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Juice-Associated Outbreaks of Human Illness in the United States, 1995 through 2005

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ABSTRACT

Outbreaks of illness associated with consumption of fruit juice have been a growing public health problem since the early 1990s. In response to epidemiologic investigations of outbreaks in which juice was implicated, the U.S. Food and Drug Administration implemented process control measures to regulate the production of fruit juice. The final juice regulation, which became effective in 2002, 2003, and 2004, depending on the size of the business, requires that juice operations comply with a hazard analysis critical control point (HACCP) plan. The Centers for Disease Control and Prevention (CDC) receives reports of food-associated outbreaks of illness. We reviewed fruit juice–associated outbreaks of illness reported to the CDC's Foodborne Outbreak Reporting System. From 1995 through 2005, 21 juice-associated outbreaks were reported to CDC; 10 implicated apple juice or cider, 8 were linked to orange juice, and 3 involved other types of fruit juice. These outbreaks caused 1,366 illnesses, with a median of 21 cases per outbreak (range, 2 to 398 cases). Among the 13 outbreaks of known etiology, 5 were caused by *Salmonella,* 5 by *Escherichia coli* O157:H7, 2 by *Cryptosporidium,* and one by Shiga toxin–producing *E. coli* O111 and *Cryptosporidium.* Fewer juice-associated outbreaks have been reported since the juice HACCP regulation was implemented. Some juice operations that are exempt from processing requirements or do not comply with the regulation continue to be implicated in outbreaks of illness.

Outbreaks of illness caused by bacteria and parasites have been linked to juices and ciders for many years *(7, 16, 19–21, 23, 25, 32, 53, 79).* Although confirmation of sources of causative agents in these outbreaks has been uncommon, contamination is thought to occur most often during the final steps of processing or preparation. The acidity of fruit juice has been historically thought to be an important barrier against survival and growth of foodborne pathogens. In 1991, however, an outbreak of *Escherichia coli* O157:H7 infections and hemolytic uremic syndrome (HUS) was linked to traditionally pressed apple cider *(7).* This pathogen has since been shown to survive for several days in fresh cider at pH values ranging between 3.6 and 4.0 *(40, 82, 92, 95),* a range previously thought to be inhibitory. This juice-associated outbreak and others caused by *E. coli* O157:H7, *Salmonella,* parasites, and other pathogens have resulted in an increased awareness of the microbiological safety of fruit juices *(62, 80).*

Outbreaks of illness associated with consumption of fruit juices has stimulated new research aimed at achieving a better understanding of the factors affecting the behavior of pathogens in fruits and fruit products and how the safety of these products can be improved. Organic acids *(2, 24, 47, 82, 83, 95),* hydrogen peroxide *(47, 90),* monocaprylin *(56),* dimethyl dicarbonate *(90),* vanillin *(55),* vanillic acid *(54),* essential oils *(70),* and nisin and cinnamon *(94)* are among the antimicrobials that kill or inhibit the growth of foodborne pathogens in fruit juices. Treatment of apple cider and orange juice with ozone causes 4.2- to >6.0-log reductions in *E. coli* O157:H7 and *Salmonella (89).* Treatment with UV radiation is effective for killing *E. coli* O157:H7 and nonpathogenic *E. coli* in fruit juices *(5, 31, 38, 59, 67).* Gamma radiation *(57, 58),* electron beam radiation *(87),* high-pressure treatment *(10, 44, 46, 68, 81),* ultrasound *(6, 29, 72),* and pulsed electric field processing *(4, 35, 49)* also show promise for inactivating pathogens.

The emergence of juice-associated outbreaks also stimulated the development of new regulatory approaches. In 1998, the U.S. Food and Drug Administration (FDA) published the final juice labeling regulation *(84)* as an interim measure to prevent illness resulting from consumption of contaminated fruit juice. The juice labeling regulation was aimed at processors of beverages containing juice or juice ingredients that had not been processed to achieve a 5-log pathogen reduction. These processors are required to use a warning label indicating the health risks associated with drinking these beverages. In 2001, the FDA published the final juice hazards analysis and critical control point (HACCP) regulation *(85),* which requires that juice processors implement HACCP plans to identify steps in the production process where contamination may occur and to put in place preventive control processes. The process used to prevent biological contamination must result in at least a 5-log reduction in the pathogen of concern to public health, usually *E. coli* O157:H7 or *Salmonella.* Processes used to

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treat juice should be validated to prove that they achieve a 5-log reduction. The juice HACCP regulation applies to all juice processors except those who qualify as retail establishments. Businesses qualify as retail establishments when they process juice themselves and sell directly and exclusively to consumers. The juice HACCP regulation became effective January 2002, 2003, and 2004, for large, medium, and small businesses, respectively. An overview of events that led to this regulation and the key points of the regulation have been summarized *(1)*.

Presented here is the epidemiology of juice-associated outbreaks in the United States as reported to the Centers for Disease Control and Prevention (CDC) during the period of 1995 through 2005. In an attempt to better understand some of the reasons why juices have been implicated in outbreaks of human illness, the survival, growth, and inactivation characteristics of foodborne pathogens in these products are briefly described.

MATERIALS AND METHODS

Data examined. Since 1966, state and local health departments have reported outbreaks of foodborne illness to the CDC via the Foodborne Outbreak Reporting System. In this system, information about foodborne disease outbreaks investigated by public health authorities is collected using a standard reporting form (CDC form 52.13). Information gathered in each outbreak includes number of ill persons, location, etiology, and implicated food item. In 1998, the CDC began more active solicitation and verification of reports, and the number of outbreaks subsequently reported increased. In October 1999, the CDC issued a revised foodborne disease outbreak reporting form *(22)*. We reviewed outbreaks for which the implicated food item was fruit juice, as reported to the Foodborne Outbreak Reporting System, with first illness onsets between January 1995 and December 2005. Foodborne disease outbreak data compiled by the CDC for 2005 are preliminary. To examine changes that occurred as new regulations were implemented, we divided this time period to reflect the stages of regulation. For simplicity, we use the term "juice" to refer to both fruit juice and cider. Outbreaks listing lemonade, punch, and other beverages containing juice as one of several ingredients of the implicated food item were not included. Additional information about the outbreaks, including juice treatments, was gathered by reviewing published outbreak summaries and public health agency reports and through personal communication with state health department personnel familiar with the outbreak investigation.

Statistical analysis. The individual outbreak investigations were conducted by local and state public health agencies via a variety of methods, including case-control and cohort studies. Details are available for studies that were published but not for those whose results only were reported to the CDC via the Foodborne Outbreak Reporting System.

RESULTS

We identified 21 juice-associated outbreaks reported to the CDC between 1995 and 2005. These outbreaks involved 35 states; four outbreaks occurred in multiple states. The 21 outbreaks caused a reported 1,366 illnesses, 149 hospitalizations, 17 cases of HUS, and one death. The median size of these 21 outbreaks was 21 cases (range, 2 to 398 cases). Between 1995 and 2005, the CDC received reports for 11,689 foodborne disease outbreaks that took place in the United States and accounted for 252,832 reported illnesses. Of the reported outbreaks, 6,569 (56%) had one or more implicated food items listed. Thus, the 21 juice-associated outbreaks accounted for 0.54% of the illnesses associated with foodborne disease outbreaks reported during this time period and 0.32% of the foodborne disease outbreaks in which one or more food items were implicated.

TABLE 1. *Reported number of cases, hospitalizations, and deaths by causative agent(s) for juice-associated outbreaks reported to the CDC, 1995 through 2005*

Agent	No. of outbreaks	No. of illnesses	No. of hospitalizations	No. of deaths
Salmonella	5	710	94	
E. coli O157:H7	5	105	36	1
Cryptosporidium parvum	2	175	3	
E. coli O111 and *C. parvum*	1	213	15	
Unknown	8	182	1	
Total	21	1,366	149	1

Of these 21 juice-associated outbreaks, 13 had a causative agent determined (Table 1). Five outbreaks were caused by *Salmonella* and accounted for 710 (52%) of the reported illnesses and 94 (63%) of the reported hospitalizations. Five outbreaks were caused by Shiga toxin–producing *E. coli* O157:H7, two by *Cryptosporidium parvum,* and one by both Shiga toxin–producing *E. coli* O111 and *C. parvum.* Apple juice or cider was implicated as the contaminated vehicle in 10 of the 21 outbreaks, orange juice in 8 outbreaks, and other types of fruit juice in 3 outbreaks, reported as pineapple juice, fruit juice, and a mixed juice (mix of apple, orange, grape, and pineapple) (Fig. 1).

Outbreaks of illness associated with apple juice were more common in the fall months; 9 of the 10 outbreaks linked to apple juice occurred between September and November (Fig. 2). Outbreaks of illness associated with orange juice occurred between February and June. Outbreaks of illness associated with other juice types did not have a seasonal pattern.

During the time period of 1995 through 1998, there was a mean of 2.0 juice-associated outbreaks reported per year with a mean of 24 cases per outbreak (median, 14 cases). Between 1999 and 2001, there was a mean of 2.3 juice-associated outbreaks reported per year with a mean of 90 cases per outbreak (median, 25 cases). During 2002 through 2005, there was a mean of 1.5 juice-associated outbreaks reported per year with a mean of 91 cases per outbreak (median, 83 cases).

Outbreaks: 1995 through 1998. From 1995 through 1998, eight juice-associated outbreaks were reported to the CDC (Fig. 1). In 1995, one outbreak occurred in which a reported 62 persons from 21 states became ill with *Salmonella* Hartford and *Salmonella* Gaminara infections associated with orange juice sold at a theme park in Florida *(25)*. In 1996, a reported 56 persons in three states became

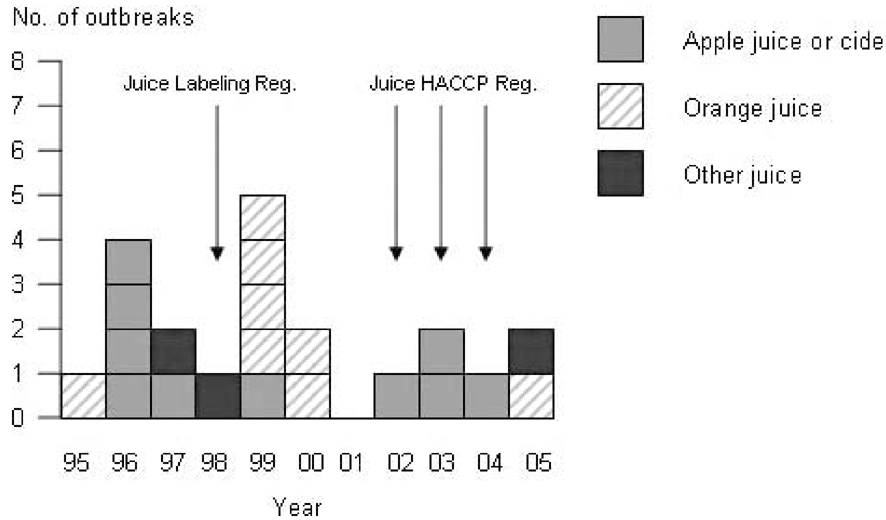

FIGURE 1. *Reported juice-associated outbreaks by juice type, United States, 1995 through 2005 (source: CDC Foodborne Outbreak Reporting System).*

ill from *E. coli* O157:H7 infections associated with apple cider that was commercially distributed in the United States and Canada *(23)*. Fourteen cases developed HUS, and one died. Pasteurization information was available for juices implicated in six of the eight outbreaks reported between 1995 and 1998, including both outbreaks described above; none of the six implicated juices was pasteurized. The FDA juice labeling regulation became effective in September 1998 for apple juice and cider and in November 1998 for all other juices.

Outbreaks: 1999 through 2001. From 1999 through 2001, seven juice-associated outbreaks were reported to the CDC. In 1999, a reported 398 persons became ill with *Salmonella* Muenchen infections associated with consuming commercially distributed orange juice in 15 states *(21)*. In 2000, the CDC investigated an outbreak of 88 cases of culture-confirmed *Salmonella* Enteritidis infection associated with orange juice. Juice from plant L was transported to plant B for mixing and bottling. Environmental investigation yielded no obvious violations in plant B but identified several potential hazards in plant L, despite the fact that this plant was operating under a validated 5-log pathogen reduction plan *(69)*. This outbreak highlighted the potential hazard of using the then relatively new process of treating the exterior of the whole fruit after culling as a step in the 5-log pathogen reduction plan and of transporting juice after the 5-log reduction process but before final packaging. Pasteurization information was available for six of the seven outbreaks reported between 1999 and 2001, including both outbreaks described above; none of the six implicated juices was pasteurized. Phase-in of the juice HACCP regulation began in January 2002, and the regulation reached full implementation in 2004.

Outbreaks: 2002 through 2005. From 2002 through 2005, six juice-associated outbreaks were reported to the CDC (Table 2). Four outbreaks were linked to apple juice or cider, one to orange juice, and one to a mixed multifruit juice. In 2002, an outbreak of three illnesses reported in Maine was associated with apple cider. Affected individuals were part of a group of campers that made the cider for their own use and did not sell it to other people. The juice was made for private use and thus was not subject to regulation.

In 2003, an outbreak of 144 *C. parvum* infections associated with commercially distributed apple cider was reported in Ohio. The cider was treated with ozone and sold

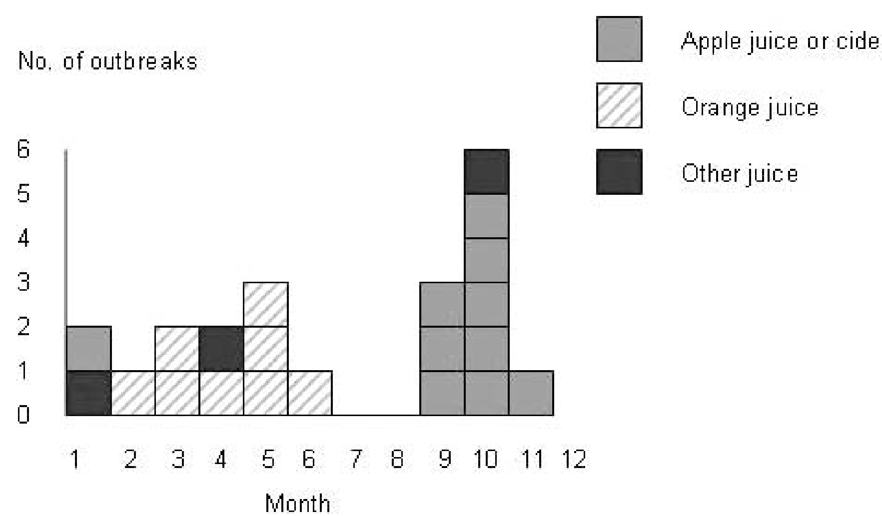

FIGURE 2. *Reported juice-associated outbreaks by juice type and month, United States, 1995 through 2005 (source: CDC Foodborne Outbreak Reporting System).*

TABLE 2. *Characteristics of fruit juice–associated outbreaks reported to the CDC, 2002 through 2005, since the publication of the juice HACCP regulation*

Yr	Causative agent	No. of ill persons	Location of outbreak	Juice type	Pasteurized	Covered by juice HACCP rule	Met HACCP requirements	Comment
2002	Unknown	3	Maine	Apple	No	No	NA[a]	Made for private use
2003	*C. parvum*	144	Ohio	Apple	No	Yes	No	Ozone treatment deemed insufficient
	Unknown, suspected chemical	10	Ohio	Apple	Yes	Yes	Yes	Contamination at point of consumption (school)
2004	*E. coli* O111 and *C. parvum*	213	New York	Apple	No	No	NA	Retail establishment
2005	*Salmonella* Typhimurium (*Salmonella* St. Paul)	152	Multiple states (23)	Orange	No	Yes	No	Multiple violations at plant
	Unknown	21	Illinois	Mixed (apple, orange, grape, pineapple)	Yes	Yes	Unknown	High numbers of yeasts found

[a] NA, not applicable.

directly to consumers and businesses. Traceback and environmental investigation deemed the ozone treatment insufficient to rid the cider of contamination *(86).* In response to this outbreak, the FDA published recommendations for apple juice and cider processors, reminding them of the requirement to use treatment processes that had been validated to achieve a 5-log pathogen reduction.

Later in 2003, an outbreak of 10 illnesses associated with apple juice was reported in Ohio. This outbreak took place in a school where children were given pasteurized commercial apple juice in individual bottles. The juice was thought to have been inadvertently contaminated with an undetermined chemical agent in the classroom. The median symptom onset was 1 h after consumption of the product, and 100% of affected individuals experienced vomiting and headache. The juice implicated in this outbreak was produced under the juice HACCP regulation. Investigators did not identify a problem with the production of the juice and suggested that contamination occurred at the place of consumption.

In 2004, an outbreak of 213 illnesses associated with apple cider was reported in New York. Culture of the cider and examination of clinical and environmental specimens yielded Shiga toxin–producing *E. coli* O111 and *C. parvum* *(26).* Laboratory results were obtained via personal communication with Epidemic Intelligence Service Officer Fatima M. Coronado *(27).* The fresh-pressed untreated apple cider was produced at an orchard and sold directly and exclusively to consumers. In this case, the facility qualified as a retail establishment and thus was exempt from the juice HACCP regulation.

In 2005, officials in 23 states reported 152 cases of *Salmonella* Typhimurium infection associated with commercially distributed unpasteurized orange juice. Isolates from these cases were linked by a common pulsed-field gel electrophoresis pattern. Although culture of the juice did not yield *Salmonella* Typhimurium, *Salmonella* St. Paul was isolated. Several cases of *Salmonella* St. Paul infection were subsequently linked to the outbreak. The juice implicated in this outbreak was traced back to a producer that operated under a validated HACCP plan. However, upon inspection, the FDA found that the production facility did not comply with the plan and that noncompliance likely contributed to this outbreak *(42).*

Later in 2005, an outbreak of 21 illnesses was reported in Illinois among students who drank a mixed multifruit juice at a middle school. No pathogen was isolated from the juice, although high yeast levels were found in unopened juice containers. The commercial juice consisted of a mixture of apple, orange, grape, and pineapple juices and had been pasteurized. Less than a month after this outbreak, fruit cups from the same producer were associated with another outbreak of similar illness in Illinois, and these fruit cups also contained high yeast levels. Information regarding the outbreaks implicating the multifruit juice and fruit cups was obtained via personal communication with State Public Health Veterinarian, Connie Austin *(3).*

DISCUSSION

Juice-associated outbreaks of infections have become an important public health problem in recent years, and their epidemiology appears to be changing. Compared with the periods 1995 through 1998 and 1999 through 2001, the mean number of outbreaks per year reported to the CDC decreased in the period 2002 through 2005, although the median number of cases per outbreak increased during this time. Like many other food items implicated in recent foodborne disease outbreaks, several of the juices associated with illness were distributed in more than one state, suggesting that contamination occurred at a central point of production or processing. Several intrinsic and extrinsic factors are known to influence the survival and growth of foodborne pathogens in juices during their intended shelf life. A better understanding of these factors would facilitate accurate assessment of the potential of juices to serve as vehicles in outbreaks of foodborne illness.

Tolerance of pathogens to acidic pH. Outbreaks of illness associated with juice consumption have been suspected or confirmed to have been caused by a variety of different pathogens, including *E. coli* O157:H7, other Shiga toxin–producing *E. coli,* several *Salmonella enterica* serotypes, and *C. parvum.* In recent years, data from both outbreak investigations and laboratory research suggest that many of these pathogens can survive in juice for prolonged periods. Besser et al. *(7)* found that *E. coli* O157:H7, some strains of which are now known to be more tolerant than others to acidic conditions, can survive at 8°C for 20 days in apple cider (pH 3.6 to 4.0) that did not contain preservatives. Ingham and Uljas *(41)* observed that an initial *E. coli* O157:H7 population of 8.0 log CFU/ml of apple juice (pH 3.5 to 3.6) decreased by only 0.1 log CFU/ml after 3 days at 5°C. At an initial population of 5 log CFU/ml of apple cider (pH 3.6 to 4.0), the pathogen survived for 10 to 31 days and 2 to 3 days at 8 and 25°C, respectively *(95). E. coli* O157:H7 survived in apple cider (pH 3.56 to 3.98) and orange juice (pH 3.82 to 3.86) held at 5 or 25°C for up to 42 days *(73).* Populations of ca. 6 log CFU/ml in mango juice (pH 3.2) decreased to 1.3 to 2.3 log CFU/ml within 8 days at 7°C *(39).*

Some strains of *Salmonella* also exhibit unexpected tolerance to acidic conditions in juices. Parish *(62)* observed that *Salmonella,* initially at ca. 6 log CFU/ml, survived in orange juice at pH 3.5, 3.8, 4.1, and 4.4 for 24, 39, 57, and 70 days, respectively, at 4°C. The number of salmonellae in apple juice (pH 3.5 to 3.6) decreased by 1.5 log CFU/ml within 3 days at 5°C, and inactivation was enhanced by the addition of cranberry juice *(40).* Sharma et al. *(77, 78)* studied the survival of salmonellae in calcium-fortified orange juice (pH 3.96 to 4.19) held at 4°C for 32 days and found that the form of calcium salt affected the rate of inactivation. *Salmonella* Poona increased by 5 log CFU/ml in cantaloupe juice (pH 6.3) stored at 20°C for 24 h and by 8 log CFU/ml within 48 h *(71),* and *Salmonella* Baildon grew well in tomato juice (pH 4.8) *(88).*

The effectiveness of processes used to preserve fruit juice depends in part on the acidity of the juice *(37, 48, 82).* Treatment processes are generally more effective for killing foodborne pathogens and controlling the growth of survivors in juice with lower pH and/or higher acidity. It has been recently observed that late season Valencia oranges have pH values as high as 4.4, compared with values rarely higher than 4.0 reported 10 to 15 years ago *(30).* The Florida Department of Citrus is currently conducting a study to determine possible causes for a decline in Florida orange and grapefruit acidity during the last 50 years *(17).* Perhaps a combination of decreased acidity of fruits used to make juice and increased acid tolerance of some strains of pathogens has contributed to a rise in juice-associated outbreaks.

Adaptation of pathogen cells. Outbreaks associated with juice have been caused by foodborne pathogens with varied adaptive mechanisms, so that any treatment used in the production of fruit juice must affect a broad spectrum of pathogenic microorganisms in various physiological states. For example, compared with nonadapted cells, acid-adapted cells of *E. coli* O157:H7 have increased resistance to inactivation when inoculated into mango juice *(39).* Yuk and Schneider *(93)* reported that adaptation of *Salmonella* in fruit juices resulted in increased tolerance to simulated gastric fluid. Acid-adapted *E. coli* O157:H7 cells are more resistant than nonadapted cells to heat inactivation in apple and orange juices *(52, 73).* Mazzotta *(52)* observed that acid-adapted *E. coli* O157:H7, *Salmonella,* and *Listeria monocytogenes* had higher heat resistance than control cells in apple, orange, and white grape juices. Acid-adapted *E. coli* O157:H7 and *Salmonella* but not *L. monocytogenes* had increased thermal tolerance in cantaloupe juice and watermelon juice *(76).* However, short-term ($<$6 h) exposure of *E. coli* O157:H7 to apple cider and apple juice (pH 3.4) hastens thermal destruction *(41).* Exposure of pathogens to high osmotic pressure also can result in increased heat resistance *(34).*

Sources of contamination. There are several routes by which fruits and fruit juices may become contaminated with enteric pathogens. In some instances, the source of contamination of fruit used to make juice, similar to the situation for other fresh produce, can be traced back to animal or human feces. Juice may become contaminated by using fruit that has fallen from trees and has come into contact with soil, water, sewage, or manure that contains bacteria, viruses, and parasites capable of causing illness *(8).* Contamination of fruits can occur both in packing sheds and processing facilities upon contact with animals and unclean water and at the point of consumption *(45, 51).* Surveys of apple cider production practices in Virginia *(91),* Iowa *(28),* and Ontario, Canada *(50)* during 1998 through 2001 revealed that washing and/or sanitization of apples commonly did not occur before pressing. Parish *(63)* recovered four *Salmonella* serotypes from orange juice, unwashed fruit surfaces, or amphibians captured outside a citrus-processing facility.

Salmonella, E. coli O157:H7, and *L. monocytogenes* inoculated onto oranges were able to spread to contact surfaces and to juice produced in a simulated foodservice environment *(51).* A survey for the presence of *Salmonella* and *Shigella* in freshly squeezed orange juice and on wiping cloths collected from public markets and street booths was conducted by Castillo et al. *(18). Salmonella* was isolated from 14, 20, and 23% of the samples of juice, orange surfaces, and wiping cloths, respectively, and *Shigella* was isolated from 6, 17, and 5%, respectively, of these samples. This may indicate poor sanitation and possible exposure to fecal contamination either of the raw materials or during the juice extraction and serving processes.

Potential for pathogen internalization. Some routes of contamination may lead to internalization of pathogens into the flesh of the fruit, where they cannot be eliminated by surface treatment *(14).* Seeman et al. *(75)* detected generic *E. coli* in the inner core of apples that had been placed on soil inoculated with the bacterium in an outdoor setting. Aided by temperature differentials at various points of processing, apples in an aqueous environment can take up *E.*

coli O157:H7 through the skin *(15),* and contamination can spread from the blossom end to the core region *(11, 13).* Eblen et al. *(33)* found that 31% of whole oranges with small (0.91-mm) holes in the surface became infiltrated with *E. coli* O157:H7 and *Salmonella* when the oranges were immersed in cell suspensions.

Heat disinfection methods used to eliminate tephritid fly larvae from mangos may promote internalization of *Salmonella.* Penteado et al. *(66)* reported that immersion of mangos in 47°C water followed by immersion in 21°C water containing *Salmonella* Enteritidis at 7 log CFU/ml resulted in internalization of the pathogen in the stem end, middle side area, and blossom end. These results illustrate the high potential for pathogen infiltration if heat-disinfected mangos are cooled in contaminated water. Janisiewicz et al. *(43)* found that fruit flies can transport generic *E. coli* from one apple to the next and can inoculate wounds in the fruit, suggesting a mechanism for contamination of blemished fruit even as it remains on the tree.

Inactivation of pathogen cells. Processes designed to inactivate pathogens in fruit juice include heat treatment, freezing and thawing, high-pressure treatment, irradiation, and the addition of antimicrobials *(12, 24, 36, 40, 64, 74, 81, 82, 89, 92).* Heat treatment, including thermal pasteurization, is the process most commonly used in the United States. About 98% of juice processors in the United States pasteurize their juice *(85).* Very cold temperatures *(64),* freezing and thawing *(40, 82, 92),* treatment with ozone *(89, 90),* and the addition of organic acids *(82)* are effective for greatly reducing populations of foodborne pathogens in juice. Holding juice at refrigeration temperatures, however, generally protects pathogens against inactivation *(56, 65, 77, 95).* Another nonthermal treatment that inactivates pathogens in juice is high pressure *(9, 10, 44, 46, 68).* Treatment with UV light also causes substantial reductions in pathogens in juices *(5, 31, 59, 67).*

In 2004, the FDA issued industry guidance recommending that processors of apple juice and cider be certain that they comply with the juice HACCP regulation, including validation of treatment processes *(86).* This guidance further stated that the FDA determined that no scientific studies had established conditions for ozone treatment of apple juice to achieve a 5-log reduction for any pathogen. Ozone treatment was considered insufficient to have prevented an outbreak of *C. parvum* infections associated with apple cider in 2003. More recent reports indicate that, depending on the temperature of the apple cider and orange juice, purging with ozone reduces populations of *E. coli* O157:H7 and salmonellae by 4.2 to >6.0 log CFU/ml *(89).* Combinations of ozone and antimicrobials, followed by refrigerated storage, can reduce populations of both pathogens in apple cider and orange juice by more than 5 log CFU/ml *(90).*

Modification of regulations. As an understanding of the public health challenge of juice-associated outbreaks has developed, regulations have been modified. The first regulatory attempt to warn consumers about the possible health risks associated with drinking untreated juice was conducted by the FDA through the 1998 proposed juice labeling regulation. Although the number of reported juice-associated outbreaks did not immediately decline after this regulation was put in place, public health agencies did become aware of a rising public health problem. During the late 1990s, academic discourse related to juice-associated illness continued, and public health agencies diligently investigated and reported foodborne disease outbreaks. In 2002, the juice HACCP regulation *(85)* became effective. This final regulation seems to have had an impact on juice-associated outbreaks; fewer such outbreaks have been reported in the last 4 years, and only one of those outbreaks implicated a processor covered by the juice HACCP regulation.

However, the juice-associated outbreaks reported to the CDC since 2002 illustrate that unresolved prevention challenges still exist. The first challenge is the contamination that occurs at the point of consumption of the product. This issue cannot be addressed by regulating juice production processes; food handlers, food service personnel, and consumers continue to be responsible for handling food safely. The second challenge, illustrated by recent outbreaks, is the risk posed by the production of fresh fruit juice and cider sold directly and exclusively to consumers. The juice HACCP regulation does not apply to retail establishments and thus does not cover direct-to-consumer sales. Retail establishments must comply with the 1998 final juice labeling regulation only when they operate in interstate commerce, i.e., either the juice is shipped across state lines or any component of the juice comes from outside the state where the juice is processed. Often, retail juice establishments are small seasonal businesses that offer products desired by consumers but may be difficult to regulate. The third challenge is noncompliance with an established HACCP plan, which can result in large volumes of contaminated juice reaching national and international markets.

The success of a HACCP program depends on (i) regular monitoring to demonstrate that specified treatments are being applied effectively and (ii) taking swift corrective action when monitoring indicates a problem. The juice HACCP regulation requires that all juice producers, except those dealing with citrus juice, apply a 5-log pathogen reduction process to the juice itself. Citrus juice processors may begin procedures and treatments to effect the 5-log pathogen reduction before juice extraction. Surface treatments of the citrus fruit may be used as part of the 5-log pathogen reduction process provided that these treatments begin after culling and cleaning of the fruit and that all treatments occur within one production facility *(85).* Washing oranges with alkaline cleaners is effective for reducing surface contamination with *E. coli* and for reducing microbial populations in juice extracted from oranges *(60, 61)* but cannot be relied upon to eliminate all pathogens. Whether compliance with the existing regulation will be sufficient to prevent future citrus juice–associated outbreaks remains to be determined. If compliance is not sufficient, a final kill step applied to the juice itself will provide an added measure of safety.

This review of juice-associated outbreaks of illness has several limitations. The data presented were gathered through a passive surveillance system that relies on voluntary reporting through local and state public health agencies. Improved surveillance resulted in an increase in the number of foodborne disease outbreaks reported in 1998 and subsequent years by approximately twofold. The mean number of juice-associated outbreaks reported to the CDC in 2002 through 2005 was lower than that in 1995 through 1998, before the juice labeling regulation, and lower than in 1999 through 2001, before the juice HACCP regulation. This decrease took place despite the change in reporting of all foodborne disease outbreaks that occurred in 1998. Through the Foodborne Outbreak Reporting System at the CDC, standard but limited information had been collected before the format change that was implemented in 1999. Additional information is now gathered when it is available. More complete data regarding some of the outbreaks described, particularly those preceding 1999, may have been useful to better understand the causes of these outbreaks.

In summary, a decrease in the number of juice-associated outbreaks reported to the CDC has occurred since 2002. Regulations have evolved concurrent with food safety research and in response to the detection and investigation of outbreaks. Clearer guidelines for the production of safe fruit juice are now available in the United States. Outbreaks of illness caused by contaminated fruit juice were a substantial problem early in the last decade. These outbreaks appear to have decreased, but not disappeared, since the implementation of the juice HACCP regulation.

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