



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

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Outbreak #2010-195 Summary Report

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INTRODUCTION

On November 3, 2010, the Maryland Department of Health and Mental Hygiene (DHMH) recognized through routine surveillance via two different local health department (LHD) case investigations that two case-patients with *Escherichia coli* (*E. coli*) O157, a Shiga toxin-producing *E. coli* (STEC) infection, had consumed unpasteurized apple cider. Reported STEC case-patients are routinely interviewed by LHDs to assess risk factors, identify possible exposures, receive health education, and to attempt to identify additional cases (e.g. “do you know anyone else who may have recently had the same illness”). The initial epidemiologic investigation included interview of case-patients using a standard gastroenteritis case report form (Attachment A) and *E. coli* O157-specific questionnaire (Attachment B). The standard forms include questions about travel history, animal contact, environmental exposures and food history.

The first case-patient reported visiting Baugher’s Orchard and Farm, (Westminster, Carroll County, Maryland), and purchased and consumed Baugher’s unpasteurized apple cider during the 7 days before illness onset. The second case-patient had not visited Baugher’s, but had purchased Baugher’s unpasteurized apple cider from another local farm, Rock Hill Orchard, Mount Airy, Frederick County, Maryland, during that case-patient’s incubation period.

In addition to those two cases, five additional cases of *E. coli* O157 with illness onset clustered over an eight-day period had recently been reported to DHMH. These seven cases were reported from only three of Maryland's 24 jurisdictions: Anne Arundel (1), Carroll (3), and Montgomery (3) Counties. On average, over the previous 10 years, 24 cases of *E. coli* O157 per year are reported to DHMH. During October 2009, no cases of *E. coli* O157 were reported in Carroll and Anne Arundel Counties; two cases were reported in Montgomery County. It was quickly determined through additional interviews conducted on November 4 with the *E. coli* O157-specific form that all cases had consumed unpasteurized apple cider from the same cider producer, Baugher Enterprises, Inc. (Baugher's).

Baugher's is a family-owned business comprised of several components located in Westminster, Carroll County, Maryland. Baugher's has five components regulated by DHMH and the U. S. Food and Drug Administration (FDA):

At 1236 Baugher Road:

- Orchard and Farm
 - Pick your own fruits and vegetables
 - Produce stand
 - Free petting zoo
 - Wagon rides
- Bakery
 - Makes pies, pastries, apple dumplings, cakes featured at market and restaurant
- Cider Mill

At 289 W. Main Street:

- Family restaurant
- Market/Country store
 - Includes baked goods, apple cider, jams, jellies

This report summarizes results from epidemiologic studies, traceback investigations, and environmental investigations conducted by DHMH and LHDs related to the outbreak.

METHODS

Epidemiologic methods:

Case finding/classification and characterization:

In Maryland, state regulations require that cases of STEC infection be reported by clinical laboratories and physicians (COMAR 10.06.01.03) to LHDs. Cases are classified for surveillance purposes as “suspect”, “probable”, “confirmed”, or “not a case” using standard case definitions established by the Council of State and Territorial Epidemiologists (CSTE).³ STEC case-patients or, for young children or case-patients unable to be interviewed, a proxy are routinely interviewed by LHDs to assess risk factors, identify possible exposures, receive health education, and to attempt to identify additional cases. The initial epidemiologic investigation included interview of case-patients, generally within 24 hours of public health’s notification of the diagnoses, using standard case report forms. These case report forms are collated at DHMH and examined for completeness, accuracy, and for possible epidemiologic links suggesting an outbreak of infectious disease for which there may need to be interventions to prevent additional illnesses from occurring.

Given that Baugher’s is located in Carroll County and a large proportion of the initial cases were residents of Carroll County, Carroll County Health Department (CCHD) issued an alert on November 4, 2010 to all Carroll County pediatricians, internists, family practice practitioners to make them aware of the situation, request that testing be performed for suspect cases, and request immediate notification to the health department. On November 4, requests for notification of related cases were sent by DHMH to all Maryland local jurisdictions via Health Officer (HO) memo; then on November 5, to all Maryland acute care facility infection preventionists via email; and to all licensed Maryland pediatricians, internists, family practice practitioners via the Maryland Board of Physicians mailing list. Providers and LHDs were asked to report possible cases to DHMH.

Clinical material from five cases that had positive STEC tests was forwarded from clinical and private laboratories for further characterization at the DHMH Laboratories Administration. Potential cases identified through initial interviews with confirmed cases, but not yet laboratory confirmed, were requested to submit a stool specimen directly to the DHMH Laboratories Administration for testing.

Per Maryland Code Annotated, State Government H-G §18-205, medical laboratories are required to submit a report and forward clinical material to DHMH if an examination of a human specimen shows evidence of *E. coli* O157:H7 or other Shiga toxin-producing *E. colis*. Upon receipt at the DHMH Laboratories Administration, these human clinical materials are routinely cultured for enteric pathogens, serotyped, and pulse-field gel electrophoresed (PFGE), or “DNA fingerprinted” and may be MLVA typed (Multiple Loci VNTR [Variable Number Tandem Repeat] Analysis). These PFGE patterns are uploaded daily to PulseNet. PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC). The network consists of: local health departments, state health departments, and federal agencies (CDC, USDA, FDA). PFGE can be used to distinguish strains of organisms such as *E. coli* O157:H7 at the DNA level. DNA “fingerprints,” or patterns, are submitted electronically to a dynamic database at the CDC. These databases are available on-demand to participants—this allows for rapid comparison of the patterns to identify potential outbreaks.¹ The PulseNet database was searched for PFGE pattern matches to cases within and outside of Maryland for 60 days prior to recognition of the outbreak.

Outbreak case definitions:

Confirmed case definition:

- An isolate matching PFGE XbaI/BlnI pattern EXHX01.0074/EXHA26.0531, and
- consumption of Baugher’s unpasteurized apple cider in 7 days prior to illness onset.

Probable case definition:

- Shiga-like toxin producing *E. coli* infection identified by isolation of Shiga toxin-producing *E. coli* by cultural methods, evidence of Shiga toxin production, or the presence of Shiga toxin genes identified from clinical material, and
- consumption of Baugher’s unpasteurized apple cider in 7 days prior to illness onset.

Exposure identification:

Because initial interviews suggested a possible association between STEC infection and consumption of unpasteurized apple cider, DHMH conducted a case-control study to more definitively establish whether or not cases were associated with consumption of a single brand of apple cider and to further assess other common exposures to specific products or locations. For this study, a case was defined as a laboratory-

confirmed infection of *E. coli* O157 in a person with illness onset date (or, if that date was not known, with date of isolation of *E. coli*) on or after September 1, 2010. The date of September 1 was chosen to more broadly capture potential early cases. Controls were well persons matched by case-patient neighborhood and age category (i.e., <18 years or ≥18 years), randomly selected using a reverse telephone directory, from a non-adjacent home in the same neighborhood. Food histories were sought for the 7 days before illness onset for case-patients and well controls using a standard questionnaire (Attachment C). A 7-day exposure period, starting with date of illness onset as Day 0 was established for each case. Well controls were identified for each case-patient and interviewed about exposures during the same 7-day period as their matched case. For example, if case-patient A had an illness onset of October 28, the exposure period of interest was October 21-October 27. The matched controls for case-patient A were asked about their exposures during October 21-October 27. During the control enrollment process, if the person reported any gastroenteritis during the case-patient matched exposure period, that person was not enrolled as a control, but was followed up as a possible case. Statistical analyses were conducted using EpiInfo v. 3.5.1 (August 2008). Odds ratios, chi-square test, and 95% confidence intervals were calculated where appropriate.

Laboratory methods:

Clinical material testing:

Clinical material forwarded from primary clinical laboratories was sent to the DHMH Laboratories Administration for confirmation and further genetic characterization of pathogenic organisms. Presumptive positive STEC clinical material from clinical labs were screened by enzyme immune-assay tests (EIA) that allow the direct testing of clinical material for Shiga toxin. Routine enteric culture and isolation screens for *Salmonella*, *Shigella*, *Campylobacter* and Shiga toxin-producing *E. coli* isolates submitted for *E. coli* O157 typing (sorbitol negative from *E. coli* culture) were sub-cultured upon arrival and tested for Shiga toxins, O157 antigen and biochemically identified as well as tested for H7 if needed. To more rapidly identify potential STEC cases, polymerase chain reaction (PCR) testing of clinical material was performed by the DHMH Laboratories Administration to identify the presence of stx1 or stx 2, the genes associated with Shiga toxin production. To distinguish related cases from unrelated cases (or outbreak cases from sporadic), *E. coli* O157 isolates were subtyped by PFGE. PFGE is a molecular fingerprinting technique used to classify bacteria based on restriction sites within the bacterial genome beyond the species level. Additionally, for this outbreak

investigation, the DHMH Laboratories Administration conducted MLVA on all *E. coli* O157 isolates from clinical materials forwarded since September 1, 2010. MLVA examines a number of DNA segments within the chromosome or plasmids of *E. coli* that have specific repeat patterns of nucleotides (fundamental DNA units). These repeats may differ by sequence and length, as well as the number of times that they are repeated. Different types of these repeats and the number of times that they are repeated provide a specific pattern that will identify different strains of the organism.

Environmental investigation:

Environmental sampling:

Three retail samples were collected from consumer homes. One sample, an unopened, full, labeled half-gallon container of Baugher's unpasteurized apple cider, date of purchase between October 16-17 from Knill's Farm, Carroll County, was collected from the home of a confirmed case on November 4 by CCHD. One sample, an opened, half-full, 1-gallon labeled container of Baugher's unpasteurized apple cider, date of purchase between October 26-27, was collected from the home of a well person on November 4 by CCHD. One sample, an opened, quarter-full, half-gallon labeled container of Baugher's unpasteurized apple cider, date of purchase between September 24-26 from Baugher's Farm, Carroll County, was collected from the home of a suspect (unconfirmed) case-patient on November 15 by CCHD.

On November 4, DHMH Office of Food Protection and Consumer Health Services (OFPCHS) submitted to the DHMH Laboratories Administration for testing four samples of unpasteurized apple cider collected directly from Baugher's apple cider processing plant that had been packaged for retail sale: two unopened, full, labeled half-gallon containers of Baugher's unpasteurized apple cider, one bottle pressed on October 27 and one on November 3; two unopened, full, labeled 1-gallon containers of Baugher's unpasteurized apple cider, one bottle pressed on October 27 and one on November 3.

On November 5, two epidemiologists from DHMH collected 29 environmental samples from Baugher's apple cider processing plant. Swabs were taken from representative locations of the apple processing machinery starting from apple receiving to bottling. Sampling locations were selected because of their potential for contact with apples and apple by-products during the cider making process. Sampling locations were swabbed, the swab placed in 1 cc of sterile water, held at room temperature and

transported to the DHMH Laboratories Administration within two hours. Sampling locations at the cider processing plant are listed below:

Sample number: Location

1: Apple receiving	16: Mill 3 rd floor
2: Sorter	17: Auger 3 rd floor
3: Apple hopper	18: 3 rd floor chiller
4: Belt one	19: Cloth chute #1
5: Sorting hopper one	20: Juice tray
6: Sort hopper #1 belt	21: Strainer #1
7: Sort hopper #2	22: Chute #2
8: Sort hopper #3	23: Tray #2
9: Sort hopper #4	24: Chiller hose
10: Sort hopper main belt	25: Holding tank
11: Second sorter	26: Press cloths
12: Chlorine wash	27: Chiller hose 1 st floor
13: Hot water wash	28: Bottler tank
14: Brushes	29: Bottler spigots
15: Apple elevator	

On November 5, during retail facility inspection of Baugher's Bakery, three water samples were collected by CCHD and tested by the DHMH Laboratories Administration by standard methods used to screen drinking water. Samples were collected from inside the kitchen at the restaurant: front hand sink, middle hand sink, "raw tap" from the well.

Environmental testing:

Samples of Baugher's unpasteurized apple cider were collected from consumer homes, from source/bottling locations and retail facilities for testing at the DHMH Laboratories Administration. Environmental samples were tested for total coliforms, fecal coliforms, *E. coli* spp using the U. S. Food and Drug Administration's (FDA) Bacteriological Analytical Manual (BAM) for the microbiological analyses of food² and for *E. coli* O157:H7 by the BAX® System PCR Assay.

Carroll County Facilities Inspections

On November 4, a sanitarian from CCHD, conducted a food service facility inspection of Baugher's Restaurant, 289 West Main Street, Westminster, Maryland 21157. On November 5, CCHD also inspected the Petting Zoo located at the Baugher's Bakery and Farm, 1236 Baugher Road, Westminster, Maryland 21157.

DHMH Cider Processing Plant Inspection

OFPPCHS, the Office responsible for review, approval, licensing, and inspection of food manufacturing facilities throughout the state, conducted on-site inspection of the cider processing facility at Baugher Enterprises, Inc., on November 4.

DHMH and Maryland Department of Agriculture Petting Zoo Inspection

On November 9, a sanitarian from CCHD, an animal health inspector from Department of Agriculture (MDA), and two public health veterinarians from the Center for Zoonotic and Vectorborne Disease (CZVBD), DHMH, visited the petting zoo at Baugher's Orchard and Farm in Westminster, Maryland. An MDA inspection was performed which involved checking for appropriate animal health records and documentation of required tests (e.g. avian influenza, equine infectious anemia) and vaccinations (rabies for those species for which there is a licensed vaccine).

RESULTS

Epidemiologic findings:

Case finding:

From September 1 to December 31, 54 possible STEC cases were reported to local health departments and entered into the Maryland National Electronic Disease Surveillance System (NEDSS). Of those 54, 8 were not ultimately considered STEC cases because of lack of positive tests at clinical and/or a public health lab; 21 were classified as "Suspect"; 4 were "Probable", 21 were "Confirmed"³. These classifications are for surveillance reporting purposes only. Of those 46 confirmed, probable and suspect cases, 44 had either a GE CRF and/or *E. coli* O157-specific questionnaire; of the remaining 2 cases with no additional interview information, 1 probable case was lost to follow-up and 1 confirmed case, also lost to follow-up ultimately, had a PFGE pattern of EXHX01.0047 (not the outbreak strain). Of the 44 reviewed cases that had any additional interview information available, 28 reported not consuming apple juice or cider in the 7 days prior to illness onset; of the remaining 16, 12 reported that they had consumed apple juice or cider in the 7 days prior to illness onset; for 4 cases, information was missing or unknown. Of the 4 cases with missing or unknown cider consumption information, 3 were further characterized as non-O157 and 1 spent the entirety of the possible incubation period in California. For the case in California, a specimen was collected and tested in California but no additional characterization of the pathogen was conducted. For the 12 cases who reported consuming apple juice or cider in the 7 days

prior to illness onset: 3 drank a grocery store brand pasteurized apple cider; 1 drank pasteurized apple juice from a fast food chain (all four of these cases were caused by non-O157 STECs); and 8 reported drinking unpasteurized apple cider or juice. Of those 8, 1 drank unpasteurized juice made in their own home from apples purchased from a large grocery store chain (this case was determined to be caused by a non-O157 STEC); 7 (outbreak-related cases, 5 confirmed and 2 probable) drank Baugher's brand unpasteurized apple cider.

In addition to the 54 possible cases reported to local health departments by health care providers or laboratories, 4 additional possible cases were identified via other case finding methods. Two additional possible cases were identified via self-report to public health. Stool specimens were collected from both of these two people and sent to the DHMH Laboratories Administration for culture and STEC testing. Neither of these two cases had any positive STEC tests at DHMH; nor were other positive STEC tests identified for either at other clinical labs. In addition to those two possible cases, from notifications to acute care facilities and to clinicians through the Maryland Board of Physicians that requested reports of clinically consistent cases with an epidemiologic link, two cases of gastroenteritis were identified, one case-patient was hospitalized, one was not. Both of these case-patients had consumed Baugher's unpasteurized apple cider in the 7 days prior to onset of illness, however, both were negative for STEC at the time of testing. None of these 4 cases are included as outbreak-related cases.

A review of PulseNet revealed only 1 additional PFGE match in the U.S. in Colorado; further characterization via MLVA showed a genetic difference of $\geq 50\%$ and follow up interview indicated no travel to Maryland or known exposure to Maryland products, including apples or apple cider/juice; this case is not considered to be outbreak-related. Subsequently, no additional outbreak-related cases have been identified.

Through all the methods above combined, seven outbreak-related cases were identified. For those for whom an onset date was reported, onsets ranged from October 21, 2010 to October 28 (Figure 1). All cases were diagnosed by either culture and/or by enzyme-linked immunosorbent assay (EIA) for Shiga toxins. For these cases, 7 (100%) experienced abdominal cramps (100%); 7 (100%) diarrhea; 6 (86%) bloody stool; 2 (29%) fever, and 1 (14%) hemolytic-uremic syndrome (HUS) (see Table 1). Symptoms lasted from 5-10 days with a median duration of 6 days (see Table 2). Incubations (from time of first exposure) ranged from 4-12 days with a median of 7 days (Table 3). Reported first exposure dates were

from October 15-19 (Figure 1). Figure 2 is the line list of the 7 case-patients identified. 3 of 5 confirmed case-patients had been hospitalized and discharged. Of the remaining 2 probable case-patients, one was hospitalized and one was not. No deaths were associated with this outbreak.

Table 1: Symptom frequency among cases (n=7)

Symptom	No (%)
Abdominal cramps	7 (100)
Diarrhea	7 (100)
Bloody stool	6 (86)
Fever	2 (29)
HUS	1 (14)

Table 2: Illness duration among cases (n=5)

Shortest	5 days
Longest	10 days
Median	6 days
Mean	6.75 days

Table 3: Incubation among cases (n=7)

Shortest	4 days
Longest	12 days
Median	7 days
Mean	7 days

Exposure identification:

Early interviews and case reports suggested a possible association with consumption of unpasteurized apple cider, specifically, Baugher's brand. By November 4, DHMH confirmed that five additional recently reported cases of *E. coli* O157 had consumed unpasteurized apple cider either purchased at Baugher's or from a location that sold only Baugher's apple cider. In the initial investigation, among the most frequently reported food exposures in the 7 days before illness began, 100% of patients interviewed reported they had consumed Baugher's apple cider and 71% had visited Baugher's Orchard & Farm. By comparison, the frequency in the general public in Maryland of drinking unpasteurized apple juice/cider in the previous 7 days was estimated to be 3.4% in a 2006-2007 FoodNet food consumption survey.⁴

Case-control study: 7 cases and 14 controls were enrolled from 3 counties. The median ages (and age range) for case-patients and controls were 13 (range 9-22 years) and 12 years (range 3-66 years), respectively; proportion female for cases and controls were 43% and 57%, respectively (see Table 4). Statistical analysis found that case-patients were significantly more likely than controls to have drunk Baugher's unpasteurized apple cider in the 7 days before illness began. For the exposures assessed by the case-control study, this was the only exposure with substantially elevated risk ($RR > 2.0$) and a proportion of $> 50\%$ of cases exposed; 7/7 (100%) of case-patients versus 3/14 (14%) of controls, unmatched OR = undefined (infinity), Fisher's exact p-value = 0.0010320, uncorrected chi-square = 11.55. The OR is mathematically "undefined" because in ordinary (real number) arithmetic, division by zero is undefined (approaches infinity). For the purposes of the interpretation of these calculations, we may consider the OR to be very large.

Only 2/7 (29%) case-patients reported eating fresh apples (both also consumed apple cider) versus 10/14 (71%) controls who consumed apples; this association was not statistically significant (see Figure 3). An apparent association was observed between illness and amount of cider consumed; during interviews of case-patients and/or their parents, ill individuals were more likely to have drunk a large amount of cider (e.g. ≥ 2 glasses) compared to well controls and well companions, who reported drinking small amounts of cider (e.g. < 2 glasses). Where information was available, 4/4 case-patients reported consuming ≥ 2 glasses of cider; of 12 non-ill dining companions and household contacts of the confirmed cases interviewed, all 12 reported consuming < 2 glasses total of cider.

Table 4: Demographic summary of persons interviewed

	Ill	Well
Sex:		
Male	4 (57%)	4 (29%)
Female	3 (43%)	8 (57%)
Unknown	0 (0%)	2 (14%)
Age:		
Age range (years)	9-22	3-66
Median age (years)	13	12
Mean age (years)	16.6	20.9

Laboratory findings:

Five of the Maryland cases with STEC isolated by culture underwent PFGE at DHMH. The 6th and 7th cases, for which no STEC was isolated by culture, did not undergo PFGE testing because a bacterial isolate is required to perform PFGE. All five cases that underwent PFGE had PFGE XbaI and BlnI patterns EXHX01.0074 and EXHA26.0531, respectively. These PFGE XbaI and BlnI patterns, EXHX01.0074 and EXHA26.0531, comprised 5.18% (1730/33383) and 0.91% (197/21623) of *E. coli* O157:H7 isolates in the national PulseNet database, respectively.

The Maryland *E. coli* O157 group of cases was designated by the Centers for Disease Control and Prevention's PulseNet as a nationally recognized cluster with code number 1011MDEXH-1. In the 60 days prior to the national recognition of the cluster, other than the uploads from MD (all uploads were outbreak-related cases), this pattern combination was reported only once by one other state, Colorado (CO). Interview of the CO source-state case-patient (actually a South Dakota resident) did not reveal consumption of unpasteurized apple cider or travel to Maryland within the 7 days prior to onset of symptoms. Further genetic characterization via MLVA typing (Multiple Loci VNTR [Variable Number Tandem Repeat] Analysis) revealed >50% genetic variation between the Maryland cases and the Colorado case. 5/6 Maryland case isolates were 100% matched by MLVA; 1 Maryland isolate (duplicate from a single case-patient) was ~90% matched; these 2 isolates were sourced from clinical materials taken on different dates, before and during hospitalization (Figure 4). MLVA typing showed this PFGE pattern and MLVA combination to be unique to this outbreak. Subsequently, with the exception of the CO case with the non-matching PFGE pattern, no additional cases with this PFGE pattern have been identified.

Environmental investigation findings:

Environmental testing:

Samples of unpasteurized apple cider were collected by CCHD from patient homes, from source/bottling locations and retail facilities for testing at the DHMH Laboratories Administration, however, DHMH was unable to locate and test the same lots or batches of cider that would have been consumed by ill persons. These submitted samples were tested using the U. S. Food and Drug Administration's (FDA) Bacteriological Analytical Manual (BAM) for the microbiological analyses of food.² 39 total cider and

environmental samples were collected and tested. All of the following samples were negative by cultural methods and PCR for *E. coli* O157:H7: three retail cider samples collected from consumers, four retail cider samples collected from the cider processing facility from two different pressing dates (10/27 and 11/3), 29 environmental swab samples collected from the cider processing facility, and three bulk water samples collected from Baugher's Restaurant and Bakery. However, all of the 7 retail cider samples, the three opened bottles collected from consumers and the four unopened bottles collected from Baugher's, were positive for total coliforms by cultural methods, 5/7 (one opened and four unopened) were positive for fecal coliforms, and 3/5 (one opened and two unopened) were positive for *E. coli* (non-Shiga toxin producing) (see Figure 5).

Carroll County Facilities Inspection and Findings

At the time of the inspection, the sanitarian from CCHD Environmental Health noted one critical violation at Baugher's Restaurant – cold-holding temperature. The Food Service Facility Inspection Report is included (see Attachment D). At the time of the inspection, all hand sinks were stocked, gloves were on-site and in use. One employee, a cook, also worked at the orchard bakery; another employee, a cook and server at the restaurant also worked in administration at the farm. Per the manager of the restaurant, no food service employees had been ill with gastroenteritis in the previous month.

Baugher's bakery and cider processing plant are located in the same building on the property and share a well. Three bulk water samples, collected from the well that serves the bakery and cider processing plant tested negative by culture at the DHMH Laboratories Administration for total coliforms and *E. coli* (see Figure 5).

On November 5, CCHD also visited the petting zoo located at the Baugher's Bakery and Farm, 1236 Baugher Road, Westminster, Maryland 21157. It was noted on CCHD's List of Observations from the November 5th inspection that hand sinks were available with bar soap (CCHD recommended a soap dispenser instead), but no towels; no employees from the petting zoo were observed entering the food processing area (see Attachment E).

DHMH Cider Processing Plant Inspection and Findings

A review of the previous routine inspection by OFPCHS of the cider processing plant on October 18, 2010 noted that it was discussed with the operator that if processing wholesale unpasteurized apple cider, that the facility must meet a 5-log pathogen reduction as described in Code of Federal Regulations (CFR), Title 21, Part 120 "Hazard Analysis and Critical Control Point (HACCP) Systems".⁵ Information was given to the facility regarding the implementation of a Juice HACCP. It was recommended that prior to the start of the 2011 season, the facility shall be in compliance with the FDA Juice HACCP requirements. During that October 18 routine inspection, seven violations were noted for correction within 30 days: pitted flooring allowing excess juice to pool and not drain, rust on outside of equipment, chipping/peeling paint in shoot to sort belt, juice from pulp shoot dripping onto lid of solids tank (possible contaminate), air leak at side door on press level, cooling temperature and cold storage logs not kept, and the lighting in the walk-in cooler was off market. No pests were observed during that inspection (see Attachment F).

It was noted by OFPCHS during their November 4 visit that the plant was not processing cider at that time. The DHMH inspection report from November 4, 2010 is attached (see Attachment G). The press dates for the previous month were 10/7/2010, 10/14/2010, 10/18/2010, 10/20/2010, 10/25/2010, 10/27/2010 and 11/3/2010. The bottling would have been within 2 days following date from the press date. At that time, the cider processing facility voluntarily detained all product on the premises. Additionally, at the store and market location at 289 W. Main St., all cider was voluntarily detained. 2.5 gallons dated 11/3/10 and 2 gallons dated 10/27/10 of unpasteurized apple cider were collected from the processing plant by OFPCHS. Those four samples tested negative by culture and PCR at the DHMH Laboratories Administration for *E. coli* O157:H7 (see Figure 5).

On November 5, a follow up inspection was conducted by OFPCHS. A voluntary recall to all receiving firms was initiated. All firms to whom apple cider had been distributed were notified to either send product back to the plant or to destroy the product. Production of cider was halted until further notice from OFPCHS (see Attachment H).

On November 10, an additional follow-up inspection by OFPCHS was conducted to obtain voluntary destruction of all cider pressed on 10/27/2010 and 11/03/2010 that was previously detained by OFPCHS during the November 4 inspection (see Attachment I).

DHMH and Maryland Department of Agriculture Petting Zoo Inspection and Findings

Observations noted by the team (CCHD, MDA, CZVBD) during their November 9 inspection:

- The farm had one donkey, two pigs, one llama, one steer, numerous goats, 4 chickens, 6 peafowl, and 3 ducks;
- Animals are housed far from any apple orchards and are unlikely to have been a source of pathogens to the apple orchards;
- All animals appeared healthy;
- The farm contact person noted that the farm uses "drops" (apples that fall to the ground) in their cider production;
- There are no known dairy or other cattle farms neighboring the properties where the apples are grown;
- The apple orchards are infrequently irrigated (irrigation used frequently for the small field crops such as pumpkins, etc.);
- The petting zoo did have signage to remind visitors to wash hands, and a small sink with soap available to visitors.

Handwashing and possibly increasing the signage and access to soap was discussed by the team with the farm's contact person. CCHD offered to provide some handwashing signs to the farm. CZVBD gave Baugher's a copy of the CDC's Animal Contact Compendium which also has sample handwashing and other petting zoo signs.⁶

DISCUSSION

Based on the epidemiologic data that implicated an association between consumption of Baugher's unpasteurized apple cider and STEC infection, and given the potential severity of STEC infection, on November 4, a recommendation was made to the producer, Baugher Enterprise, Inc. (Baugher's) that the existing product be recalled and that Baugher's unpasteurized cider not be consumed. Baugher's issued a voluntary recall of all its apple cider. No other Baugher's products were affected by the recall. A press

release notifying the public was released by Baugher's and DHMH on November 4 (see Attachment J); a recall notice was posted to the FDA website on November 5.⁸ Subsequently, despite enhanced surveillance (with the exception of the CO case with the non-matching MLVA pattern), no additional cases with this PFGE pattern or additional STEC infections with a Baugher's exposure have been identified.

There are known health risks associated with the consumption of unpasteurized juice or cider. Outbreaks of *E. coli* O157:H7 associated with unpasteurized apple cider/juice have been previously documented.⁷ Animals are the primary reservoir for *E. coli* O157:H7. In particular, cattle, deer, sheep, and other animals can asymptotically carry *E. coli* O157:H7. While the exact mechanism of contamination for this outbreak cannot be determined, it is possible that feces (droppings) may have contaminated the apples used for cider production. The practice of using drop apples for making apple cider is common.⁸ The facility reported using this practice to DHMH and MDA; apples can become contaminated by resting on ground contaminated with droppings. The presence of animals near a cider mill can result in droppings inadvertently contacting apples, equipment, or workers' hands. In addition, apples can become contaminated if transported or stored in areas that contain droppings or manure, or if rinsed with contaminated water.

An environmental inspection was conducted of the cider processing facility and environmental swabs were collected as soon as possible. However, by the time investigators arrived, the plant was in the process of being cleaned and bleached, therefore, actual conditions under which the implicated cider was processed could not be ascertained. DHMH was unable to locate and test the same lots or batches of cider that would have been consumed by ill persons. The cider samples collected and tested from the processing plant and from patient homes were not the same lot or batch as those consumed prior to case-patients' illnesses.

Outbreaks of *E. coli* O157 associated with visits to farms where consumers came into direct contact with farm animals have been documented.¹⁰ While the petting zoo and the cider mill were on the same property, it was noted that the zoo and mill did not share staff, nor did the general public have access to the facility where cider was made. No other Baugher's products were implicated by the investigation; nor was Baugher's Restaurant or the petting zoo.

Notably, despite the presence on Baugher's products of Maryland state regulation (COMAR 10.150.04.16) -required labeling indicating the product has not been pasteurized and the risk associated with consuming untreated juice (see Figure 6), interviews revealed that at least two case-patients were unaware that they had purchased and consumed unpasteurized apple cider. This indicates that the public may not be aware that unpasteurized cider is available in MD, or of when they are purchasing unpasteurized cider, and suggests an enhanced roll for public health education and awareness about food safety.

RECOMMENDATIONS

Recommendations made to Baugher's facilities by public health (DHMH and Carroll County Health Department) during cider production:

To reduce risk during cider production:

- 1) Meet a 5-log pathogen reduction as described in Code of Federal Regulations (CFR), Title 21, Part 120 "Hazard Analysis and Critical Control Point (HACCP) Systems"
 - o By start of 2011 season, be in compliance with the FDA Juice HACCP requirements, including submission of a hazard analysis, HACCP plan and written SOPs (standard operating procedures).
- 2) Avoid use of apples that have fallen to the ground
- 3) Prevent the introduction of animal manure into orchards

To prevent possible contamination from employees:

- 4) Employees at any of the Baugher's facilities who have direct contact with food or cider production should not work while ill with gastroenteritis.

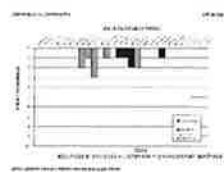
To prevent possible contamination from petting zoo:

- 5) Provide a soap dispenser and towel dispenser at petting zoo for visitors and employees
- 6) Clean manure from zoo area more than once per day

Persons who work at petting zoo should not on the same day then work at cider mill (cohort employees).

Per previous recommendations made during an October 18, 2010 routine inspection, Baugher's submitted to OFPCHS, an application for installation of pasteurization equipment and production of pasteurized

apple cider. This application was reviewed by OFPCHS on September 14, 2011. Upon approval by OFPCHS of the application and Juice HACCP, cider production was allowed on October 24, 2011.



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Phylogenetic tree of the 12S rDNA region of the 18S rDNA gene. The tree shows relationships between various species, with bootstrap values indicated at the nodes. The species names are abbreviated: H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens, H. sapiens. The tree is rooted at the bottom left and branches upwards and to the right.

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