U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Coordinated Outbreak Response,
Evaluation, & Emergency Preparedness (CORE+EP)

# FOOD REPORT

**Foodborne Outbreak Overview of Data (FOOD) Report**

## FOOD 1: Hepatitis A Virus (HAV) in Berries

September 2025 (ver.2)



Coordinated Outbreak Response,
Evaluation, & Emergency Preparedness (CORE+EP)

# FOOD REPORT

**Foodborne Outbreak Overview of Data (FOOD) Report**

## FOOD 1: Hepatitis A Virus (HAV) in Berries

September 2025

## Contents


Background on CORE ..... 1
Overview of FOOD Reports ..... 1
- Abbreviations/Acronyms ..... 1
- Berry Definition ..... 1

Overview of Outbreaks and Inclusion Criteria ..... 2
- Associated CORE Outbreak Investigations ..... 2

Background on the Food-Pathogen Pair ..... 3
- Past Outbreaks ..... 3
- Laboratory Findings and Surveillance ..... 4

CORE Outbreak Data Analysis ..... 4
- Epidemiologic Findings ..... 4
- Laboratory Findings ..... 9
- Traceback Findings ..... 9

Historical Inspections, Events, and Actions ..... 10
- Establishment Inspections and Investigations ..... 10
- Inspection Results ..... 10
- Product and Compliance Actions ..... 10
- Recalls ..... 10
- Import Alerts ..... 10

Post-Response Analysis ..... 11
- Education and Outreach ..... 11
- Food Safety/Preventive Controls ..... 11
- Research ..... 11

Conclusions ..... 12
Acknowledgements ..... 11
References ..... 13


FOOD Report data compiled and accurate as of August 2025

# Background on CORE

FDA's Coordinated Outbreak Response & Evaluation (CORE) Network was established in August 2011 to coordinate efforts to detect, stop, and prevent foodborne illness. Since its founding, CORE has evaluated more than 1,300 possible outbreaks, responded to more than 350 outbreaks potentially linked to FDA-regulated food products, identified a specific food in more than 200 outbreaks, and warned consumers to avoid these foods through more than 700 public health advisories (as of August 2025). 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.

# Overview of FOOD Reports

CORE Foodborne Outbreak Overview of Data (FOOD) Reports provide information for industry and consumers on food-pathogen pairs that have been linked to repeated outbreaks of foodborne illness. FOOD Reports include historical epidemiologic data, laboratory analysis, traceback and investigational findings, and post-response prevention activities taken by FDA and our partners. These reports were developed to identify opportunities for action that may help prevent future foodborne illnesses.

*Disclaimer: FOOD Reports tell the story of the outbreak response actions and post-response activities directed or initiated by CORE and may not reflect all activities undertaken by all agencies in response to foodborne illness. The data included here was verified and is accurate as of the date listed on the Table of Contents page. Additional actions and prevention activities may have taken place after this date that are not included in this report.*

## Abbreviations/Acronyms

| | |
|---|---|
| **CFIA** | Canadian Food Inspection Agency; the regulatory agency dedicated to safeguarding of food, plants, and animals in Canada |
| **HAV** | Hepatitis A Virus; a human virus often spread through contaminated foods |
| **PCR** | Polymerase Chain Reaction; a laboratory method for detecting the genetic material of pathogens |
| **PFGE** | Pulse Field Gel Electrophoresis; a method of genetic analysis used prior to the introduction of WGS |
| **POS** | Point of Service, such as a restaurant or grocery store |
| **RNA** | Ribonucleic Acid; the genetic material of Hepatitis A Virus |
| **WGS** | Whole Genome Sequencing; a method of genetic analysis that is more advanced than PFGE and able to differentiate virtually all strains of foodborne pathogens |

## Berry Definition

Berry, as used in this report, is defined as the fruits typically considered berries by retailers and consumers in practice. Examples of these fruits include strawberries, raspberries, blueberries blackberries, cranberries, cherries, and pomegranate seeds (arils or kernels). This may differ from the formal botanical definition of a berry.

## Associated CORE Outbreak Investigations

1. **Investigation beginning May 2013**
   Hepatitis A virus linked to Frozen Pomegranate Seeds
2. **Investigation beginning August 2016**
   Hepatitis A virus linked to Frozen Strawberries
3. **Investigation beginning November 2019**
   Hepatitis A virus linked to Fresh Blackberries (suspect)
4. **Investigation beginning May 2022**
   Hepatitis A virus linked to Fresh Strawberries
5. **Investigation beginning February 2023**
   Hepatitis A virus linked to Frozen Strawberries



# Overview of Outbreaks and Inclusion Criteria

This report includes HAV outbreaks investigated by CORE from August 2011 (CORE's inception) through August 2025 with an identified or suspect vehicle of a fresh or frozen berry. Outbreaks that were associated with berries that have been cooked or further processed are not included.

FDA investigated two outbreaks of HAV linked to frozen strawberries in 1997 and 2000. These outbreaks predate CORE and are not included in this report.

While this report focuses on HAV, foodborne outbreaks associated with berries have been linked to other pathogens: an outbreak of norovirus was associated with frozen, imported raspberries used in ice cream products in 2016, an outbreak of *E. coli* O157:H7 with a suspect vehicle of fresh, domestically grown strawberries in 2011, and an outbreak of *Salmonella* in 2021 where blueberries were suspected to be the cause but could not be confirmed.

# Background on the Food–Pathogen Pair

This section summarizes some of the available scientific literature on hepatitis A virus outbreaks and the association with berries. This is not intended to be a comprehensive or authoritative review, but to give a general overview. Outbreak descriptions, illness (case) counts, and other quantitative information may vary between this report and other publications or FDA documents based on the data source, data collection methodology, and data inclusion/exclusion criteria.

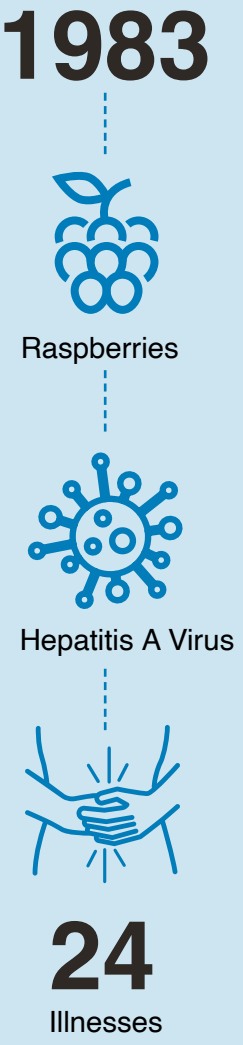
## Past Outbreaks

Foodborne outbreaks of hepatitis A virus (HAV) associated with consumption of fresh and frozen berries have been observed worldwide. Prompt identification of outbreaks is critical, since those exposed can be given HAV vaccine within two weeks to prevent illness [1]. The first documented HAV outbreak linked to berries was an outbreak in Scotland in 1983 linked to raspberries that sickened 24 people [2]. Fresh and frozen berries (including strawberries, raspberries, and berry mixes) were implicated in an additional 21 outbreaks of HAV from 1983 through 2018 across 24 countries, including the United States.

An extended outbreak of HAV from 2013-2014 in Italy was linked to mixed frozen berries. A total of 1,803 people were sickened, with 1,102 hospitalizations and one death reported [3]. Berries were confirmed as the contaminated food based on epidemiology, product traceback, and positive product laboratory tests for HAV RNA, the genetic material of the hepatitis A virus. The outbreak ended after authorities in the European Union issued recalls for implicated berry products [3,4].

An outbreak in Canada in 2012 was identified with nine confirmed cases linked to consumption of a frozen fruit blend. Laboratory testing by Canadian authorities detected HAV in the pomegranate seeds included in the fruit mix [5].

The first documented Hepatitis A virus outbreak linked to berries was an outbreak in Scotland in 1983 linked to raspberries that sickened 24 people.



## August 2011–August 2025 Impacts of Multistate Outbreaks

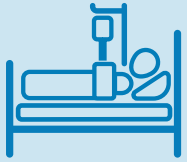
Linked to the Berries and Hepatitis A Virus Food-Pathogen Pair



**5**
Outbreaks



**354**
Illnesses



**150**
Hospitalizations



**0**
Deaths



**25**
States

### Laboratory Findings and Surveillance

In addition to the outbreak-associated laboratory testing described above, scientists and food safety regulators in several countries have conducted surveillance sampling on fresh and frozen berries. Canadian food safety authorities, the Canadian Food Inspection Agency (CFIA), conducted enteric virus surveillance sampling in fresh and frozen berries from 2016-2021. No HAV was detected in the samples analyzed [6].

A study in Ireland conducted surveillance sampling of retail fresh berries in 2018. Out of 239 samples tested, five (5/239; 2.1%) tested positive for the presence of HAV [7].

## CORE Outbreak Data Analysis

### Epidemiologic Findings

From August 2011 through August 2025, five outbreaks with a total of 354 confirmed cases and 150 hospitalizations (150/354; 42%) were reported from 25 states and were linked to the berries/HAV food-pathogen pair. No deaths were reported. According to the CDC, the true number of sick people in these outbreaks may be higher than the number reported — some ill people recover without medical care and are not tested for HAV. Most people who get HAV do not get very sick. However, in some cases, the virus can cause severe illness that lasts several months.

Although uncommon, HAV can cause death. People who are older or have other serious health issues have a higher risk of dying from hepatitis A. To learn more about HAV, visit CDC's Hepatitis A Basics resource page.

### Multistate Outbreaks of Hepatitis A Virus (HAV) Linked to Imported Berries

1. **HAV/Frozen Pomegranate Seeds/May 2013:**
   a total of 165 confirmed cases, 69 hospitalizations (69/165; 42%), and zero deaths were reported from ten states.
2. **HAV/Frozen Strawberries/August 2016:**
   a total of 141 confirmed cases, 53 hospitalizations (53/143; 38%), and zero deaths were reported from nine states.
3. **HAV/Fresh Blackberries (suspect)/November 2019:**
   a total of 20 confirmed cases, 11 hospitalizations (11/20; 55%), and zero deaths were reported from seven states.
4. **HAV/Fresh Strawberries/May 2022 (CIT Ref #1066):**
   a total of 18 confirmed cases, 13 hospitalizations (13/18; 72%), and zero deaths were reported from three states.
5. **HAV/Frozen Strawberries/February 2023 (CIT Ref #1143):**
   a total of 10 confirmed cases, 4 hospitalizations (4/10; 40%), and zero deaths were reported from four states.

### Case Maps by State for Each Outbreak

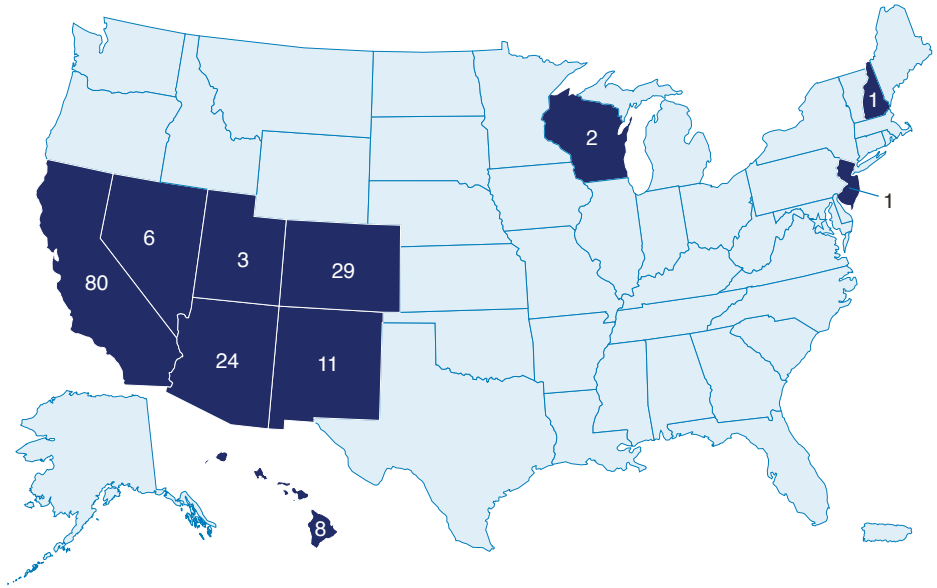



Figure 1A: HAV Cases Linked to Frozen Pomegranate Seeds, by State, 2013 (n=165)

**Figure 1A: Number of HAV Cases Linked to Frozen Pomegranate Seeds, by State, 2013 (n=165)**

| State/Territory | Cases |
|---|---|
| Arizona | 24 |
| California | 80 |
| Colorado | 29 |
| New Mexico | 11 |
| Hawaii | 8 |
| Nevada | 6 |
| New Jersey | 1 |
| New Hampshire | 1 |
| Utah | 3 |
| Wisconsin | 2 |

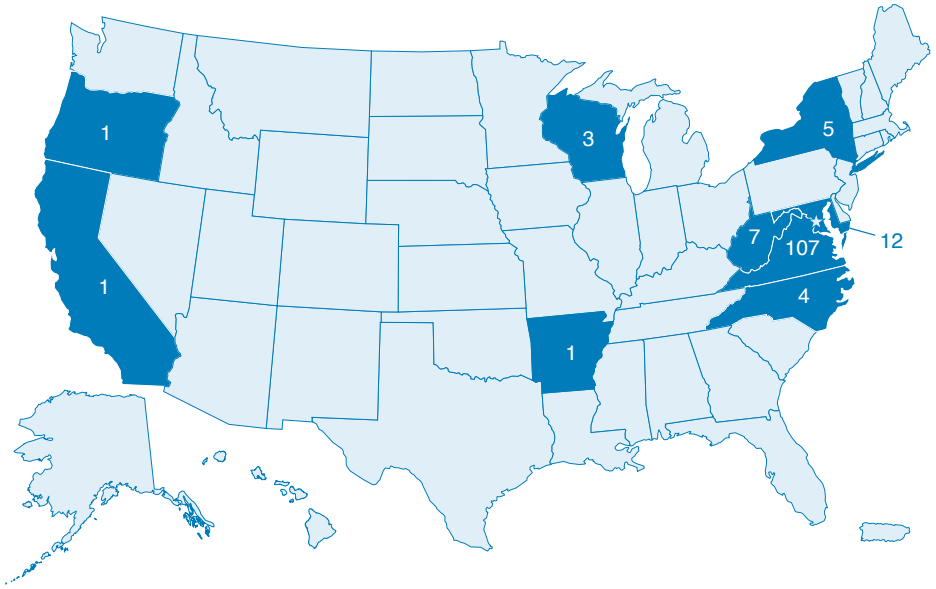



Figure 1B: HAV Cases Linked to Frozen Strawberries, by State, 2016 (n=141)

**Figure 1B: Number of HAV Cases Linked to Frozen Strawberries, by State, 2016 (n=143)**

| State/Territory | Cases |
|---|---|
| Arkansas | 1 |
| California | 1 |
| Maryland | 12 |
| New York | 5 |
| North Carolina | 4 |
| Oregon | 1 |
| Virginia | 107 |
| West Virginia | 7 |
| Wisconsin | 3 |

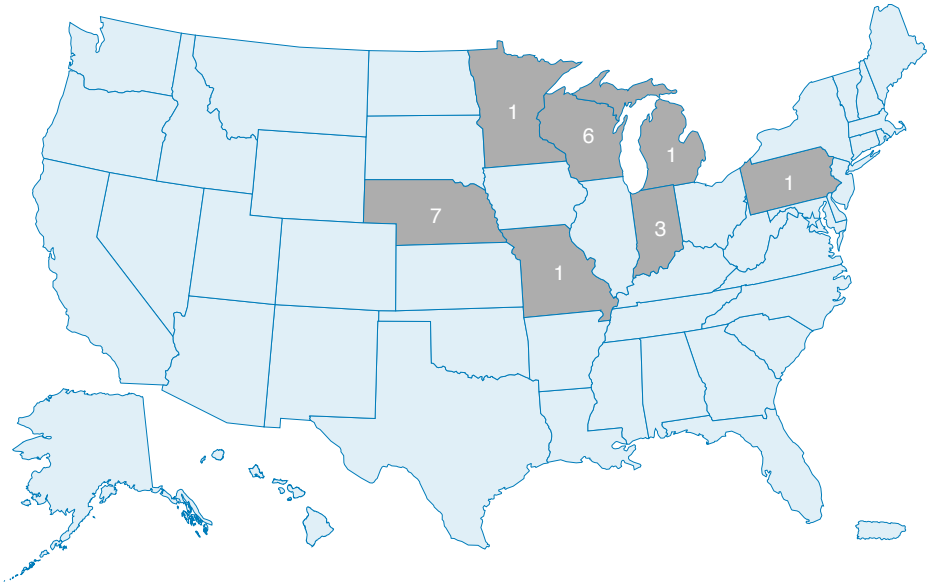



Figure 1C: HAV Cases Suspected to be Linked to Fresh Blackberries, by State, 2019 (n=20)

**Figure 1C: Number of HAV Cases Suspected to be Linked to Fresh Blackberries, by State, 2019 (n=20)**

| State/Territory | Cases |
|---|---|
| Indiana | 3 |
| Michigan | 1 |
| Minnesota | 1 |
| Missouri | 1 |
| Nebraska | 7 |
| Pennsylvania | 1 |
| Wisconsin | 6 |

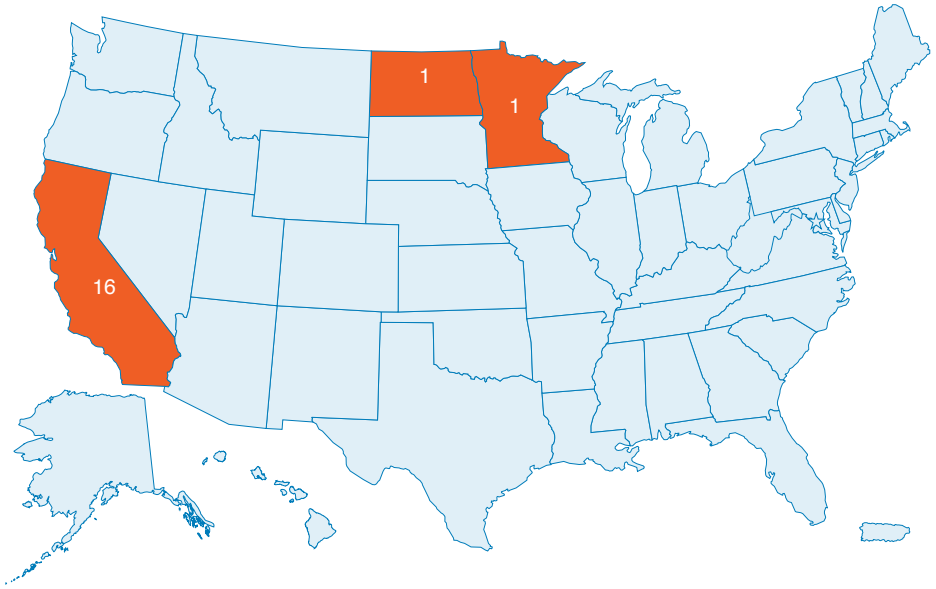



Figure 1D: HAV Cases Linked to Fresh Strawberries, by State, 2022 (n=18)

**Figure 1D: Number of HAV Cases Linked to Fresh Strawberries, by State, 2022 (n=18)**

| State/Territory | Cases |
|---|---|
| California | 16 |
| Minnesota | 1 |
| North Dakota | 1 |

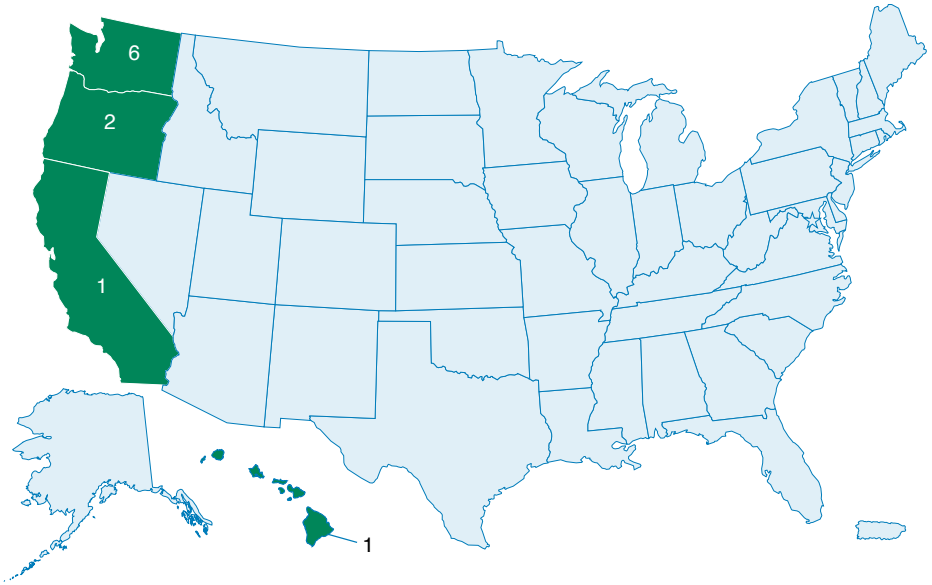
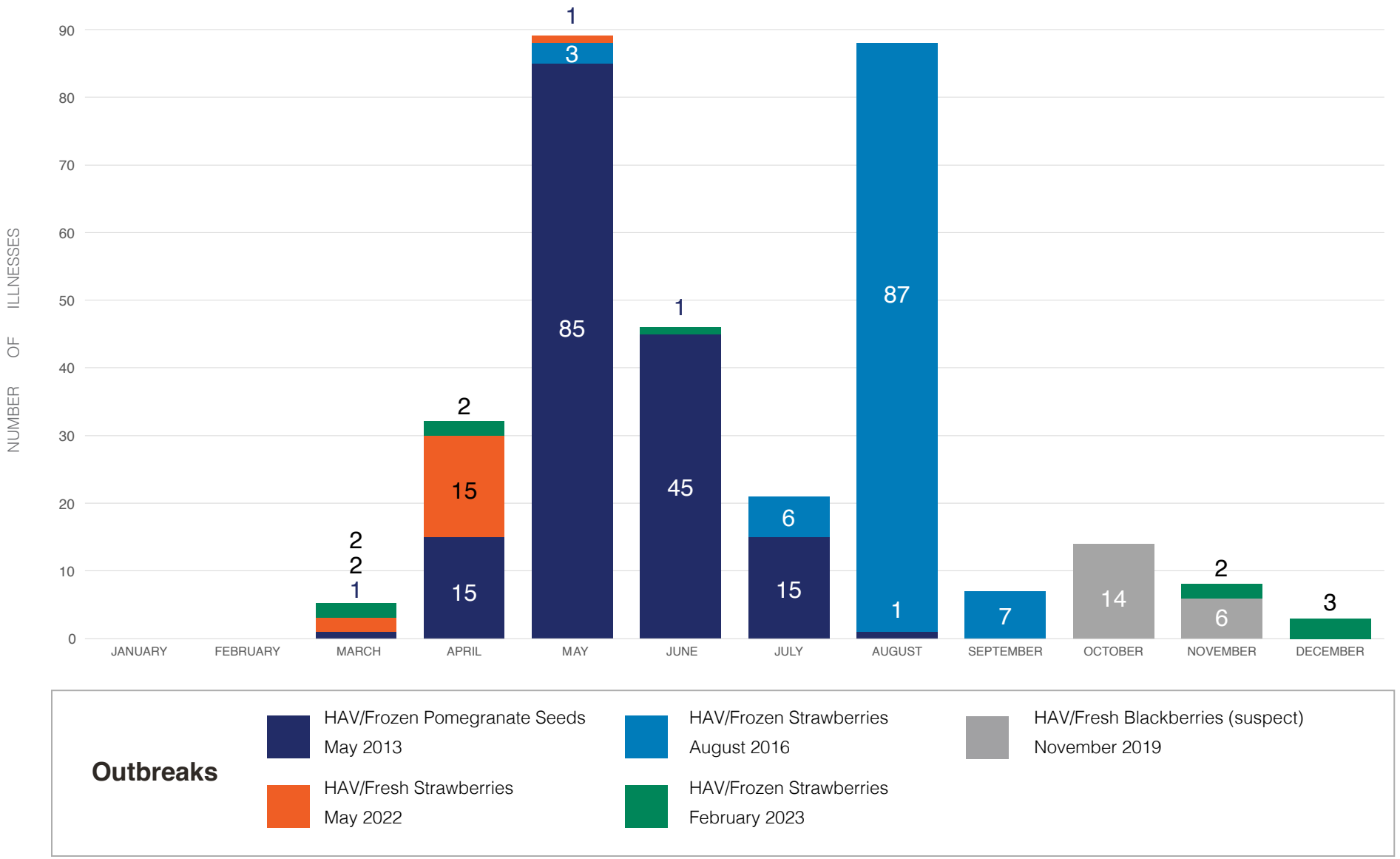



Figure 1E: HAV Cases Linked to Frozen Strawberries, by State, 2023 (n=10)

**Figure 1E: Number of HAV Cases Suspected to be Linked to Frozen Strawberries, by State, 2023 (n=10)**

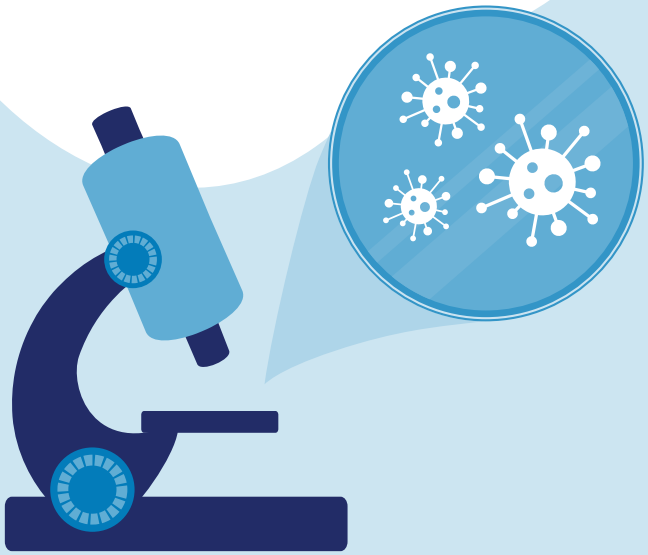
| State/Territory | Cases |
|---|---|
| Washington | 6 |
| California | 2 |
| Oregon | 1 |
| Hawaii | 1 |

**Figure 2: Hepatitis A Virus Outbreaks, Linked to Berries, Illnesses by Month (2013, 2016, 2019, 2022, 2023)**




*Totals may not equal number in Figures 1A-1C; onset date not known for all cases in all outbreaks.

In each outbreak, the berries implicated were traced back to a foreign supplier (in Turkey, Egypt, and Mexico, respectively).



## Laboratory Findings

Laboratory analysis helps identify products that may be contaminated and making people sick. Once a pathogen is found, molecular techniques such as PFGE and WGS can help investigators find linked cases that are a genetic match and determine the source of an outbreak.

During each of the outbreaks, product samples were collected. Out of a total of 139 samples collected during the five investigations, six samples collected during one outbreak (Frozen Strawberries/2016) were found to be positive for HAV RNA by PCR (6/139; 4.3%). These samples were collected by FDA and public health partners during warehouse inspections, point-of-service (POS) inspections, and during import review. No positive product samples were recovered in the other two outbreaks. No environmental swabbing samples were collected for any of the outbreaks.

Product samples are often collected during an outbreak investigation once a food is suspected of being the source of illness. The prevalence of HAV in these samples should not be assumed to be the prevalence of HAV in the food overall.

## Traceback Findings

Once foodborne illness is detected, FDA and our public health partners attempt to identify the food linked to illnesses. Traceback investigations examine supply chain data to identify the source of food sold or served at a specific location. Traceback findings complement laboratory and epidemiologic evidence during a public health investigation. To learn more about the traceback investigation process and how they help protect public health, read How the FDA Uses Traceback to Respond to Foodborne Illness Outbreaks.

Traceback was performed to identify the sources of berries implicated in each outbreak. In each outbreak, the berries implicated were traced back to a foreign supplier (Turkey, Egypt, and Mexico, respectively). The 2022 and 2023 outbreaks were both traced to the same foreign supplier. In some cases, traceback efforts were limited by a lack of recordkeeping traceability (such as failing to document critical details like production dates and supplier information), and in others, the long incubation period of HAV made it difficult to identify the specific lots of food consumed because too much time had passed.

# Historical Inspections, Events, and Actions

## Establishment Inspections and Investigations

FDA conducted 30 field investigations during the three outbreaks. Of those, eight were full firm inspections. Two were farm inspections at foreign berry growers in Mexico during the same outbreak investigation (Frozen Strawberries/2023). More information about the FDA inspection process and inspectional citations are available on the FDA website.

## Inspection Results

Of the eight inspections, three were found to have violative conditions. Two firms received observations on an FDA Form 483 (Frozen Pomegranate Seeds/2013 and Fresh Strawberries/2022). One firm received observations on an FDA Form 4056, the form issued after on-farm produce inspections (Frozen Strawberries/2023).

Firms were cited for deficiencies in sanitary operations, equipment and utensil maintenance, Foreign Supplier Verification Programs, and processes and controls.

For general information on FDA Form 483s, see FDA Form 483 Frequently Asked Questions. For more information about produce inspections, see FDA's information on farm inspections and Form 4056.

## Product and Compliance Actions

Product actions are measures taken to remove affected products from the marketplace and mitigate their risk to consumers. Compliance actions are steps taken to correct and prevent violations of food safety regulations. These activities may include recalls, court-ordered product seizures, warning letters, import controls, and other enforcement actions needed to protect public health.

## Recalls

| Outbreak | Date | Firm | Product(s) |
|---|---|---|---|
| **Frozen Pomegranate Seeds / 2013** | 6/4/2013 | Townsend Farms | Organic frozen berry mixes |
| **Frozen Pomegranate Seeds / 2013** | 6/28/2013 | Townsend Farms | Additional frozen berry mixes |
| **Frozen Pomegranate Seeds / 2013** | 6/26/2013 | Scenic Fruit Company | Organic pomegranate kernels |
| **Frozen Strawberries / 2016** | 10/25/2016 | ICAPP | All frozen strawberry products (whole, diced, and sugar-coated) |
| **Frozen Strawberries / 2023** | 3/15/2023 | California Splendor | Frozen whole and sliced strawberries |
| **Frozen Strawberries / 2023** | 3/16/2023 | Scenic Fruit | Frozen strawberries |
| **Frozen Strawberries / 2023** | 5/25/2023 | Cascade International Foods | Frozen strawberries |
| **Frozen Strawberries / 2023** | 6/5/2023 | Wawona Frozen Foods | Frozen fruit blends |
| **Frozen Strawberries / 2023** | 6/7/2023 | Oregon Potato Co. | Frozen fruit blends |

## Import Alerts

Three firms were added to FDA Import Alert #99-35, "Detention without Physical Examination of Fresh Produce that Appears to Have Been Prepared, Packed or Held Under Insanitary Conditions."

## Acknowledgements

Investigating an outbreak requires the contributions of many individuals—domestic and foreign FDA field staff, laboratory scientists at labs across the country, disease experts at the CDC, and our collaborators in state, local, tribal, and territorial public health agencies. Each outbreak investigation described in this document required cooperation between CORE and these public health partners and would not have been possible without them. We also appreciate the partnership and collaborative efforts of our federal partners within FDA and CDC.

# Post-Response Analysis

The list below provides a summary of related activities that have occurred and were shared with CORE as of August 2025.

## Education and Outreach

In 2022, FDA notified the public of its ongoing berry surveillance sampling program and the development of a prevention strategy to reduce the risk of viruses in fresh and frozen berries. In 2025, CORE published a manuscript describing the investigation of the 2022 and 2023 outbreaks in the Journal of Food Protection [8].

## Food Safety/Preventive Controls

In 2016, FDA developed a microbiological surveillance sampling assignment of frozen berries for HAV. The sampling assignment was initiated in 2018 and concluded in September 2023. The full summary of the sampling program and results are posted on the FDA website.

FDA is committed to engagement with industry and other stakeholders to identify root causes of these outbreaks and to develop collaborative strategies for preventing future outbreaks. In January 2025 FDA published a prevention strategy focused on preventing illness from enteric viruses in fresh and frozen berries and similar foods. The strategy was developed and is being implemented through engagement and collaboration with the global berry industry and other interest holders. It leverages industry learnings and experience with effective management practices so that they can be communicated throughout the global berry industry, and to identify information gaps to inform research needs. A summary of the Berries/Enteric Virus Prevention Plan is posted on the FDA website.

## Research

FDA conducted applied research in HAV detection method development in 2014-2015. A new multi-laboratory-validated methodology for detecting HAV in foods was published to the FDA Bacteriological Analysis Manual (BAM) on July 29, 2015. A revision of the testing protocol was published in 2022, following input from scientific experts by adding Sanger sequencing which evaluates a greater portion of the virus genome.

## Conclusions

Outbreaks of foodborne HAV were identified using epidemiological and traceback information, and in one instance, was also identified by laboratory confirmation of HAV RNA in an implicated berry product. Repeated outbreaks of HAV associated with fresh and frozen imported berries indicate the need for improved practices to ensure the safety of the food supply and reduce risks to public health.

The international nature of the product and supply chain complicates nearly every aspect of outbreak investigations, including illness detection, traceback, and foreign inspections. This, combined with the harvest method (by hand), short production window for berries, and long incubation period for HAV severely limited our ability to investigate sources of contamination on foreign farms and processing facilities during production. Despite these limitations, hygienic practices were found to be challenges for the control of HAV in berries.

# References


1. Hofmeister MG, Weng MK, Thoroughman D, Thomasson ED, McBee S, Foster MA, Collins J, Burkholder C, Augustine RJ, Spradling PR. Prevalence of indications for adult hepatitis A vaccination among hepatitis A outbreak-associated cases, Three US States, 2016-2019. Vaccine. 2021 Oct 22;39(44):6460-6463. doi: 10.1016/j.vaccine.2021.09.051. Epub 2021 Sep 28.

2. Bozkurt H, Phan-Thien KY, van Ogtrop F, Bell T, McConchie R. Outbreaks, occurrence, and control of norovirus and hepatitis a virus contamination in berries: A review. Crit Rev Food Sci Nutr. 2021;61(1):116-138. doi: 10.1080/10408398.2020.1719383. Epub 2020 Feb 3.

3. Scavia G, Alfonsi V, Taffon S, Escher M, Bruni R, Medici D, Pasquale SD, Guizzardi S, Cappelletti B, Iannazzo S, Losio NM, Pavoni E, Decastelli L, Ciccaglione AR, Equestre M, Tosti ME, Rizzo C, National Italian Task Force On Hepatitis A. A large prolonged outbreak of hepatitis A associated with consumption of frozen berries, Italy, 2013-14. J Med Microbiol. 2017 Mar;66(3):342-349. doi: 10.1099/jmm.0.000433. Epub 2017 Mar 23.

4. Severi E, Verhoef L, Thornton L, Guzman-Herrador BR, Faber M, Sundqvist L, Rimhanen-Finne R, Roque-Afonso AM, Ngui SL, Allerberger F, Baumann-Popczyk A, Muller L, Parmakova K, Alfonsi V, Tavoschi L, Vennema H, Fitzgerald M, Myrmel M, Gertler M, Ederth J, Kontio M, Vanbockstael C, Mandal S, Sadkowska-Todys M, Tosti ME, Schimmer B, O Gorman J, Stene-Johansen K, Wenzel JJ, Jones G, Balogun K, Ciccaglione AR, O' Connor L, Vold L, Takkinen J, Rizzo C. Large and prolonged food-borne multistate hepatitis A outbreak in Europe associated with consumption of frozen berries, 2013 to 2014. Euro Surveill. 2015 Jul 23;20(29):21192. doi: 10.2807/1560-7917.es2015.20.29.21192.

5. Swinkels HM, Kuo M, Embree G; Fraser Health Environmental Health Investigation Team; Andonov A, Henry B, Buxton JA. Hepatitis A outbreak in British Columbia, Canada: the roles of established surveillance, consumer loyalty cards and collaboration, February to May 2012. Euro Surveill. 2014 May 8;19(18):20792.

6. Steele M, Lambert D, Bissonnette R, Yamamoto E, Hardie K, Locas A. Norovirus GI and GII and hepatitis A virus in berries and pomegranate arils in Canada. Int J Food Microbiol. 2022 Oct 16;379:109840.

7. Bennett C, Hunt K, Butler F, Keaveney S, Fanning S, De Gascun C, Coughlan S, O'Gorman J. Detection of Hepatitis A RNA, Hepatitis E RNA, Human Adenovirus F DNA, and Norovirus RNA in Fresh and Frozen Berry Products at Point of Retail in Ireland. Food Environ Virol. 2023 Sep;15(3):246-254.

8. McClure M, Kirchner M, Greenlee T, Seelman S, Madad A, Nsubuga J, Sandoval AL, Jackson T, Tijerina M, Tung G, Nolte K, da Silva AJ, Read J, Noelte V, Woods J, Swinford A, Jones JL, LaGrossa M, McKenna C, Papafragkou E, Yu C, Ou O, Hofmeister MG, Samuel CR, Atkinson R, To M, Orr A, Cheng J, Borlang J, Lamba K, Adcock B, Bond C, Needham M, Adams S, Grilli G, Stewart LK, Martin T, Wagendorf J, Pinnick D, Smilanich E, Sorenson A, Manuzak A, Salter M, Crosby A, Viazis S. Investigation of Two Outbreaks of Hepatitis A Virus Infections Linked to Fresh and Frozen Strawberries Imported from Mexico - 2022-2023. J Food Prot. 2025 May 22;88(6):100505. doi: 10.1016/j.jfp.2025.100505. Epub 2025 Apr 15.



U.S. Food and Drug Administration
Human Foods Program
**Coordinated Outbreak Response, Evaluation, & Emergency Preparedness (CORE+EP)**
College Park, Maryland 20740
**www.fda.gov**