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General Interest

Investigation of Two Outbreaks of Hepatitis A Virus Infections Linked to Fresh and Frozen Strawberries Imported from Mexico – 2022–2023 ☆

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ABSTRACT

Foodborne hepatitis A illnesses and outbreaks have been associated with the consumption of ready-to-eat foods contaminated with the feces of person(s) shedding hepatitis A virus (HAV). Outbreaks have been linked to fresh and frozen produce imported from countries where HAV is endemic, hygiene and sanitation are inadequate, or food safety standards are lacking or unenforced. In 2022 and 2023, federal, state, and international partners investigated two multijurisdictional outbreaks of infections involving the same HAV genotype IA strain linked to fresh and frozen organic strawberries sourced from a single grower in Baja California, Mexico. These resulted in 39 reported cases in the U.S. and Canada, 21 hospitalizations, and no reported deaths. The United States Food and Drug Administration (FDA), Canadian Food Inspection Agency, and U.S. state partners conducted traceback investigations for fresh strawberries in 2022, while FDA and U.S. state partners traced back frozen strawberries in 2023. Based on the traceback investigations, implicated strawberries were harvested during the 2022 growing season and sold to fresh and frozen berry markets. During a farm inspection in Mexico in 2023, gaps were observed in agricultural practices that could have contributed to the contamination of strawberries with HAV. FDA did not detect HAV in the two frozen strawberry samples linked to the recalled lots or environmental water samples collected at the implicated grower in 2023; no samples were collected during the 2022 investigation. Indicator organisms associated with human fecal contamination (male-specific coliphage and

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crAssphge) were detected in environmental water. Challenges in these investigations included limited recall of food exposures, exposures associated with multiple purchase dates, commingling of strawberries within the frozen market supply chains, and complexities with communicating these outbreak investigations to the public.

Hepatitis A virus (HAV) is a highly contagious liver-targeting virus that can be contracted through the consumption of food or water contaminated with the feces of a person shedding HAV. While HAV infection is most often asymptomatic, it can cause acute hepatitis (liver inflammation), jaundice, fatigue, and gastroenteritis; symptomatic infection is more common in adults than in children (U.S. Centers for Disease Control and Prevention, 2020). In rare cases, it can also result in liver failure and death. The incubation period of HAV infection can range from 15 to 50 days (U.S. Centers for Disease Control and Prevention, 2021b). Vaccination is the most effective way to prevent hepatitis A; however, in the United States in 2021, self-reported vaccination data showed that only 24.8% of adults aged 19 and older had received at least one dose of hepatitis A vaccine (Hung et al., 2024; U.S. Centers for Disease Control and Prevention, 2021b). According to a study from 2011, an estimated 1,566 foodborne HAV infections occur in the U.S. every year (Scallan et al., 2011) Historically, HAV foodborne illnesses and/or outbreaks have been associated with the consumption of ready-to-eat foods contaminated with the feces of a person shedding HAV, as well as consumption of raw shellfish (especially bivalves) grown in water contaminated with human sewage (Di Cola, Fantilli, Pisano, & Ré, 2021). In recent years, a number of hepatitis A outbreaks in the U.S. also have been linked to the consumption of fresh and frozen produce imported from regions where HAV is endemic or where there are deficiencies in hygiene compliance and/or food safety standards enforcement (Hu, Collier, & Xu, 2020). Mexico is one of those regions considered to have intermediate endemicity of hepatitis A, with higher endemicity in specific regions, including rural areas (López-Gatell et al., 2018), accounting for a higher risk of HAV contamination of foods imported into the U.S.

In 2022 and 2023, an identical HAV genotype IA strain was associated with two outbreaks linked to the consumption of strawberries (fresh and frozen, respectively), imported from the Baja California region of Mexico (U.S. Food and Drug Administration, 2022b, 2023). These outbreaks, in combination, led to 39 total reported cases (19 in the U.S. and 10 in Canada in 2022, and 10 in the U.S. in 2023) that were investigated by the U.S. Food and Drug Administration (FDA); the Centers for Disease Control and Prevention (CDC); state and local public health agencies, Mexico's Federal Commission for Protection against Sanitary Risk (COFEPRIS) and National Service of Agro-Alimentary Health, Safety and Quality (SENASICA); the Public Health Agency of Canada (PHAC); and the Canadian Food Inspection Agency (CFIA) (U.S. Food and Drug Administration, 2022b, 2023).

Here, we describe both the 2022 and 2023 investigations, including epidemiologic and traceback findings that identified imported strawberries as the source of these outbreaks, and the subsequent actions taken to protect public health. We also discuss how the 2022 outbreak investigation guided the subsequent 2023 investigation and delineate steps that could be taken to prevent similar outbreaks from reoccurring in the future.

Materials and methods

Epidemiologic investigations. Hepatitis A is a nationally notifiable disease in both the United States and Canada (U.S. Centers for Disease Control and Prevention, 2019). Ill people were diagnosed by healthcare providers and identified through reporting to state and local health departments. State and local public health agencies interviewed ill persons using a hepatitis A-specific case investigation form to collect demographic information and details on foods, grocery store, and restaurant exposures in the 15–50 days preceding illness onset. In the U.S. and Canada, besides food exposure, patients were assessed for other risk factors for HAV infection, such as drug use, homelessness, male-to-male sexual contact, and international travel.

The frequency of reported foods consumed by people in the U.S. outbreaks was compared with food frequencies from the CDC FoodNet Population Survey using a cumulative binomial probability model. Ill people associated with the U.S. outbreaks were defined as having acute hepatitis A, with illness after March 19, 2022, and after October 28, 2022, for the 2022 and 2023 outbreaks, respectively. Included cases were required to meet the current Council of State and Territorial Epidemiologists (CSTE) acute hepatitis A case definition (U.S. Centers for Disease Control and Prevention, 2021a), with either sequencing related to the outbreak strain (0–1 nucleotide difference) in 2022 and 2023, or reported consumption of frozen recalled strawberries during the 15–50 days before illness onset for the 2023 outbreak (U.S. Food and Drug Administration, 2023). Canadian cases were defined as confirmed based solely on an identical RNA fingerprint (0 nucleotide difference).

Traceback investigations. Traceback investigations in the U.S. were initiated following standard FDA and state traceback practices (Council to Improve Foodborne Outbreak Response, 2020; Irvin et al., 2021; McClure et al., 2022). In the U.S., ill people included in traceback investigations were either individuals and/or subclusters of ill persons with documented purchase dates (if available) of fresh organic strawberries within the 50 days preceding illness onset for the 2022 outbreak, and individuals and/or subclusters of illnesses with documented purchase dates of frozen organic strawberries within the six months prior to illness for the 2023 outbreak (McClure et al., 2022). The results from the 2022 investigation informed the traceback approach used during the 2023 investigation. Notably, supply chain data obtained during the 2022 investigation were utilized to determine if a common grower supplied organic strawberries to frozen berry processors during the timeframe of interest in 2023.

In Canada, a parallel traceback investigation was conducted in 2022, and the information was shared with U.S. counterparts, according to the Foodborne Illness Outbreak Response Protocol (FIORP) (Government of Canada, 2017). Under the Food Incident Response Process (Government of Canada, 2021), CFIA investigated exposure for the ten Canadian cases and their associated points of service (POS) to identify the specific product lots and growers implicated in the outbreak.

Inspections and on-farm investigation. In 2022, the FDA conducted one inspection at a U.S. importer and distributor to assess compliance with the Foreign Supplier Verification Programs (FSVP) Rule. This type of inspection reviews the importing firm's FSVP to ensure that food from their foreign supplier(s) is produced in a manner that provides the same level of public health protection as the Produce Safety (PSR) and Preventive Controls for Human and Animal Foods Rules (PCHF and PCAF Rules), as applicable (U.S. Food and Drug Administration, 2018, 2020). In 2023, the FDA conducted two inspections at U.S. importers and distributors covering traceability records and product sample collection. Additionally, from April 17–22, 2023, the FDA conducted PSR inspections (U.S. Food and Drug Administration, 2019) at two strawberry-growing operations of interest in Mexico: Growers J and K.

Microbiological investigations. ***Strawberries.*** During the 2023 investigation, the FDA Human and Animal Foods Labs analyzed 30 fresh and frozen strawberry samples for the presence of HAV. These included 14 firm-retained frozen berry samples, three frozen berry packages that were previously opened samples from ill patients, and

13 fresh imported strawberry samples from multiple growers. Samples were analyzed for the presence of HAV RNA using methods from the FDA Bacteriological Analytical Manual (BAM) (U.S. Food and Drug Administration, 2022a).

Environmental water. In 2023, four environmental water samples (10–350 L) were collected during the foreign inspections at Grower J (two samples) and Grower K (two samples) using Dead-End Hollow Fiber Ultrafiltration. These samples were processed using a method based on the Kahler et al protocol (Kahler et al., 2015), with the addition of murine norovirus (MNV) as a process control. Viruses were concentrated from the backflush using polyethylene glycol (PEG) and RNA was extracted from the resuspended PEG pellet. HAV and MNV RNA were detected by RT-qPCR protocols as described in FDA BAM Chapter 26 (U.S. Food and Drug Administration, 2022a) including appropriate controls (positive/negative qPCR controls and Internal Amplification Control). Nucleic acids isolated from the water samples were also tested via qPCR for the presence of cross-assembly phage (crAssphage), as an indicator of human fecal contamination, as previously described (Park et al., 2020).

Results

A timeline of events that took place during the 2022 and 2023 respective outbreak responses, including the outbreak detection, inspections, recalls, public health advisories, and regulatory actions taken, can be found in Figure 1.

2022 outbreak: Epidemiologic investigation. A total of 19 reported cases were associated with the 2022 multistate foodborne hepatitis A outbreak in the U.S (U.S. Centers for Disease Control and Prevention, 2023). Ill persons were reported from four states: Arizona, California, Minnesota, and North Dakota (Fig. 2). Illness onset dates ranged from March 28 to May 6, 2022 (Fig. 3). Ill persons ranged in age from 9 to 73 years, with a median age of 57 years. Sixty-three percent of ill persons were female. Thirteen (68%) were hospitalized, and there were no reported deaths. Of the 16 cases interviewed, 11 (69%) reported eating fresh organic strawberries during their exposure period.

The PHAC reported ten outbreak-associated cases in the Canadian provinces of Alberta and Saskatchewan. Illness onset dates ranged from April 4 to 17, 2022. Ill persons ranged in age from 10 to 75 years, with a median age of 24.5 years. Four (40%) were hospitalized, and no deaths were reported (Canada, 2023). Of the 10 cases interviewed, nine (90%) reported eating strawberries during their exposure period. Purchase records showed that eight cases confirmed purchasing organic strawberries from the same grocery chain from March 5 to 9, 2022. An identical HAV genotype IA strain was sequenced from clinical specimens from all cases in both the U.S. and Canadian outbreaks in 2022.

Traceback investigation. Traceback, coordinated by the FDA with significant contributions by California and other state partners, was conducted in 2022 for fresh organic strawberries reportedly consumed by six U.S. outbreak-associated cases purchased from five POS, including three POS from the same retail chain (Fig. 4; US POS A-C). Among these locations, only one POS location included in the traceback investigation was associated with two cases, while the other four were associated with a single case each. Additionally, most cases included in the traceback reported multiple purchases of fresh organic strawberries prior to illness onset. The CFIA also conducted a traceback of organic strawberries consumed by the ten Canadian cases associated with the outbreak. This included linking seven cases to seven POS of the same grocery store chain in Alberta and Saskatchewan from February 10 to March 20, 2022. The U.S. traceback investigation determined that 1-lb and 2-lb. containers of fresh organic strawberries sourced from Baja California, Mexico, could account for all illnesses included in the traceback. A single distributor, Distributor H, was identified as supplying all fresh organic strawberries provided to the U.S. and Canadian POS included in the traceback investigations during the timeframe of interest. Upon identification of Distributor H, California partners conducted a thorough traceforward investigation to ensure all affected product was accounted for. This included tracking approximately 300,000 lbs. of fresh strawberries distributed by Distributor H to wholesale customers across the U.S. and Canada. Distributor H received organic strawberries from Distributors I, J, K, and L, who sourced fresh strawberries from multiple growers in Baja California, Mexico. However, analysis of available information did not identify a single grower that could have accounted for all the illnesses included in the traceback analysis.

Firm inspections. On June 6, 2022, the FDA initiated an FSVP inspection at Distributor H due to their association with the 2022 outbreak. In addition to obtaining further information about three foreign suppliers of strawberries through the FSVP inspection, investigators determined that Distributor H had not developed a FSVP program

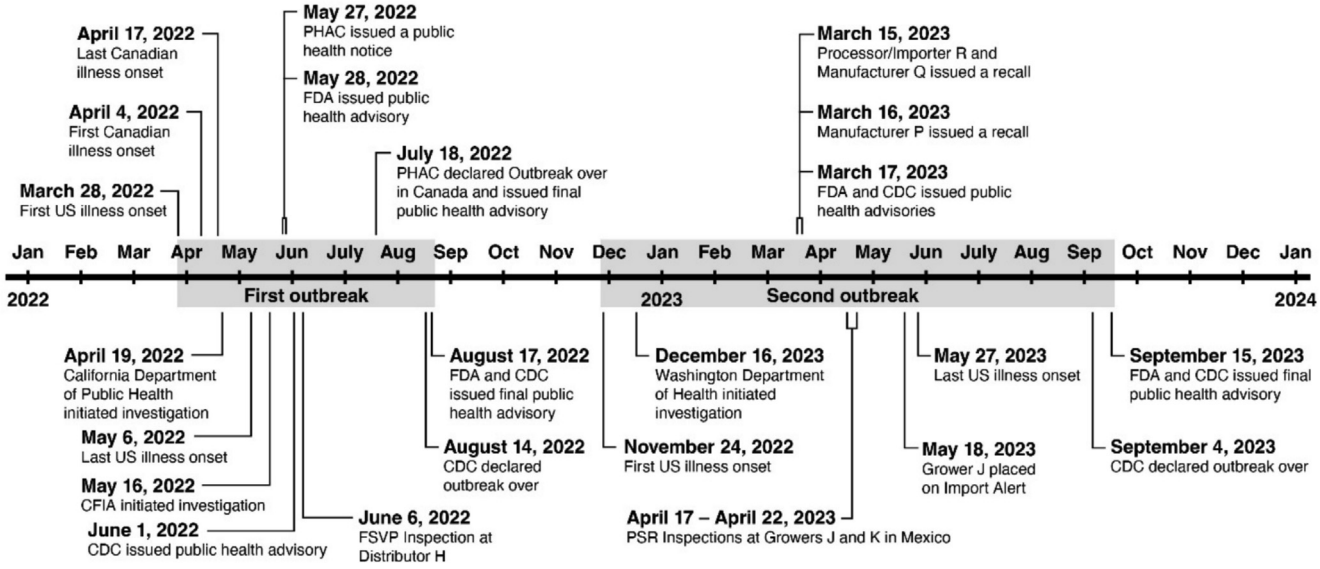

Figure 1. Timeline of events during the 2022 and 2023 outbreak responses, including the outbreak detection, inspections, recalls, public health advisories, and regulatory actions taken.

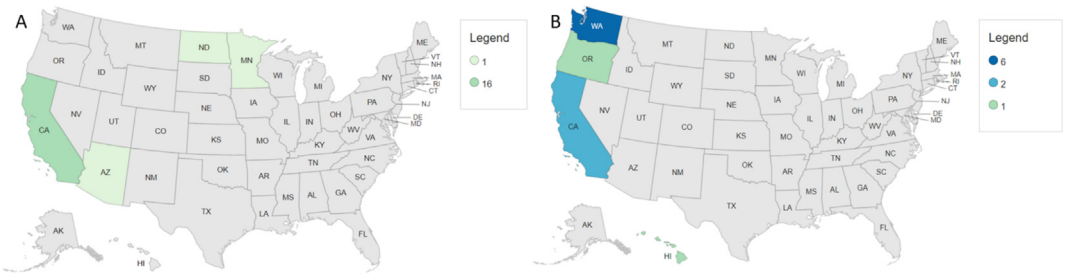

Figure 2. State of residence of U.S. cases in the 2022 and 2023 foodborne hepatitis A outbreaks linked to strawberries. (A) 2022 outbreak associated with fresh strawberries (19 cases from 4 states), and (B) 2023 outbreak associated with frozen strawberries (10 cases from 4 states).

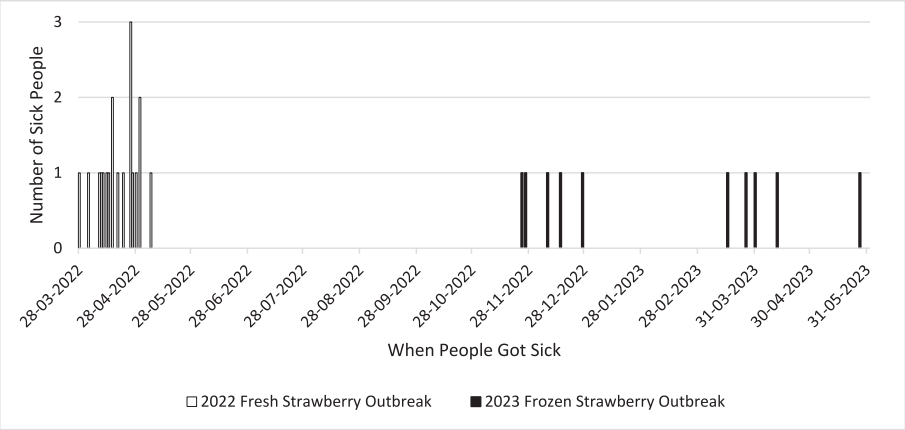

Figure 3. Date of hepatitis A illness onset of U.S. cases, 2022–2023. The epidemiologic curve depicts the date of illness onset for U.S. cases in the 2022 fresh strawberry (white) and 2023 frozen strawberry (black) foodborne hepatitis A outbreaks in the United States.

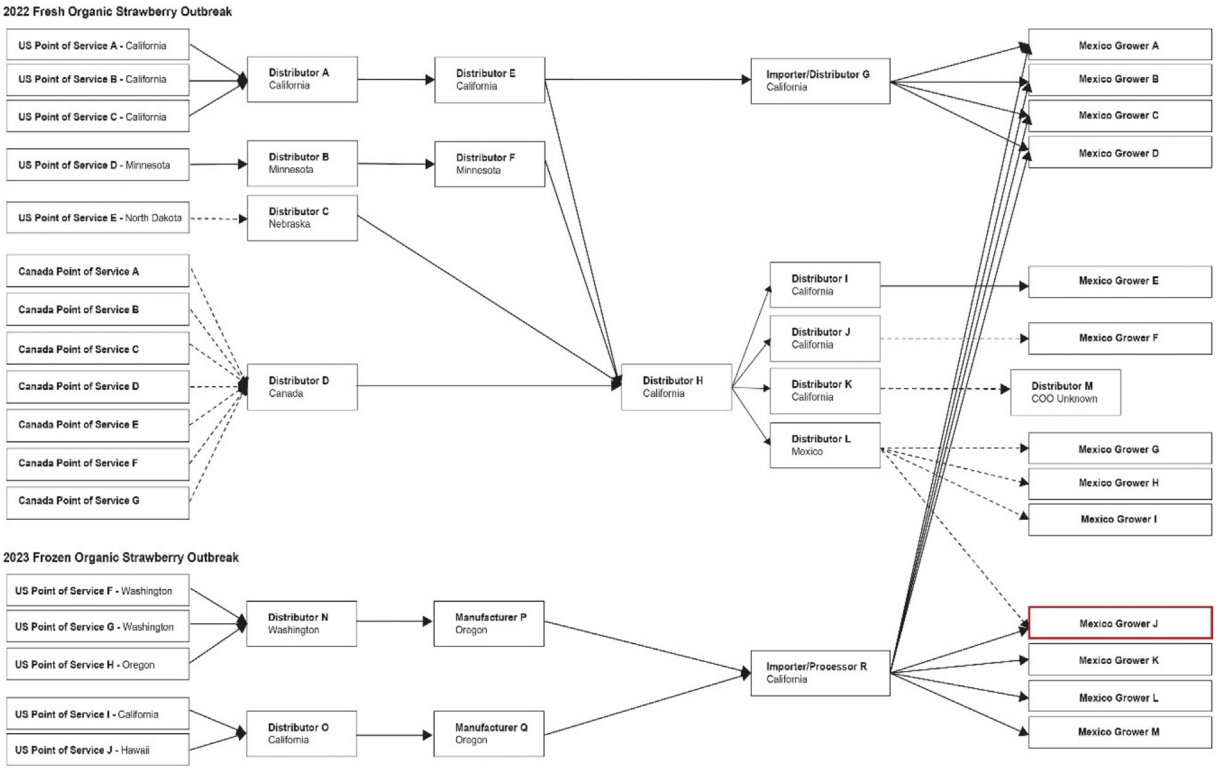

Figure 4. Traceback diagram for multistate outbreak of hepatitis A virus infections in the United States and Canada linked to fresh and frozen strawberries imported from Mexico, 2022–2023. Purchases of implicated products are traced from points of service (POS), through the distribution chain, to distributors and importers. Product originates from growers that are denoted on the right side of the diagram.

for all imported products (including fresh organic strawberries) and did not provide FSVP documents in English for review, as required. Voluntary corrective actions related to these inspectional observations were later received by the FDA from Distributor H.

Investigational outcomes and public communications. The FDA regularly collects samples associated with foreign suppliers identified during any outbreak investigation. However, when growers from Baja California, Mexico, were identified, strawberries were no longer being grown and imported; therefore, no product samples were collected in 2022. Additionally, since all the affected fresh organic strawberries were past shelf life, no product samples were collected from consumers and Distributor H did not issue a recall.

On May 28, 2022, the FDA issued an initial webpost indicating that this outbreak was linked to fresh organic strawberries purchased between March 5 and April 25, 2022, with available brand names and/or retail customers disclosed. It was advised that even though the fresh strawberries were past their expiration date/shelf life, consumers should discard any berries purchased during that timeframe, especially if they had been frozen to extend their shelf life. Subsequent updates included revising the purchase date range for affected berries based on additional investigational information obtained and clarifying actions taken by downstream customers of Distributor H. On June 1, 2022, CDC issued a food safety alert webpost for this outbreak. Subsequent updates mirrored FDA's webposts (U.S. Food and Drug Administration, 2022b). On August 17, 2022, both CDC and FDA issued a final webpost update for the U.S. outbreak. On May 27, 2022, PHAC issued a public health notice for the outbreak in Canada (Government of Canada, 2022). Updates were made on June 2, 2022, and a final webpost was issued on July 18, 2022, closing out the Canadian investigation.

2023 U.S. outbreak: Epidemiologic investigation. As of September 4, 2023, a total of ten outbreak-associated cases of hepatitis A were reported from four states: California, Hawaii, Oregon, and Washington (Fig. 2). Illness onset dates ranged from November 24, 2022 to May 27, 2023 (Fig. 3). Ill persons ranged in age from 38 to 65 years, with a median age of 56.5 years. Thirty percent of ill persons were female. Four cases (40%) were hospitalized, and no deaths were reported. All ten cases were interviewed, and all ten (100%) reported eating frozen organic strawberries during their exposure period and provided purchase records. This proportion was significantly higher compared to a survey of healthy people in which 24% reported eating frozen berries in the week before they were interviewed. Among patients with clinical specimens available for sequencing, the resulting sequences were an identical match to the HAV genotype IA strain seen in the 2022 hepatitis A outbreak linked to fresh strawberries. There were no cases in Canada reported during the 2023 outbreak.

Traceback investigation. The FDA and states conducted traceback for a specific brand of frozen organic strawberries purchased from Distributors N and O, which were distribution centers owned and operated by the same corporation (Fig. 4). The FDA's traceback included five stores of the same chain representing eight cases. Consumer purchase data, including purchase date and product description, but not lot codes, were available for all the cases included in this traceback investigation. Three POS locations each had two cases linked to purchases of frozen organic strawberries, while the other two locations each had one case with multiple purchases of frozen organic strawberries. The frozen organic strawberries that may have been available for these documented purchases by cases were imported between January and March 2022 from multiple growers in the Baja California, Mexico, region by a common processor (Processor/Importer R). Processor/Importer R commingled strawberries from different growers into bulk lot products, removing the potential for a single source to be identified via lot coding. Based on the information collected, strawberries received by Processor/Importer R in early 2022 were individually quick frozen (IQF) and then sold later in 2022 and 2023, resulting in the 2023 outbreak. There was no evidence that these frozen strawberries entered Canada during the 2023 outbreak.

The FDA evaluated the traceback information from the 2022 outbreak in combination with information received during the 2023 outbreak and concluded that a single grower, Grower J in Baja California, Mexico was linked to the 2022 U.S. and Canadian traceback, and the 2023 U.S. traceback. Based on the combined traceback information collected, this grower was noted to be the only supplier that was linked to all illnesses included in the traceback investigations from both 2022 and 2023.

On-farm investigations. The FDA conducted two inspections with SENASICA's Mexican officials and Baja California's State Committee representatives at Grower J and Grower K in Baja California, Mexico, from April 17 to 22, 2023. While traceback identified Grower J as the farm that could explain all illnesses in 2022 and 2023, Grower K was also of interest based on a potential association with a firm in the supply chain of the 2022 traceback. SENASICA accompanied FDA on the inspection at Grower K and the Baja California State Committee accompanied the FDA to Grower J. Grower K was operating under the voluntary System for Risk Reduction from Contamination (SRRC) program certified by SENASICA (Servicio Nacional de Sanidad, 2021), PrimusGFS, and Equitable Food Initiative (EFI) and no significant observations were documented during the inspection. However, the investigators noted significant observations during the inspection of Grower J, which was Global G.A.P. certified but not SRRC certified. These observations included poor personal hygienic practices, such as inadequate or lack of handwashing, workers reporting that they had been picking for three days but had received no food safety training, poor maintenance of sanitary facilities (such as dirty handwash water, grey handwash water leaking onto the ground throughout the growing area, and no water for handwashing in one toilet facility), failure to implement measures to prevent contamination of produce and food contact surfaces through ceilings and condensate, and failure to take necessary measures to identify and not harvest produce that was reasonably likely to be contaminated. Lastly, there was an apparent lack of consistent processes to address failures in the food safety system, such as standard operating procedures in place describing when and how to respond to any out-of-specification findings in the water that was used for agricultural purposes. The inspections of Grower J and K confirmed the traceback findings; no association of Grower K to the supply chain in 2022 was identified, and Grower J was the only supplier that was linked to all cases in both the 2022 and 2023 outbreaks.

Microbiological investigation. In response to the 2023 outbreak, the FDA collected 34 samples, including three opened consumer frozen strawberry samples, 14 samples from frozen strawberries retained by Processor/Importer R and Manufacturer P, which supplied Distributor N; 13 fresh strawberry samples collected at import, and four environmental agriculture water samples collected during inspections at Grower J and Grower K in Baja California, Mexico. No HAV was detected in any of the fresh or frozen product samples collected, making it difficult to determine a potential source of contamination through laboratory testing alone. According to the respective firms, the retained samples collected were from the lots of interest, imported and frozen in the spring of 2022. These lots of frozen product contained berries imported from multiple suppliers, commingled into single lots of mixed berries. The import samples were fresh berries collected at import from Growers C, D, L, and M, suppliers which had been identified in the 2023 traceback investigation. No import samples were available for collection from Grower J. As the import samples were all fresh strawberries, they represented the 2023 harvest season rather than the 2022 harvest of interest. The three opened consumer samples were not a part of the recalled product. Likewise, the environmental samples were collected in 2023, over a year past when the implicated product was harvested and imported to the U.S. One of the two agricultural water samples collected from Grower K tested pos-

itive for HAV by RT-qPCR (detected in 1 of 3 replicate reactions with a Ct value of 41.4); however, sequencing was unsuccessful. CrAssphage DNA was detected in one of the four water samples (Grower J).

Investigational outcomes and public communications. Five firms issued voluntary recalls for strawberry products after being notified of the outbreak by the FDA, which resulted in extensive downstream recalls. Manufacturers P and Q issued recalls due to their products being linked to illnesses in the 2023 outbreak. Processor/Importer R and Manufacturer Q issued recalls for multiple lots and sizes of frozen strawberries on March 15, 2023. Manufacturer P issued a recall for multiple brands, lots, and sizes of frozen organic strawberry products on March 16, 2023. As a result of the traceback, traceforward, and inspectional findings at Grower J, additional firms not known to be related to the outbreak issued recalls in June 2023 for strawberries that had been imported in 2022 from Grower J. In response to this outbreak investigation and the on-farm inspection, Grower J was placed on Import Alert #99–35 for strawberries and raspberries in May 2023 (U.S. Food and Drug Administration, 2021b, 2021c); these products from Grower J would be detained on import into the U.S. without physical examination until released from import alert. Early in the outbreak response, eight firms (Growers A, B, C, D, J, K, L, and M) were placed on increased import screening (sampling) based on the 2023 traceback findings, prior to evaluating the commonalities with the 2022 traceback and identifying the grower that caused the outbreak. As a follow-up to this outbreak investigation, the FDA also conducted a PCHF inspection at Processor/Importer R from August 4–18, 2023, though the firm had completed production for the season. The investigators identified multiple observations at the firm, including an inadequate supply chain program (e.g., the firm did not conduct annual onsite audits or review third−party audit results of their raw strawberry supplier to verify controls were in place for pathogenic hazards), and a lack of written procedures for monitoring employee practices to prevent cross−contamination of ready-to-eat products. On March 17, 2023, FDA, CDC, and state and local public health agencies issued public communications related to this outbreak, with subsequent updates including case count updates and recall information (U.S. Food and Drug Administration, 2023).

Discussion

Hepatitis A outbreaks and berries. In the U.S., fresh or frozen berries and pomegranates imported from Egypt, Mexico, and Turkey have been implicated in five outbreaks between 2013 and 2023. Hepatitis A is endemic in parts of Africa, Asia, Eastern Europe, as well as North, Central, and South America (Collier et al., 2014; McClure et al., 2022; U.S. Centers for Disease Control and Prevention, 2021b). Asymptomatic or presymptomatic farm workers may shed the virus while working, without an awareness that they are infected.

An infected person may excrete the virus in their stool up to two weeks prior to becoming symptomatic. Contamination of food with HAV can happen at any point in the supply chain, including growing, harvesting, processing, and handling. In addition, washing of fruits during processing may distribute localized contamination throughout an entire lot of berries, and freezing preserves the viable viral particles for long periods of time. Inactivation of HAV on fresh or frozen berries has been studied but no process is in place to inactivate enteric viruses' contamination on fresh or frozen products (Bozkurt et al., 2021; Gómez-López et al., 2021). Firms must comply with the PSR, PCHF Rule, and the FSVP Rules in addition to consistent application of good agricultural and manufacturing practices, as applicable. Measures such as hygienic controls including personal hygiene, handwashing, management of sanitary facilities, equipment sanitation, and management of agricultural water, are critical to prevent fecal contamination of fruit, equipment, and food contact surfaces. In addition, frozen berry processors who identify HAV as a hazard requiring a supply-chain-applied control must establish and implement a robust risk-based supply chain program to ensure suppliers effectively control human pathogens such as HAV. Hepatitis A is a vaccine-preventable disease and vaccination strategies could be used for harvest and handling crews to prevent future outbreaks. However, farm workers are not represented among the groups for which HAV vaccination is recommended (U.S. Centers for Disease Control and Prevention, 2020).

Investigational challenges. There are several challenges inherent to conducting foodborne hepatitis A outbreak investigations. The lack of a systematic and publicly available molecular surveillance system, such as PulseNet, for HAV in the U.S. means that there is not a standardized system in place to prospectively identify outbreaks potentially linked to commercially distributed foods. Additionally, the lengthy incubation and exposure periods for hepatitis A make it difficult to obtain exposure information from ill people associated with outbreaks as it is challenging for patients to recall their food exposures accurately and comprehensively. In the U.S., the standard viral hepatitis case report form, on which many health departments base their local case investigations on, does not contain questions about specific food exposures. This means that many patients are not asked about food exposures during their initial case investigation interviews with health department staff and must be recontacted for an additional interview to complete a comprehensive food exposure questionnaire once they are suspected of being part of a foodborne hepatitis A outbreak.

2022 traceback challenges. There were several limitations to the traceback during the 2022 outbreak investigation. The lack of confirmed purchase documentation and/or multiple exposures for several ill people included in the traceback limited the ability to narrow to specific shipments of strawberries. The traceback data indicated convergence at Distributor H, but this firm was not the only distributor identified during the traceback, which resulted in a prolonged investigation to determine if product supplied by a second distributor (Distributor G) could also potentially explain illnesses. Furthermore, although multiple growers in Baja California, Mexico were identified, FDA was unable to obtain and/or confirm GPS coordinates for all growers of interest with Mexican partners. This also contributed to the inability to narrow to a single grower or field of interest in the 2022 investigation until additional traceback information was obtained and convergence was determined in the 2023 outbreak investigation. In addition, information obtained during the 2022 traceback investigation did not indicate that the fresh strawberries of interest were further distributed to the frozen market. In hindsight, an investigation to determine if fresh produce is also entering the frozen produce market during a fresh produce outbreak investigation should be standard practice; this was a lesson learned.

2022 investigational challenges. The long incubation period associated with hepatitis A, coupled with exposure to a fresh product with a short shelf life (e.g., fresh, organic strawberries) and a production season that was already completed by the time grower information was available, resulted in an inability to collect product samples from within the supply chain and consumer households during the 2022 investigation. Also of note, public communications challenges were complicated by the lack of a formal recall given that the fresh strawberries were past their shelf life and no longer being sold in retail stores. Given concern with consumers potentially freezing fresh strawberries implicated in the outbreak, available brand names and/or retail customer information was disclosed. However, as additional investigational information became available, subsequent communication updates, such as a revision of the implicated strawberry purchase date range of interest, as well as revision to product actions taken by a downstream customer of Distributor H could have led to confusion among the public as to what strawberry products were of concern.

2023 traceback challenges. Most ill people included in the 2023 traceback investigation had multiple purchase dates for the same

branded frozen strawberry product and ill people all purchased the contaminated product at POS owned and operated by a single business chain. While the business chain has retail stores across the globe, the POS identified in the traceback were not widely distributed, which limited some conclusions that could be drawn from the analysis. As previously noted, hepatitis A has an incubation period of up to 50 days. Frozen strawberries can have a shelf life of up to two years, and HAV can remain infectious even after freezing (Homan et al., 2022; Sattar et al., 2000). Taken together, this makes for a broad range of dates where people could have purchased product leading to illness. During manufacturing at Processor/Importer R, strawberries from different growers were comingled into bulk lot products, making it difficult to identify a single source through lot coding. The traceback shows that the frozen organic strawberries purchased and consumed by persons who experienced illness were received fresh in the U.S. and frozen between January 2022 and March 2022. Due to the manufacturer's comingling practices and timespan between the initial IQF process to final packaging, scoping of the recalls was challenging in that it was difficult to definitively determine the amount of product that needed to be removed from the market (McClure et al., 2022). Additionally, consumer purchase data provided by the ill people did not include product lot numbers, further hindering our ability to narrow the product action scope.

2023 microbiological challenges. CrAssphage has recently been investigated as an indicator of human fecal pollution in water environments (e.g., irrigation water, surface water, and wastewater) due to its abundance and strong correlation with enteric viruses, mostly norovirus (Meuchi et al., 2023; Suh et al., 2024). The lack of correlation between HAV occurrence and crAssphage in the water samples is likely due to the small number of samples tested and low viral contamination which limits the ability to evaluate crAssphage as an indicator of human fecal contamination.

Traceback successes. Despite the challenges independently faced in both the 2022 and 2023 traceback investigations, ultimately, when the traceback information from the individual outbreaks were combined, a single common grower was identified (Grower J). Consumer purchase data assisted the 2023 investigation by identifying a common frozen strawberry product. Based exclusively on the information gathered from the 2023 outbreak investigation, a single supplying grower could not have been identified due to the comingling during processing and lack of lot coding for products associated with the obtained consumer purchase data. However, considering that sequencing results from the 2022 and 2023 confirmed cases shared an identical HAV genotype IA strain, the most likely explanation is that the outbreak-associated illnesses from both investigations shared a common food exposure along the supply chain.

Based on combined epidemiologic and traceback information, the common food exposure was determined to be organic strawberries harvested during the 2022 growing season in Baja California, Mexico. The hypothesis that the 2023 outbreak associated with frozen strawberries was linked to the 2022 outbreak associated with fresh strawberries was noted once sequencing was available during the 2023 investigation and further supported by the traceback evidence obtained identifying a common supplier.

Another component of the overall 2023 investigation that should be highlighted is the use of traceforward and other investigational information to recommend additional recalls. Once investigators had completed the traceback and the inspection at Grower J, concern focused on what, if any, additional products could pose a threat to human health. This concern was underscored by the fact that FDA import records showed additional U.S. recipients of strawberries harvested from Grower J during the period of concern in 2022 with the potential for these firms to have frozen the received fresh strawberries to greatly increase the shelf life. FDA held calls with these firms to discuss concerns and work through the voluntary recall process. Unfortunately, not only was comingling of strawberries from multiple growers into a single frozen bulk lot a traceback challenge but also the comingling increased the amount of product subject to recall. FDA is cognizant of the concerns regarding food waste, and the availability of more specific traceability data combined with limited comingling could have avoided some waste in this scenario.

On-farm investigation and collaboration. During the 2022 outbreak investigation, the available traceback investigation information identified multiple growers of interest but was not able to identify specific growers for inspection and it was not feasible to conduct multiple on-farm FDA inspections. However, in 2023, with a narrower scope and inclusion of 2022 traceback data, two foreign suppliers (Growers J and K) were identified for inspection by FDA. The challenges faced in conducting an accompanied and unannounced foreign inspection should not be understated. However, many of the logistical challenges faced were eased by FDA's partnerships and previously agreed-upon protocols with Mexican authorities (U.S. Food and Drug Administration, 2021a). The investigation at Grower J revealed many concerning observations, strengthening the overarching traceback conclusion.

Sample collection and analysis challenges. In 2022, there was a lack of retail samples available for testing due to the short shelf life of the fresh product and the lengthy incubation time resulting in consumers not reporting any product of interest still in their possession. Lastly, investigators were unable to obtain import samples as the strawberry growing season had ended. As a result, no samples were collected during the 2022 investigation.

In contrast, in 2023, a total of 34 samples were collected; however, HAV was not detected in any of these samples collected. It should be noted that the 13 import samples and four environmental water samples collected in 2023 were not temporally representative of the 2022 timeframe of most concern. However, two firms involved in the frozen berry market provided retained samples to FDA for testing. These samples may be representative of the 2022 harvest season, but not necessarily associated with the strawberries consumed leading to illnesses, due to insufficient traceability data. In addition, of the 30 product samples tested, only two were associated with the implicated lots based on the recall information. The lack of HAV detected in these samples could be explained by a few potential factors: the likelihood that contamination in the berries was not homogenous throughout the entire supplied lot of discrete fruits, unavailability of the recalled product for testing, the comingling of berries from multiple growers into a single lot, and, lastly, the potential that contamination in the berries was at levels too low to be detected. There have been outbreak investigations where the pathogen has been detected in the implicated frozen berry product (Saupe et al., 2020; U.S. Food and Drug Administration, 2016). In the 2016 frozen strawberry outbreak, 19 samples from the implicated lots were tested and HAV was detected in six samples and characterized in five of the six samples (U.S. Food and Drug Administration, 2016). In any outbreak investigation, sampling, and testing the implicated lots increase the chance of detecting the pathogen and in 2016 and 2022/2023 outbreaks, the levels of contamination were low and not homogenous.

Conclusions

In 2022, epidemiologic and traceback evidence collected during a foodborne hepatitis A outbreak by U.S. federal and state partners along with Canadian partners, determined that fresh organic strawberries sourced from the Baja California region of Mexico supplied by Distributor H were the likely source of contamination. In 2023, investigational partners responded to a second foodborne outbreak of the same strain of HAV. The sequencing results and traceback analysis for the 2022 and 2023 outbreaks indicated that they likely shared a common food source. By actively utilizing traceback data from prior outbreaks of the same strain, investigators may be able to have a clearer picture of where contamination may have originated and what

food safety issues may lead to outbreak reoccurrence. These investigations also highlight that a strong traceability program will be an increasingly important aspect of food safety as supply chains continue to become increasingly more complex and global and the compliance date for the FDA Food Traceability Rule (which applies to certain foods) comes into effect (U.S. Food and Drug Administration, 2021b, 2021c). Multiple issues noted during the farm inspections indicated that contamination at the farm level, especially in regions like Mexico where hepatitis A is endemic (Guzman-Holst et al., 2022), was likely and mitigation steps could be employed to prevent future issues. Overall, these investigations emphasize that basic food safety measures and strong traceability programs continue to be vital in foodborne outbreak prevention and response.

Disclaimer

The findings, views, and conclusions expressed in this article are those of the authors and do not necessarily reflect the official policy of the Department of Health and Human Services, the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, the U.S. Government, the California Department of Public Health, the California Health and Human Services Agency, the Public Health Agency of Canada, or the Canadian Food Inspection Agency. Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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