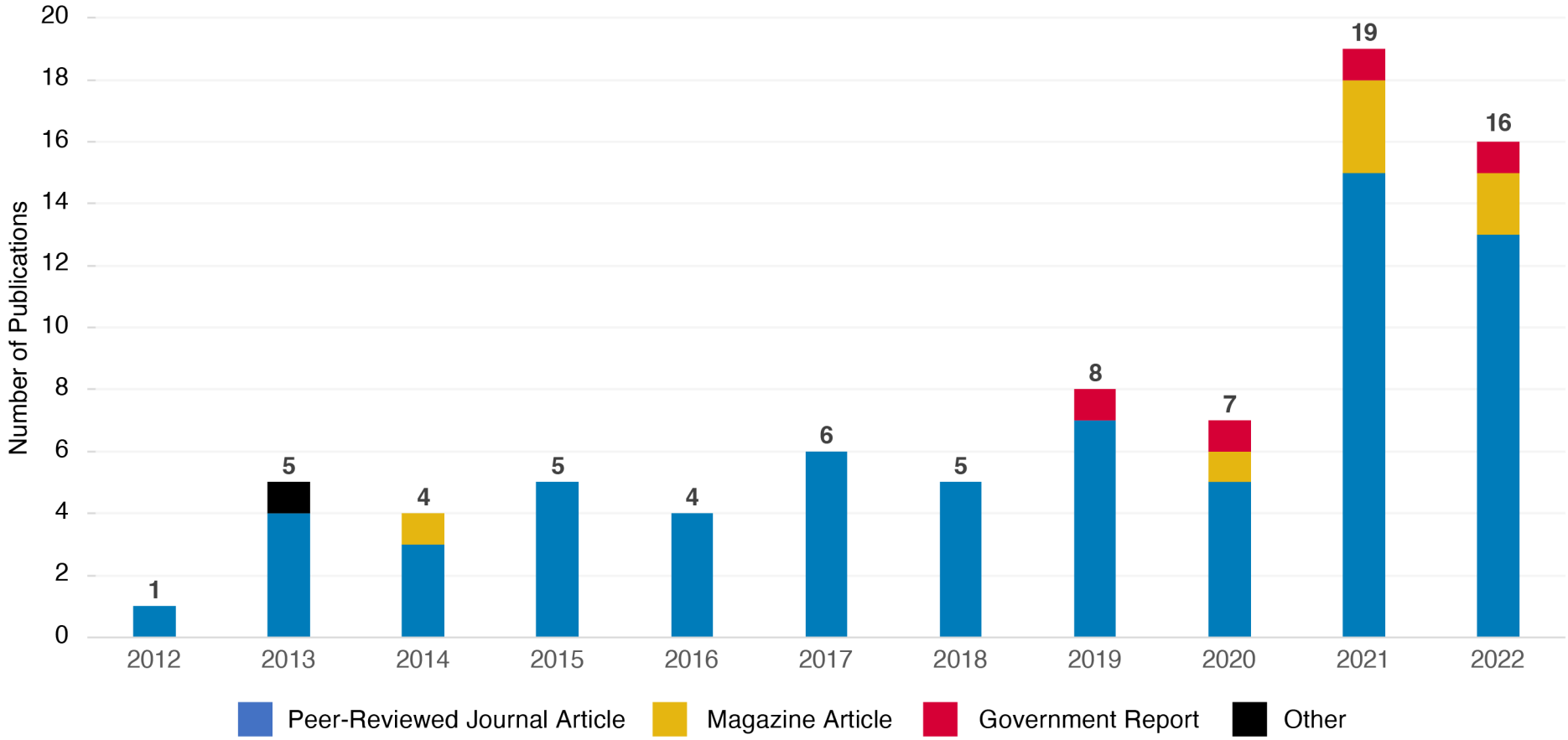
The company voluntarily recalled certain peanut butter products, and additional recalls were initiated for products that contained the recalled peanut butter. In addition, the FDA issued a Warning Letter on January 24, 2023, as a result of an inspection that was initiated as a part of this outbreak investigation.

FDA is preparing future communications to discuss findings and provide information to assist in future prevention efforts.

CORE Publications

One of the ways that CORE guides and supports outbreak prevention efforts is by sharing CORE's outbreak investigations and analytic summaries with internal and external stakeholders through publications and presentations. CORE publishes articles on the FDA website, in peer-reviewed scientific journals, and in other food safety and public health related periodicals. CORE staff also present at conferences and scientific meetings. In 2019, CORE created the Outbreak Analytics Team to support this mission and has since successfully published an increased number of articles since inception, compared to previous years. Specifically, from 2020 to 2022, CORE produced a total of 42 publications, which tripled the average annual publication efforts during the 2012-2019 time period.

CORE Publications, by Type of Published Material, Per Calendar Year, 2012 – 2022



2022 CORE Scientific Publications

A list of 2022 publications that include trade-press magazine articles geared towards the food industry and scientific journal articles which CORE team members led (*) or contributed to alongside other public health partners are presented below. Historical and subsequent CORE publications can be found on CORE's publication website.

CORE publications are any published materials that includes at least one CORE co-author at the time the material is being developed or in the process of publishing. CORE-led publications are defined as any published materials where CORE co-author(s) provide a majority of the contribution and bear responsibility for the integrity of the work as a whole from inception to publication/distribution, which is typically reflected with the first and/or senior co-authorship.

Trade-Press Magazine Articles

*The Incident Command System and Foodborne Illness Outbreak Investigations. Food Safety Magazine. October 2022.

*Outbreak Investigations of Cyclospora cayetanensis Infections 2013–2020: Progress Made and Challenges Remaining. Food Safety Magazine. April 2022.

Scientific Journal Articles (Peer-Reviewed Publications)

Bi-National Outbreak of Salmonella Newport Infections Linked to Onions: The United States Experience. Epidemiology and Infection. November 16, 2022.

Foodborne Illness Outbreaks Linked to Unpasteurized Milk and Relationship to Changes in State Laws — United States, 1998-2018. Epidemiology and Infection. October 25, 2022.

Preliminary Incidence and Trends of Infections Caused by Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016-2021. MMWR. October 07, 2022.

*Burkholderia cepacia Complex Outbreak Linked to a No-Rinse Cleansing Foam Product, United States — 2017-2018. Epidemiology and Infection. August 4, 2022.

*A 2019 Outbreak Investigation of Hepatitis A Virus Infections in the United States Linked to Imported Fresh Blackberries. Food and Environmental Virology. July 23, 2022.

Characteristics of U.S. Consumers Reporting Past Year Intake of Raw (Unpasteurized) Milk: Results from the 2016 Food Safety Survey and 2019 Food Safety and Nutrition Survey. Journal of Food Protection. July 1, 2022.

Multistate outbreak of Salmonella Mbandaka Infections Linked to Sweetened Puffed Wheat Cereal — United States, 2018. Epidemiology and Infection. June 20, 2022.

Foodborne Illness Outbreaks Reported to National Surveillance, United States, 2009–2018. Emerging Infectious Diseases. June 1, 2022.

Multistate Outbreak of Listeria monocytogenes Infections Linked to Fresh, Soft Hispanic-Style Cheese — United States, 2021. MMWR. May 27, 2022.

*Multistate Outbreak Investigation of Salmonella Infections Linked to Kratom: A Focus on Traceback, Laboratory, and Regulatory Activities. Journal of Food Protection. May 1, 2022.

Use of Whole-Genome Sequencing by the Federal Interagency Collaboration for Genomics for Food and Feed Safety in the United States. Journal of Food Protection. May 1, 2022.

Leveraging Risk Assessment for Foodborne Outbreak Investigations: The Quantitative Risk Assessment-Epidemic Curve Prediction Model. Risk Analysis. February 16, 2022.

Consumption of Raw Flour in the United States: Results from the 2019 U.S. Food and Drug Administration Food Safety and Nutrition Survey. Journal of Food Protection. January 1, 2022.

* CORE-led publications

CORE Resources

[About the CORE Network]

[Traceback Infographic]

[Investigations of Foodborne Illness Outbreaks]

[Public Health Advisories from Investigations of Foodborne Illness Outbreaks]

Acknowledgments

CORE's work to find, stop, and aid in the prevention of foodborne illness outbreaks would not be possible without all our partners. CORE would like to extend our greatest appreciation for the continued collaborations with the local, state, tribal, and territorial health and agriculture departments; the Centers for Disease Control and Prevention; the U.S. Department of Agriculture; and internal partners at FDA.

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