May 14, 2018

The Honorable Paul Ryan
Speaker
United States House of Representatives
H-232, US Capitol Building
Washington, D.C. 20515

The Honorable Nancy Pelosi
Minority Leader
United States House of Representatives
H-204, US Capitol Building
Washington, D.C. 20515

Re: Oppose Amendment 30 of H.R. 2, allowing interstate direct sale of raw milk and milk products

Dear Speaker Ryan and Minority Leader Pelosi:

Due to the significant public health risks associated with the consumption of raw milk, the National Milk Producers Federation (NMPF) and the International Dairy Foods Association (IDFA) respectfully urge you to **oppose Amendment 30 to H.R. 2,** the Agriculture and Nutrition Act of 2018, offered by Rep. Thomas Massie (KY-04), legislation designed to allow the interstate sale of unpasteurized (raw) milk and milk products. The amendment would remove existing regulations prohibiting the direct sale of raw milk and milk products, consumption of which has been opposed by every major health organization in the United States, including the American Medical Association and the American Academy of Pediatrics.

Consumption of raw milk is a demonstrated public health risk. The link between raw milk and foodborne illness has been well-documented in the scientific literature, with evidence spanning nearly 100 years. Raw milk is a key vehicle in the transmission of human pathogens, including *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*, and *Salmonella*.

Based on a 2012 report[1] from the Centers for Disease Control and Prevention (CDC), between 1993 and 2006, unpasteurized dairy products resulted in 73 known outbreaks – causing 1,571 cases of foodborne illness, 202 hospitalizations, and 2 deaths. Most recently, analyzing data collected between 2009 and 2014, researchers recently concluded that unpasteurized milk is 840 times more likely to cause foodborne illness than pasteurized milk, and such illnesses have a

[1] Langer, AJ, et al. Non-pasteurized dairy products, disease outbreaks, and state laws – United States, 1993-2006. Emerging Infectious Diseases. 2012; 18(3):385

hospitalization rate 45 times higher than those involving pasteurized dairy products[2].

The CDC has reported nearly 75% of raw milk-associated outbreaks have occurred in states where sale of raw milk was legal. Eliminating the regulations that currently prohibit the interstate sale of raw milk in the United States increases the risk to public health, opening up consumers to the inevitable consequence of falling victim to a foodborne illness. No matter how carefully it is produced, raw milk is inherently dangerous. Americans have become ill after consuming raw milk obtained from farms of varying sizes, from cow-share programs, and from licensed, permitted, or certified raw milk producers.

Nearly two-thirds of all outbreaks associated with raw milk or raw milk products involve children and nearly half of outbreaks involve a child younger than five years old. For example, in 2011, five children in California were infected with *E. coli* O157:H7 after drinking raw milk; three required hospitalization with hemolytic uremic syndrome (HUS), a devastating condition that can lead to permanent kidney failure. At a school event in Wisconsin, also in 2011, sixteen fourth grade students and adults who drank raw milk donated by a parent later suffered from diarrhea, abdominal cramping, nausea, and vomiting from *Campylobacter* infections. It is the responsibility of America's leaders to make decisions to protect the health of the public, most especially children who are unable to make fully informed choices – choices that can have profound harmful consequences for the rest of their lives.

One critical aspect of this high-profile issue is the tremendous amount of mythology and misinformation that has been disseminated regarding the supposed health benefits of raw milk. It is important to emphasize that no claim related to the health benefits of consuming raw milk has been substantiated in any of the medical literature. The scientific consensus is that raw milk can cause serious illnesses and hospitalizations, as well as result in life-long negative health complications and death.

Another misleading claim is that testing or regulating the sale of raw milk will protect consumers from the risks of raw milk consumption. This is also unfounded. Product testing is not an adequate substitute and cannot ensure the same level of safety as pasteurization. Legalizing and regulating the sale of raw milk sends a signal to consumers that drinking unpasteurized milk is safe when, in fact, the opposite is true.

Nationally, our dairy industry benefits from a very high degree of consumer confidence – confidence built in large part due to the excellent food safety record of milk and dairy products. Current statistics estimate only 1-2% of reported foodborne outbreaks are attributed to dairy products. However, of those, over 70% have been attributed to raw milk and inappropriately-aged

[2] Costard S, Espejo L, Groenendaal H, Zagmutt FJ. Outbreak-related disease burden associated with consumption of unpasteurized cow's milk and cheese, United States, 2009–2014. Emerging Infectious Diseases. 2017; 23(6):957.

raw milk cheeses. In a 2007 report,[3] the CDC concluded that "State milk regulations and methods for their enforcement should be reviewed and strengthened to minimize the hazards of raw milk". Allowing the sale of raw milk or any raw milk product through Amendment 30 to H.R. 2 would be a step in the wrong direction.

While choice is an important value, it should not pre-empt consumers' well-being. To allow the interstate sale of raw milk and milk products is an unnecessary risk to consumer safety and public health. Therefore, we strongly oppose Amendment 30 to H.R. 2.

Please feel free to contact us with any questions.

Sincerely,

James Mulhern
President and CEO
National Milk Producers Federation

Michael Dykes, DVM
President and CEO
International Dairy Foods Association

Enclosures

The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

The International Dairy Foods Association (www.idfa.org), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, that employs nearly 1 million skilled individuals, generates more than $39 billion in direct wages and has an overall economic impact of more than $200 billion. IDFA is the umbrella organization for the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). Our members range from large multinational organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States and sold throughout the world. Our diverse membership includes numerous food retailers, suppliers and companies that offer infant formula and a wide variety of milk ingredients.

[3] Bhat, M, et al. *Escherichia coli* O157:H7 Infection Associated with Drinking Raw Milk – Washington and Oregon, November–December 2005. MMWR. 2007; 56(8):165.

Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993–2006

Adam J. Langer, Tracy Ayers, Julian Grass, Michael Lynch, Frederick J. Angulo, and Barbara E. Mahon

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Release date: February 21, 2012; Expiration date: February 21, 2013

Learning Objectives

Upon completion of this activity, participants will be able to:

- Evaluate the epidemiology of foodborne illness related to the consumption of dairy products
- Analyze the clinical presentation and outcomes of foodborne disease related to the consumption of dairy products
- Distinguish the organism most commonly associated with foodborne illness after consumption of unpasteurized dairy products
- Assess sources of contamination of pasteurized dairy products

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Although pasteurization eliminates pathogens and consumption of nonpasteurized dairy products is uncommon, dairy-associated disease outbreaks continue to occur. To determine the association of outbreaks caused by nonpasteurized dairy products with state laws regarding sale of these products, we reviewed dairy-associated outbreaks during 1993–2006. We found 121 outbreaks for which the product's pasteurization status was known; among these, 73 (60%) involved nonpasteurized products and resulted in 1,571 cases, 202 hospitalizations, and 2 deaths. A total of 55 (75%) outbreaks occurred in 21 states that permitted sale of nonpasteurized products; incidence of nonpasteurized product–associated outbreaks was higher in these states. Nonpasteurized products caused a disproportionate number (≈150× greater/unit of product consumed) of outbreaks and outbreak-associated illnesses and also disproportionately affected persons <20 years of age. States that restricted sale of nonpasteurized products had fewer outbreaks and illnesses; stronger restrictions and enforcement should be considered.

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DOI: http://dx.doi.org/10.3201/eid1803.111370

In the United States, milk and other dairy products are dietary staples; the 2010 Dietary Guidelines for Americans recommend that most Americans include dairy products in their diet (*1*). However, numerous pathogens can contaminate dairy products and cause illness and death. Milkborne infections were relatively common before the advent of pasteurization in the late 19th century (*2*), and in the United States today, illness related to consumption of nonpasteurized dairy products remains a public health problem.

In 1948, Michigan enacted the first statewide requirement that dairy products be pasteurized, and many other states soon did the same (*2*). In 1987, the United States Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers (*3*). However, sale of nonpasteurized dairy products within the state where they are produced is regulated by each state, and some states permit sale of these products. Despite the federal ban on the sale of nonpasteurized products in interstate commerce, the broad use of pasteurization by the dairy industry, and the infrequency with which nonpasteurized dairy products are consumed, illnesses and outbreaks associated with consumption of these products continue to occur (*4*–*23*).

State and local health departments report foodborne disease outbreaks to the Centers for Disease Control and Prevention (CDC) through the Foodborne Disease Outbreak Surveillance System. As a result of efforts to enhance outbreak surveillance starting in 1998, the total number of outbreak reports increased substantially (*24*). A recent comprehensive analysis of foodborne disease outbreaks associated with dairy products (dairy-associated outbreaks) reported to CDC reviewed outbreaks that occurred during 1973–1992 (*4*). We reviewed subsequent dairy-associated outbreaks, reported in the United States during 1993–2006. We characterized the outbreaks and examined their association with state laws regarding sale of nonpasteurized dairy products.

Methods

To compare the incidence of foodborne outbreaks involving nonpasteurized dairy products among states with differing laws with regard to the sale of these products (i.e., states that permitted their sale vs. states that prohibited their sale), we reviewed reports of foodborne disease outbreaks involving dairy products reported to CDC during 1993–2006. These reports, completed by state and local health departments, typically included the number of cases associated with the outbreak; the age and sex distribution of outbreak-associated case-patients; the number of hospitalizations and deaths; the etiologic agent associated with the outbreak; the type of dairy product implicated (e.g., fluid milk, cheese); and whether the implicated dairy product was marketed, labeled, or otherwise presented to the consumer as pasteurized or nonpasteurized. Hereafter, we refer to these products as pasteurized or nonpasteurized. Thus, any outbreak involving a dairy product that was contaminated after pasteurization or that was intended to be pasteurized but underwent inadequate pasteurization was classified as involving pasteurized product. When possible, we corrected missing or incomplete data by asking the health department that conducted the investigation for more information.

To determine whether the sale of nonpasteurized dairy products was legal at the time of each outbreak, we contacted the 50 state departments of health and agriculture and requested data on whether the state permitted the sale of nonpasteurized dairy products produced in that state for each year from 1993 through 2006. We defined an illegal state-year as a year in which a state prohibited the sale of all nonpasteurized products, and we defined a legal state-year as a year in which a state permitted the sale of nonpasteurized dairy products produced in that state. Data on the estimated population, by state, for each year were obtained from the US Census Bureau. To compare the incidence of outbreak and outbreak-associated cases during illegal state-years to that during legal state-years, we stratified the outbreaks by legal status of the state in which the outbreak occurred at the time of the outbreak and calculated incidence density ratios for reported outbreaks (Poisson model) and for outbreak-associated cases (zero-inflated negative binomial model).

Results

During 1993–2006, a total of 30 states reported 122 foodborne disease outbreaks caused by contaminated dairy products. Dairy-associated outbreaks occurred in all years except 1996, and outbreaks involving nonpasteurized dairy products occurred in all years except 1994 and 1996. The number of reported dairy-associated outbreaks increased in 1998 after surveillance for foodborne disease outbreaks was enhanced (Figure 1).

Whether the product was pasteurized or nonpasteurized was known for 121 of the 122 outbreaks, and most outbreaks (73 [60%]) involved nonpasteurized dairy products. Of the 121 outbreaks for which product pasteurization status was known, 65 (54%) involved cheese and 56 (46%) involved fluid milk. Of the 65 outbreaks involving cheese, 27 (42%) involved cheese made from nonpasteurized milk. Of the 56 outbreaks involving fluid milk, an even higher percentage (82%) involved nonpasteurized milk.

The 121 outbreaks involving dairy products for which pasteurization status was known resulted in 4,413 reported illnesses. Among these illnesses, 1,571 (36%) resulted from nonpasteurized dairy products. The median number of persons reported ill during outbreaks involving

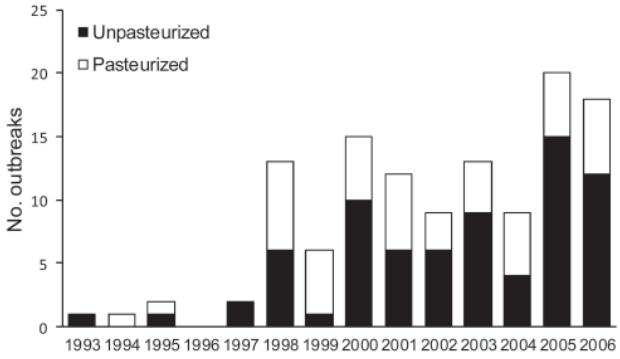

Figure 1. Number of dairy product–associated outbreaks, by year and pasteurization status of product, United States, 1993–2006.

nonpasteurized dairy products was 11 (range 2–202). Outbreaks involving nonpasteurized dairy products resulted in 202 hospitalizations (hospitalization rate 13%). In contrast, outbreaks involving pasteurized dairy products resulted in 37 hospitalizations (hospitalization rate 1%). Two deaths were associated with an outbreak caused by consuming nonpasteurized dairy products, and 1 death was associated with an outbreak caused by a pasteurized product (Table).

Ill persons in outbreaks involving nonpasteurized dairy products were generally younger than those in outbreaks involving pasteurized dairy products. For the 60 outbreaks involving nonpasteurized dairy products for which age of patients was known, 60% of patients were <20 years of age; for the 37 outbreaks involving pasteurized dairy products for which age of patients was known, 23% of patients were <20 years of age ($p<0.001$).

The causative agent was identified for all 73 outbreaks involving nonpasteurized dairy products; all were caused by bacteria. One outbreak was caused by *Campylobacter* spp. and Shiga toxin–producing *Escherichia coli*. Among the remaining 72 outbreaks, 39 (54%) were caused by *Campylobacter* spp., 16 (22%) by *Salmonella* spp., 9 (13%) by Shiga toxin–producing *E. coli*, 3 (4%) by *Brucella* spp., 3 (4%) by *Listeria* spp., and 2 (3%) by *Shigella* spp. Among the 30 outbreaks involving pasteurized dairy products for which the causative agent was reported, 13 (44%) were caused by norovirus, 6 (20%) by *Salmonella* spp., 4 (13%) by *Campylobacter* spp., 3 (10%) by *Staphylococcus aureus*, and 1 (3%) each by *Clostridium perfringens*, *Bacillus cereus*, *Listeria* spp., and *Shigella* spp.

A total of 48 reported outbreaks involved pasteurized dairy products. The source of contamination was reported for 7 (14%) of these outbreaks, of which at least 4 (57%) probably resulted from post-pasteurization contamination by an infected food handler. Failure of the consumer to store the dairy product at an appropriate temperature probably contributed to 3 other outbreaks. Such temperature abuse can enable pathogens (present because they either survived pasteurization in low numbers or were introduced after pasteurization) to multiply to concentrations capable of causing illness.

During the study period, 43 (86%) states did not change their legal status regarding the sale of nonpasteurized dairy products produced in that state. Among these 43 states, selling nonpasteurized dairy products produced in that state was legal in 21 (49%). Of the 7 states that changed their legal status, 3 changed from legal to illegal (Mississippi in 2005, Ohio in 2003, and Wisconsin in 2005), 3 changed from illegal to legal (Arkansas in 2005, Illinois in 2005, and Nevada in 2005), and 1 (Oregon) changed from legal to illegal in 1999 and then back to legal in 2005 (Figure 2).

Among the 700 state-years (14 years × 50 states) included in our analysis of the association of legal sales status and nonpasteurized dairy–associated outbreaks, sale of nonpasteurized dairy products produced in the state was legal for 342 state-years and illegal for 358 state-years. We excluded from analysis 2 outbreaks caused by nonpasteurized dairy products because each occurred in multiple states with differing laws. Of the 71 remaining outbreaks involving nonpasteurized dairy products, 55 (77%) occurred in states where sale of nonpasteurized dairy products produced in that state was legal. Among these 71 outbreaks involving nonpasteurized dairy products, 1,526 persons became ill and 1,112 (73%) of these illnesses occurred in states where it was legal to sell nonpasteurized dairy products. Also among these 71 outbreaks involving nonpasteurized dairy products, 15 occurred in states where sale of nonpasteurized dairy

Table. Characteristics of disease outbreaks after consumption of dairy products, United States, 1993–2006

Product	Outbreak characteristic, no.			
	Total	Associated illnesses	Associated hospitalizations	Associated deaths
Nonpasteurized				
Fluid milk	46	930	71	0
Cheese	27	641	131	2
Total	73	1,571	202	2
Pasteurized				
Fluid milk	10	2,098	20	0
Cheese	38	744	17	1
Total	48	2,842	37	1
All dairy	121	4,413	239	3

products was illegal. The source of the nonpasteurized dairy products was reported for 9 of these outbreaks: 7 (78%) were associated with nonpasteurized dairy products obtained directly from the producing dairy farm, 1 was associated with nonpasteurized dairy products obtained under a communal program to purchase shares in dairy cows (i.e., cow shares, a scheme used to circumvent state restrictions on commercial sales of nonpasteurized dairy products) (*11*), and 1 was limited to members of a large extended family who consumed nonpasteurized milk from their own cow.

Figure 2. Legal status of nonpasteurized dairy product sale or distribution, by state, United States, for A) 1993, B) 1999, and C) 2006. Gray shading indicates states where nonpasteurized dairy product sale or distribution was permitted. States outlined in black changed legal status during the study period.

Incidence density ratios (IDRs) for nonpasteurized product–associated outbreaks and outbreak-associated cases during legal and illegal state-years varied by the type of dairy product (milk or cheese) and are reported separately. In states where it was legal to sell nonpasteurized dairy products, the rate of outbreaks caused by nonpasteurized fluid milk was >2× as high as in states where it was illegal to sell nonpasteurized dairy products (IDR 2.20, 95% CI 1.14–4.25). The rate of outbreak-associated illnesses caused by nonpasteurized fluid milk was 15% higher in states where it was legal to sell nonpasteurized dairy products, but this result was not statistically significant (IDR 1.15, 95% CI 0.24–5.54). States where it was legal to sell nonpasteurized dairy products had nearly 6× the rate of outbreaks caused by cheese made from nonpasteurized milk (IDR 5.70, 95% CI 1.71–19.05) and nearly 6× the rate of outbreak-associated illnesses (IDR 5.77, 95% CI 0.59–56.31), although the IDR for outbreak-associated illnesses was not statistically significant.

Discussion

Incidence of outbreaks caused by nonpasteurized dairy products was higher in states that permitted the sale of nonpasteurized dairy products than in states that prohibited such sale. This association was evident for nonpasteurized fluid milk and cheese made from nonpasteurized milk. Although this association did not extend to the rates of outbreak-associated cases, factors other than whether it was legal to sell nonpasteurized dairy products probably affect the number of cases that occur in an outbreak. These factors include the volume and area of distribution of the contaminated product, the pathogen involved, the underlying health status of the exposed persons, and the ability of the responding public health agency to swiftly intervene to terminate the outbreak.

Because consumption of nonpasteurized dairy products is uncommon in the United States, the high incidence of outbreaks and outbreak-associated illness involving nonpasteurized dairy products is remarkable and greatly disproportionate to the incidence involving dairy products that were marketed, labeled, or otherwise presented as pasteurized. In a population-based survey conducted in 1996–1997, only 1.5% of respondents reported having consumed nonpasteurized dairy products in the 7 days before being interviewed; and in the 2003–2004 and 2005–2006 National Health and Nutrition Examination Surveys, only <1% of respondents who drank milk reported that they usually drank nonpasteurized milk (*21*,*25*,*26*). Because many of these respondents also reported consuming pasteurized dairy products, the proportion of dairy products consumed nonpasteurized by volume or weight is probably <1%. To illustrate this point, it is useful if we provide a hypothetical weighting of the findings in this study by the

amount of nonpasteurized and pasteurized dairy products consumed. Total milk production in the United States in 2010 was estimated at 193 billion pounds, suggesting that ≈2.7 trillion pounds of milk were consumed during the 14 years from 1993 through 2006 (*27*). If 1% of dairy products were consumed nonpasteurized, then during these 14 years, 73 outbreaks were caused by the 27 billion pounds of nonpasteurized dairy products that were consumed and 48 by the 2,673 billion pounds of pasteurized products that were consumed. Therefore, the incidence of reported outbreaks involving nonpasteurized dairy products was ≈150× greater, per unit of dairy product consumed, than the incidence involving pasteurized products. If, as is probably more likely, <1% of dairy products are consumed nonpasteurized, then the relative risk per unit of nonpasteurized dairy product consumed would be even higher.

After 1998, when surveillance for foodborne outbreaks was enhanced, the number of reported foodborne disease outbreaks caused by dairy products increased, as did the total number of reported foodborne outbreaks. Outbreaks involving nonpasteurized dairy products were all associated with bacterial enteric pathogens, most of which have known animal reservoirs. In contrast, among outbreaks in which a pasteurized dairy product was implicated, the most commonly reported causative agent was norovirus (44% of outbreaks), a pathogen with a human reservoir. These results suggest that outbreaks caused by nonpasteurized dairy products are probably caused by pathogens in the dairy environment, which would be eliminated by proper pasteurization, and that outbreaks caused by pasteurized dairy products are probably caused by contamination of the products at some point after pasteurization.

The objective of pasteurization is to eliminate from fluid milk those pathogens that originate in the dairy environment; however, pasteurization does not protect against contamination that might occur later, such as during food handling. In addition, if pasteurization is not performed properly (for appropriate times and at appropriate temperatures), pathogens might not be eliminated from the milk. Appropriate post-pasteurization food-handling practices can minimize the risk for reintroduction of pathogens into dairy products after pasteurization. In addition, other precautions, such as maintaining the dairy product at an appropriate temperature and disposing of expired products, reduce the risk to the consumer should the product become contaminated after pasteurization. When outbreaks do occur because of contamination of dairy products that are marketed as pasteurized, the source of contamination is typically traced to improper pasteurization, improper storage, or improper handling of the products after marketing (*28*–*30*). In our study, all outbreaks associated with pasteurized products for which information on the source of contamination was available were attributed to post-pasteurization mishandling.

Among outbreak-associated cases involving nonpasteurized dairy products, 60% involved persons <20 years of age. Public health and regulatory authorities are obligated to protect persons who cannot make fully informed decisions (e.g., children) from potential health hazards. Dietary decisions for younger children, in particular, are often made by caregivers. The American Academy of Pediatrics advises against giving nonpasteurized dairy products to children and recommends that pediatricians counsel caregivers against use of these products (*31*).

Proportionately more persons were hospitalized during outbreaks caused by nonpasteurized (13%) than by pasteurized dairy products (1%). This observation suggests that infections associated with nonpasteurized dairy products might be more severe, and it is consistent with the more frequent identification of bacterial, rather than viral or toxic, causative agents and with the larger proportion of illnesses affecting children.

Limitations of this analysis are primarily associated with the nature of the CDC Foodborne Disease Outbreak Surveillance System. Outbreak reporting by state and local health departments is voluntary, and outbreak reports are not always complete. For this analysis, we obtained missing data whenever possible by contacting the reporting state health department. In addition, the CDC outbreak surveillance database is dynamic; reporting agencies can submit new reports and can change or delete previous reports at any time as new information becomes available. Therefore, the results of this analysis represent data available at 1 point in time and might differ from those published earlier or subsequently.

In summary, foodborne outbreaks involving dairy products continue to be a public health problem in the United States, and this problem is disproportionately attributable to nonpasteurized dairy products. Since the US Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers in 1987, all legal sale and distribution has occurred within states that permit the sale of nonpasteurized dairy products that originated in that state. How much illegal distribution in interstate commerce continues is unknown. The increased risk for outbreaks associated with legal intrastate sale of nonpasteurized dairy products demonstrated in this analysis can be weighed against the purported nutritional or other health benefits attributed to these products. Scientifically credible evidence for the health benefits of nonpasteurized dairy products beyond the benefits of those of otherwise equivalent pasteurized products is lacking (*32*). The risk for outbreaks resulting from cheese made from nonpasteurized milk in states where nonpasteurized

milk sale is legal may be higher for particular groups within those states. For example, in recent years, foodborne outbreaks involving nonpasteurized dairy products have been reported in association with traditional nonpasteurized products marketed to the growing Hispanic community in the United States (*5*,*33*).

Our analysis shows that legal intrastate sale of nonpasteurized dairy products is associated with a higher risk for dairy-related outbreaks and implies that restricting sale of nonpasteurized dairy products reduces the risk for dairy-related outbreaks within that state. Pasteurization is the most reliable and feasible way to render dairy products safe for consumption. Although warning labels and signs or government-issued permits are prudent where the sale of nonpasteurized dairy products is legal, they have not been shown to be effective and, given the results of this analysis, do not seem to reduce the incidence of outbreaks involving nonpasteurized dairy products to the degree that pasteurization does (*18*). Whether certain types of warnings or more explicit health advisories might be more effective than others is unknown. Public health officials at all levels should continue to develop innovative methods to educate consumers and caregivers about the dangers associated with nonpasteurized dairy products. State officials should consider further restricting or prohibiting the sale or distribution of nonpasteurized dairy products within their states. Federal and state regulators should continue to enforce existing regulations to prevent distribution of nonpasteurized dairy products to consumers. Consumption of nonpasteurized dairy products cannot be considered safe under any circumstances.

Acknowledgments

We gratefully acknowledge Patricia Griffin and Casey Barton Behravesh for review of the manuscript and the state and local health departments that investigate and report enteric disease outbreaks to CDC.

Dr Langer was a CDC Preventive Medicine Fellow assigned to the Division of Foodborne, Bacterial, and Mycotic Diseases at the time of this study. He is now an epidemiologist with the CDC Division of Tuberculosis Elimination. His research interests include the investigation of infectious disease outbreaks and animal-to-human transmission of infectious agents.

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Table of contents
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Ahead of Print
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Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009–2014

Solenne Costard, Luis Espejo, Huybert Groenendaal, Francisco J. Zagmutt

The growing popularity of unpasteurized milk in the United States raises public health concerns. We estimated outbreak-related illnesses and hospitalizations caused by the consumption of cow's milk and cheese contaminated with Shiga toxin–producing *Escherichia coli*, *Salmonella* spp., *Listeria monocytogenes*, and *Campylobacter* spp. using a model relying on publicly available outbreak data. In the United States, outbreaks associated with dairy consumption cause, on average, 760 illnesses/year and 22 hospitalizations/year, mostly from *Salmonella* spp. and *Campylobacter* spp. Unpasteurized milk, consumed by only 3.2% of the population, and cheese, consumed by only 1.6% of the population, caused 96% of illnesses caused by contaminated dairy products. Unpasteurized dairy products thus cause 840 (95% CrI 611–1,158) times more illnesses and 45 (95% CrI 34–59) times more hospitalizations than pasteurized products. As consumption of unpasteurized dairy products grows, illnesses will increase steadily; a doubling in the consumption of unpasteurized milk or cheese could increase outbreak-related illnesses by 96%.

Consumer demand for organic and natural foods (i.e., minimally processed foods) has been on the rise (*1*). However, in contrast to some perceptions (*2*), natural food products are not necessarily safer than conventional ones, as evidenced by higher rates of foodborne illnesses associated with unpasteurized dairy products (*3*–*6*). Pasteurization has greatly reduced the number of foodborne illnesses attributed to dairy products, and continuous efforts to reduce milk contamination pre- and post-pasteurization are further decreasing the disease burden (*3*). Yet, despite a decrease in dairy consumption in the United States (*7*), recent studies (*3*,*6*) suggest that over the past 15 years the number of outbreaks associated with unpasteurized dairy products has increased. In parallel with this increase, an easing of regulations has facilitated greater access of consumers to unpasteurized milk (e.g., through farm sales or cow share programs). The number of states where the sale of unpasteurized milk is prohibited decreased to 20 in 2011 from 29 in 2004 (*8*–*10*). This trend toward increased availability of unpasteurized dairy products raises public health concerns, especially because raw milk consumers include children (*2*,*4*,*6*).

Our study aimed at estimating the outbreak-related disease burden associated with the consumption of fluid cow's milk and cheese made from cow's milk (herein also referred to as milk and cheese or dairy products) that are unpasteurized and contaminated with *Campylobacter* spp., *Salmonella* spp., Shiga toxin–producing *Escherichia coli* (STEC), and *Listeria monocytogenes*. We also assessed how hypothetical increases in unpasteurized dairy consumption would affect this outbreak-related disease burden.

Methods

Data Sources

We used outbreak data from the National Outbreak Reporting System (NORS) (*11*) to estimate the incidence rates of illnesses and hospitalizations. NORS is a web-based platform that stores data on all foodborne disease outbreaks reported by local, state, and territorial health departments in the United States that have occurred since 2009. We included all outbreaks that occurred during 2009–2014 in which the confirmed etiologic agents were any of the 4 pathogens of interest (*Campylobacter* spp., *Salmonella* spp., STEC, and *L. monocytogenes*) and the implicated food vehicle or contaminated ingredient was milk or cheese (Figure 1). Outbreaks associated with multiple products; processed dairy products other than milk and cheese (e.g., cream, butter, yogurt, and kefir); milk produced by species other than cows; and cheese originating from species other than cows were excluded from the analysis (online Technical Appendix 1, https://wwwnc.cdc.gov/EID/article/23/6/15-1603-Techapp1.xlsx).

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DOI: https://dx.doi.org/10.3201/eid2306.151603

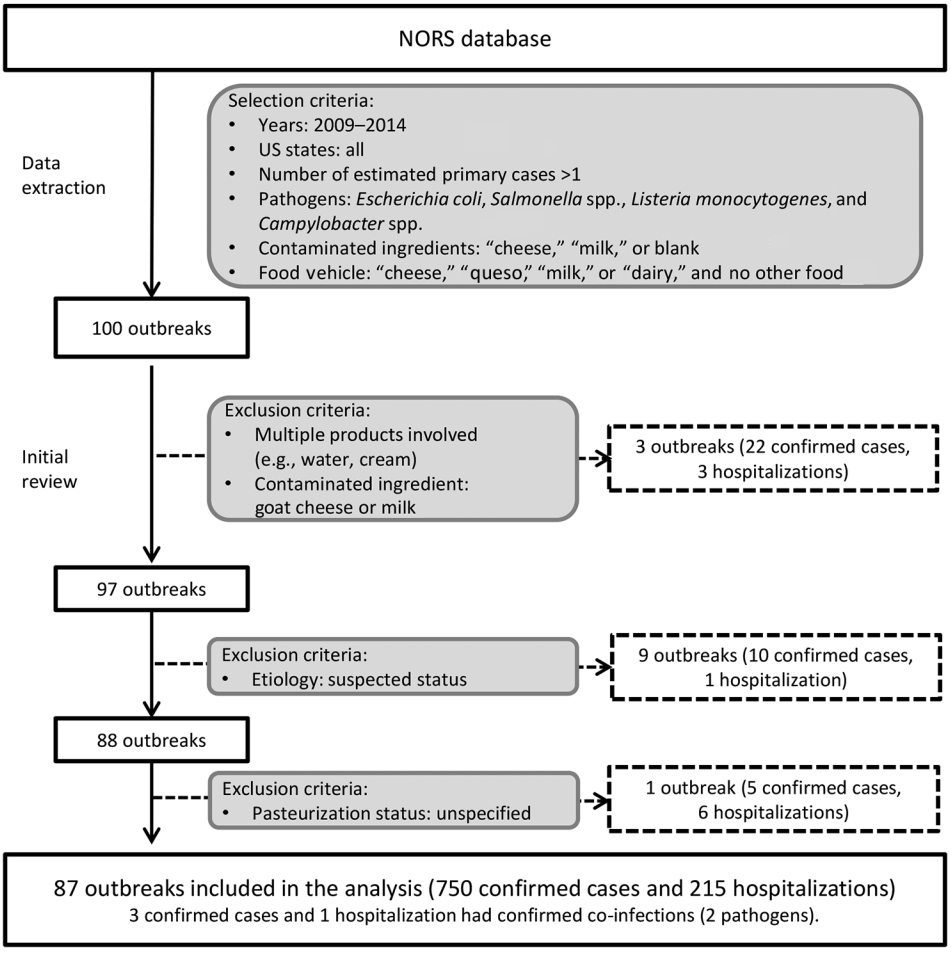

Figure 1. Process for selecting US outbreaks associated with cow's milk and cheese, 2009–2014. Laboratory-confirmed cases are cases with illness in which a specimen was collected and a laboratory was able to confirm the pathogen(s) or agent(s) causing illness. Hospitalizations are cases in which the patient was hospitalized as a result of becoming ill during the outbreak. NORS, National Outbreak Reporting System.

In addition, outbreaks with a suspected etiology status or associated with a dairy product with an unknown pasteurization status were excluded.

The stochastic model (Figure 2) was developed to estimate the following: the incidence rates of illness and hospitalization for pasteurized and unpasteurized dairy products, the excess risk associated with unpasteurized milk and cheese consumption, and the effect potential increases in consumption of unpasteurized dairy products would have on the outbreak-related disease burden (online Technical Appendix 2 Tables 1–5, https://wwwnc.cdc.gov/EID/article/23/6/15-1603-Techapp2.pdf). Inputs (other than the outbreak data) used in the stochastic model were derived from readily available sources of information (online Technical Appendix 2). Dairy consumption estimates were derived from the Foodborne Active Surveillance Network (FoodNet) Population Survey (*12*).

Estimation of the Incidence of Outbreak-Related Illnesses and Hospitalizations

We modeled the uncertainty of the pathogen-specific and pasteurization status–specific incidence rates of illness and hospitalization (λ) in the United States per serving of dairy product using a conjugate gamma distribution (*13*). The number of hospitalizations and laboratory-confirmed cases occurring during the study period (2009–2014) that were caused by a given pathogen after consumption of milk or cheese of a certain pasteurization status was obtained from the NORS database. For laboratory-confirmed cases, this number was adjusted for underreporting, under testing (only a proportion of suspected cases were sampled and tested), and underdiagnosis (based on diagnostic test sensitivity), in order to estimate illnesses for 2009–2014. These pathogen-specific factors were assumed to be independent of the product consumed and its pasteurization status, and constant for the years considered. The analysis did not include adjustment factors for potential misclassification in terms of etiology or pasteurization status. These 2 outbreak characteristics were carefully reviewed, and any outbreak for which the information could not be verified was excluded. It was thus assumed that etiology and pasteurization status misclassifications were negligible in this analysis.

Because NORS is a passive surveillance system, the inherent underreporting associated with it needed to be accounted for. We estimated an underreporting factor by

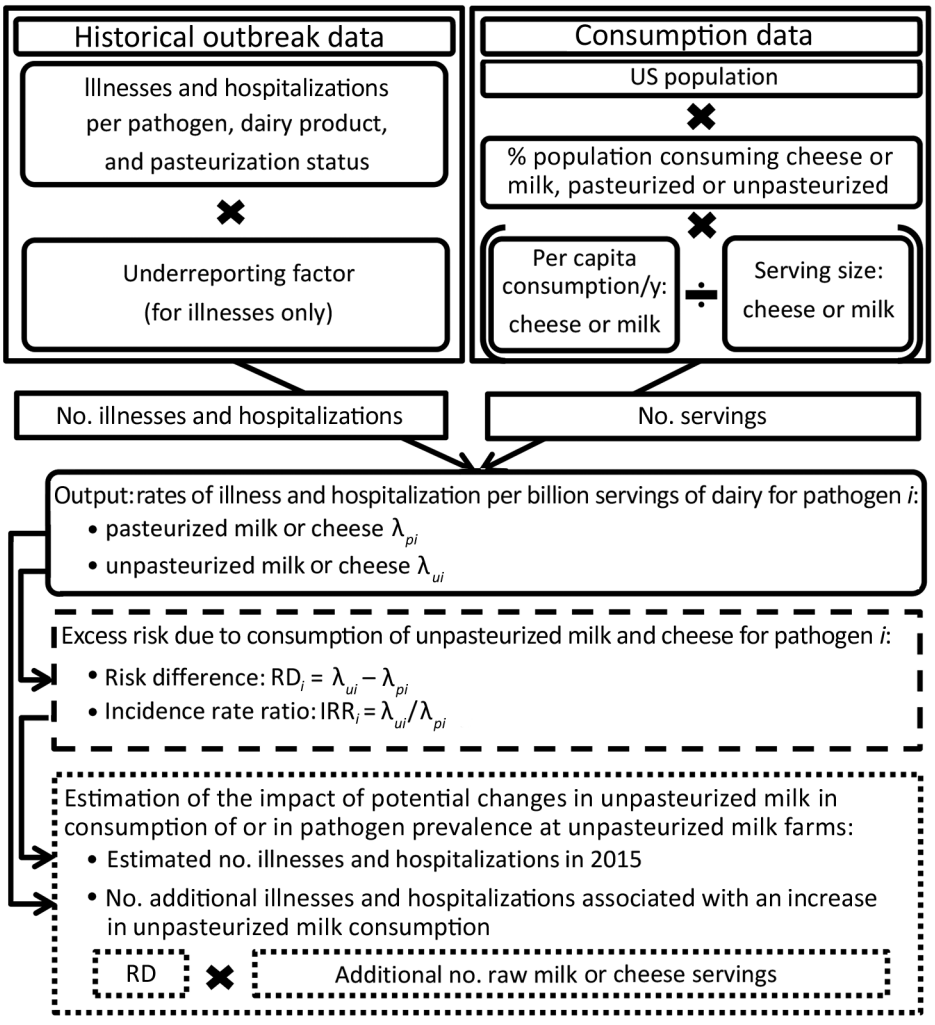

Figure 2. Stochastic model used to estimate the excess risk of outbreak-related illnesses and hospitalization due to unpasteurized dairy product consumption in the United States, 2009–2014. Model contains 3 main components: estimation of the incidence rates of illness and hospitalization for pasteurized and unpasteurized dairy products (elements in the boxes with solid lines), estimation of the excess risk associated with unpasteurized milk or cheese consumption (elements in box with dashed lines), and evaluation of the impact of hypothetical changes in consumption of unpasteurized dairy products (elements in boxes with dotted lines).

using FoodNet data, which is an active surveillance system assumed to include virtually all identified cases (online Technical Appendix 2). First, we extrapolated the total number of laboratory-confirmed cases in the US population during 2009–2013 using the incidence rates reported by FoodNet and considering the proportions of the US population included in FoodNet surveillance sites (*14*). Second, we estimated the total number of outbreak-related cases using the fraction of the US laboratory-confirmed cases that were outbreak-related (*15*). Third, we extracted the proportion of outbreak-related illnesses attributable to dairy (*16*). Fourth, we calculated the ratio of the number of outbreak-related, laboratory-confirmed cases linked to dairy consumption derived from the previously described calculations and the number of dairy-related, laboratory-confirmed cases reported through NORS to use as the underreporting factor in the analysis (online Technical Appendix 2). When estimating the underreporting factor, we assumed that the FoodNet surveillance population and reporting practices were representative of the entire United States and that the food source attribution pertaining to the illnesses from confirmed and suspected outbreaks (*16*) were equally relevant to laboratory-confirmed cases from outbreaks of confirmed status only. We used the sensitivity of the diagnostic tests as described in Scallan et al. (*15*) to estimate the proportion of false-negative, laboratory-confirmed cases from NORS (underdiagnosis factor). Finally, we derived the under-testing factor by using the ratio of laboratory-confirmed primary cases to the estimated total number of primary illnesses reported to NORS (*17*).

The annual number of servings of milk or cheese of a given pasteurization status was calculated as the product of the number of servings of milk or cheese per person for a certain year, the resident population in the United States for that year (*18*) and the percentage of the population of dairy consumers that consume milk or cheese of a particular pasteurization status. The annual per capita consumption of a given dairy product (*19*) was divided by its average serving size (i.e., the amount of milk or cheese that is generally served) (*7*,*20*,*21*) to estimate the annual per capita number

of servings of milk and cheese. These totals were then summed across the years of the study period. The per capita consumption data (*19*) were assumed to include both pasteurized and unpasteurized dairy products. Because unpasteurized dairy products constitute a small percentage of the total consumption, this assumption (if inaccurate) would likely have only a small effect on results. We also hypothesized that the serving sizes (*7*,*20*,*21*) were the same for pasteurized and unpasteurized dairy products.

The estimates of the proportion of dairy consumers that consume milk or cheese of a given pasteurization status were derived from the FoodNet Atlas of Exposure (*12*). Answers from this FoodNet survey are provided as aggregates per survey site, rather than per respondent. Therefore, answers regarding milk and cheese consumption were treated as independent. In addition, we assumed that respondents who reported consumption of unpasteurized milk or cheese did not consume pasteurized milk or cheese. Because the information to calculate the overall proportion of the US population consuming any type of cheese was unavailable, we assumed it to be equal to the proportion of the population reporting consumption of any cheese sold as or cut from solid blocks (i.e., the type of cheese consumed most commonly). We further assumed the proportion of the US population consuming unpasteurized cheese to be equal to the proportion reporting exposure to any cheese made from unpasteurized milk in the previous 7 days.

Estimation of the Excess Risks Attributed to the Consumption of Unpasteurized Milk and Cheese

We estimated the additional risks for illness and hospitalization for consumers of unpasteurized dairy products compared with consumers of pasteurized ones. We calculated excess risk using 1) risk difference (RD), which measures the absolute difference in the observed risks for illness and hospitalization between consumers of unpasteurized dairy products and consumers of pasteurized ones, and 2) incidence rate ratio (IRR), which provides a relative comparison of the risks for illness and hospitalization between the 2 exposure groups (*22*).

Effects of Hypothetical Changes in Consumption of Unpasteurized Milk or Cheese

We assessed the potential public health effects of hypothetical changes in unpasteurized milk consumption. We determined the number of illnesses in 2015 in the United States using the pathogen-specific rates of illnesses and hospitalizations per serving of dairy product. The number of hospitalizations was calculated as pathogen-specific fractions of these illnesses. The pathogen-specific probabilities of hospitalization in cases of illness were assumed unconditional on the pasteurization status of the dairy product involved, but rather dependent on the severity of illness (*23*,*24*).

We estimated the additional illnesses and the additional hospitalizations for each pathogen if a hypothetical increase in consumption of unpasteurized milk or cheese occurred using 1) the change in the proportion of the population consuming unpasteurized milk or cheese, 2) the number of servings of milk or cheese for 2015, and 3) the risk difference in illnesses per serving of dairy for that pathogen. We assumed that the overall proportion of the US population consuming milk or cheese did not change; therefore, the increase in the proportion of the US population consuming unpasteurized milk or cheese corresponded to a shift of dairy consumers from pasteurized to unpasteurized. Six hypothetical scenarios were considered: 10%, 20%, 50%, 100%, 200%, and 500% increases in the proportion of the US population consuming unpasteurized milk or cheese.

Scenario and Sensitivity Analyses

We performed a sensitivity analysis to identify the parameters that most influenced our estimates. The sensitivity of the estimates to the input parameter uncertainties was calculated by using conditional means as implemented in @RISK 6.1.2 (Palisade Corporation, Ithaca, NY, USA). In addition, we assessed the robustness of our sensitivity analysis with a scenario analysis in which we calculated our estimates with different sets of outbreak data. For the main analysis, the model was run on outbreaks of confirmed etiology and pasteurization status. In the scenario analysis, the model was then re-run with either of the 2 following sets of outbreaks added to the main data set: outbreaks of suspected etiology status (*17*) and outbreaks involving dairy products of unspecified pasteurization status assumed to be caused by pasteurized dairy products.

Model Implementation

The model was developed in Excel 2010 (Microsoft Corporation, Redmond, WA, USA) with the Monte-Carlo simulation add-in @RISK 6.1.2. Results are expressed as means and 95% credibility intervals (CrIs, a Bayesian equivalent to the confidence interval) or prediction intervals (PIs, which provides uncertainty bounds for predictions), unless stated otherwise.

Results

Incidence Rates and Increased Risks Associated with the Consumption of Unpasteurized Milk and Cheese

We used a total of 87 outbreaks causing 750 laboratory-confirmed illnesses and 215 hospitalizations in this analysis (Table 1). The incidence rates of STEC, *Salmonella* spp., and *Campylobacter* spp. illnesses and hospitalizations per 1 billion servings were higher for unpasteurized dairy product consumers than for pasteurized dairy product consumers. Illnesses and hospitalizations caused by *L. monocytogenes*

Table 1. Dairy-related illnesses and hospitalizations from 87 outbreaks, National Outbreak Reporting System, United States, 2009–2014*

	Outbreaks associated with milk and cheese consumption, N = 87†					
	Pasteurized			Unpasteurized		
Pathogen	Outbreaks	Illnesses	Hospitalizations	Outbreaks	Illnesses	Hospitalizations
STEC	0	0	0	14‡	99	42
Salmonella spp.	0	0	0	8§	83	29
Listeria monocytogenes	10	100	87	1	1	1
Campylobacter spp.	1	2	0	53‡§	465	56
Overall	11	102	87	76	648	128

*Illnesses and hospitalizations had confirmed etiologies and were associated with the consumption of milk or cheese of known pasteurization status. STEC, Shiga toxin–producing *Escherichia coli*.
†Out of the 87 outbreaks, 10 outbreaks reported a total of 17 deaths, 16 of them were linked to *L. monocytogenes* and 1 to *Campylobacter* spp.
‡One outbreak (38 illnesses and 10 hospitalizations) had 3 cases with confirmed coinfection (STEC and *Campylobacter* spp.). These 3 cases were duplicated because they were assigned to each pathogen.
§One outbreak (4 illnesses and 1 hospitalization) involved 2 pathogens: 3 Illnesses and 1 hospitalization were linked to *Campylobacter* spp. and 1 illness and 0 hospitalizations were linked to *Salmonella* spp.

infections were more often attributed to the consumption of pasteurized cheese than unpasteurized cheese (Table 2). Assuming no change in the consumption of unpasteurized dairy, dairy products contaminated with STEC, *Salmonella* spp., *L. monocytogenes*, and *Campylobacter* spp. were predicted to cause 761 (95% PI 598–994) outbreak-related illnesses and 22 (PI 13–32) hospitalizations in 2015. Unpasteurized dairy products caused 96% (PI 94%–98%) of these illnesses.

We calculated the excess risk attributable to the consumption of unpasteurized milk and cheese (Table 2; Figure 3). Because no reported illnesses were caused by *Salmonella* spp. and STEC during 2009–2014 and no hospitalizations were caused by *Campylobacter* spp., the corresponding incidence rates were extremely low (Table 2). Therefore, only RDs (and not IRRs) were reported for these pathogens. If all milk and cheese consumed were pasteurized, an average of 732 (95% PI 570–966) illnesses and 21 (95% PI 12–32) hospitalizations would be prevented per year in the United States. Of these prevented cases, 54% would be salmonellosis and 43% campylobacteriosis. The mean IRR of illnesses was 838.8 (95% CrI 611.0–1,158.0) overall from all 4 pathogens of interest (Figure 3), with 0.4 (95% CrI 0–1.2) from *L. monocytogenes* and 7,601 (95% CrI 3,711–15,346) from *Campylobacter* spp. The rate of hospitalization was higher for unpasteurized dairy consumers than for pasteurized dairy consumers (mean IRR 45.1, 95% CrI 33.7–59.2), with an IRR of 0.5 (95% CrI 0–1.7) for *L. monocytogenes*.

Effects of Hypothetical Scenarios

If the percentage of unpasteurized milk consumers in the United States were to increase to 3.8% and unpasteurized cheese consumers to 1.9% (i.e., an increase of 20%), the number of illnesses per year would increase by an average of 19% and the number of hospitalizations by 21%. If the percentages of unpasteurized milk and cheese consumers were to double, the number of illnesses would increase by an average of 96%, and the number of hospitalizations would increase by 104%, resulting in an additional 733 (95% PI 571–966) illnesses/year and 22 (95% PI 13–32) hospitalizations/year, which corresponds to a total of 1,493 (95% PI 1,180–1,955) illnesses/year (Figure 4), most caused by *Salmonella* spp. and *Campylobacter* spp.

Scenario and Sensitivity Analyses

The following conditional means sensitivity analysis reports the change in the output mean if the input variable is set to its 5th and 95th percentiles while other inputs are sampled at random. The rates of illnesses (λ) caused by the

Table 2. Incidence rates and risk differences for illness and hospitalization per 1 billion servings of milk or cheese, by pasteurization status and pathogen, United States, 2009–2014*

	Illnesses			Hospitalizations		
Pathogen	Unpasteurized	Pasteurized	Risk difference†	Unpasteurized	Pasteurized	Risk difference†
STEC	3.5 (2.7–4.5)	3.4×10^{-4} (3.1×10^{-7} to 1.7×10^{-3})	3.5 (2.7 to 4.5)	0.9 (0.6 to 1.2)	3.4×10^{-4} (3.0×10^{-7} to 1.7×10^{-3})	0.9 (0.6 to 1.2)
Salmonella spp.	49.1 (32.7–76.7)	3.4×10^{-4} (3.3×10^{-7} to 1.7×10^{-3})	49.1 (32.7 to 76.7)	0.6 (0.4 to 0.9)	3.5×10^{-4} (3.4×10^{-7} to 1.7×10^{-3})	0.6 (0.4 to 0.9)
Listeria monocytogenes	0.04 (0.003–0.100)	0.1 (0.08 to 0.12)	–0.06 (–0.11 to 0.02)	0.03 (2.2×10^{-3} to 0.1)	0.06 (0.05 to 0.07)	–0.03 (–0.06 to 0.04)
Campylobacter spp.	39.0 (30.8–48.3)	5.8×10^{-3} (2.4×10^{-3} to 1.1×10^{-2})	39.0 (30.8 to 48.3)	1.2 (0.9 to 1.5)	3.5×10^{-4} (3.5×10^{-7} to 1.7×10^{-3})	1.2 (0.9 to 1.5)
Overall	91.7 (71.8–120.9)	0.11 (0.09 to 0.13)	91.6 (71.7 to 120.8)	2.7 (2.2 to 3.3)	6.1×10^{-2} (4.9×10^{-2} to 7.5×10^{-2})	2.7 (2.2 to 3.2)

*Values are shown as mean incidence (95% credibility interval). STEC, Shiga toxin–producing *Escherichia coli*.
†Excess risk is attributable to unpasteurized dairy.

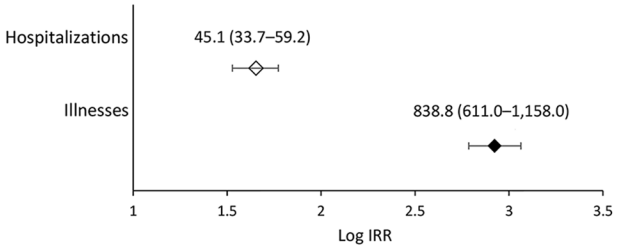

Figure 3. Forest plot showing, on a logarithmic scale, the excess risk for outbreak-related illnesses and hospitalizations caused by consumption of pasteurized and unpasteurized milk and cheese, United States, 2009–2014. Markers indicate mean log IRR of outbreak-related illnesses and hospitalizations caused by the food pathogens *Campylobacter* spp., *Listeria monocytogenes*, *Salmonella* spp., and Shiga toxin–producing *Escherichia coli* per 1 billion servings of unpasteurized milk or cheese relative to pasteurized products. Error bars indicate 95% credibility interval (CrI). Numbers above markers and bars are the IRR (not in log scale) and 95% CrI. log (IRR) = 0 indicates no difference in incidence rates between unpasteurized and pasteurized milk and cheese. IRR, incidence rate ratio.

consumption of unpasteurized milk and cheese were most sensitive to the underreporting factors (γ) for *Salmonella* spp. (mean range λ 34.9–72.5), *Campylobacter* spp. (mean range λ 33.1–45.3), and STEC (mean range λ 3.1–4.1), and at a secondary level to the undertesting (ρ) and underdiagnosis (μ) factors (results not shown). The overall IRR of illnesses was most sensitive to the underreporting factor for *Salmonella* spp. (mean range IRR 710.1–1,049.6). The number of illnesses per year caused by the consumption of milk or cheese was most sensitive to the rates of illnesses caused by *Salmonella* spp. and *Campylobacter* spp., as the main uncertainties apply to the incidence calculations for all pathogens (results not shown). Including the 9 outbreaks with a suspected-etiology status or the outbreak of unspecified pasteurization status (Figure 1) into the main analysis did not change the IRRs or the predicted number of illnesses or hospitalizations per year (results not shown).

Discussion

Unpasteurized dairy products are responsible for almost all of the 761 illnesses and 22 hospitalizations in the United States that occur annually because of dairy-related outbreaks caused by STEC, *Salmonella* spp., *L. monocytogenes*, and *Campylobacter* spp. More than 95% of these illnesses are salmonellosis and campylobacteriosis. Consumers of unpasteurized milk and cheese are a small proportion of the US population (3.2% and 1.6%, respectively), but compared with consumers of pasteurized dairy products, they are 838.8 times more likely to experience an illness and 45.1 times more likely to be hospitalized. Illnesses caused by *L. monocytogenes*, however, were found to be more often associated with the consumption of pasteurized cheese, albeit only causing 1 additional outbreak-related illness per year on average.

An easing of regulations has allowed greater access to unpasteurized milk in recent years (*8–10*), and this study shows that illnesses and hospitalizations will rise as consumption of unpasteurized dairy products increases. If such consumption were to double, the mean number of outbreak-related illnesses that occur every year would increase by 96%. Most unpasteurized dairy–related outbreaks are caused by pathogen contamination at the dairy farm (versus postpasteurization contamination for pasteurized products) (*3*); thus, one could assume that decreasing pathogen prevalence in bulk milk tanks on raw milk farms would help reduce illnesses. STEC has been found in 2.5% (95% CrI 0.1%–9.1%), *Salmonella* spp. in 4.6% (3.7%–5.6%), *L. monocytogenes* in 2.5% (0.1%–9.0%), and *Campylobacter* spp. in 4.7% (2.8%–7.0%) of bulk milk tanks on US raw milk farms (*25–29*). Given these low prevalences, strategies for further reduction are limited and involve multiple aspects of unpasteurized milk production (*30*). Boiling of milk before consumption seems to be a more realistic mitigation strategy, but this practice is unlikely to be implemented by unpasteurized dairy product advocates because it would affect the perceived benefits.

This study focused on the outbreak-related illnesses, which is only a fraction of all dairy-related illnesses in the United States. Two studies have documented the fraction of outbreak-related cases among FoodNet laboratory-confirmed cases (*15*,*31*); the fraction ranges from 0.5% for *Campylobacter* spp. to 19.0% for STEC according to Ebel et al. (*31*). These data suggest that the number of sporadic illnesses caused by contaminated dairy products in the United States might be much larger than that for outbreak-related illnesses. However, because of the lack of information on the characteristics of sporadic illnesses (such as food source attribution), we restricted the scope of this analysis to outbreak-related disease burden.

Our analysis relied on outbreak data from NORS (*11*), which is a passive reporting system affected by underreporting. We used dairy-related outbreak cases from FoodNet (*14–16*) as a comparison to estimate underreporting; therefore, any potential bias of this comparison was carried over to our estimation of outbreak-related illnesses. By extrapolating incidence rates of cases from the FoodNet catchment areas to the overall United States, we assumed that the FoodNet surveillance population and reporting practices were representative of the entire United States. However, the FoodNet catchment population represents only 15% of the US population from 10 nonrandom sites. Also, a recent study (*31*) suggested state-to-state variations in reporting practices; these variations might be even greater between FoodNet and non-FoodNet states. This difference might influence state-specific incidence rates or underreporting

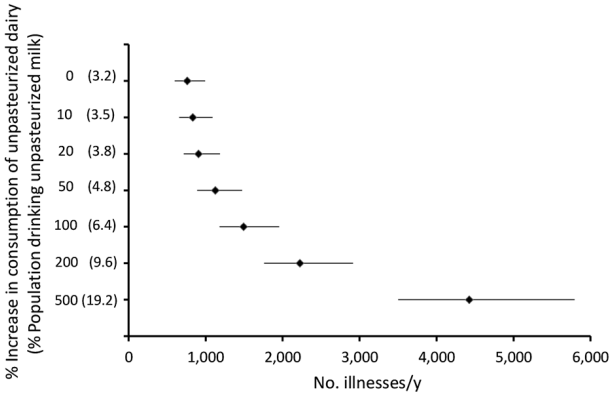

Figure 4. Number of dairy-related outbreak illnesses predicted per year in the United States if unpasteurized cow's milk and cheese consumption increases 0%, 10%, 20%, 50%, 100%, 200%, and 500%. Numbers in parentheses indicate percentage of total population consuming unpasteurized cow's milk. The illnesses graphed are those from outbreaks associated with cow's milk or cheese contaminated with Shiga toxin–producing *Escherichia coli*, *Salmonella* spp., *Listeria monocytogenes*, and *Campylobacter* spp. Markers indicate means; bars indicate 95% prediction intervals. The consumption estimates were based on the year 2015, and a 0% increase corresponds to the current proportion of the US population consuming unpasteurized dairy products.

ratios, as well as other characteristics of the reported cases. For example, if a state reported the incriminated food source as the food item (e.g., homemade yogurt), it would not have been selected for inclusion in this analysis, but if they reported the ingredient used for preparation (e.g., in the case of homemade yogurt, fluid milk), it would have been included in our analysis. However, the size and direction of such biases and uncertainties associated with these complex surveillance systems (NORS and FoodNet) are difficult to quantify because of the paucity of data.

The rates of illnesses were most sensitive to the estimated underreporting factors, which were assumed to be associated with the severity of symptoms (*23*,*24*) and other factors, such as state health department resources, and thus independent of the pasteurization status. Also, because this analysis only considered outbreaks involving milk and cheese (and no other dairy products), we are probably underestimating the incidence of illnesses and hospitalizations. However, milk and cheese are the most commonly consumed dairy sources and cause the most outbreaks (milk and cheese caused 99% of dairy-related outbreaks reported to NORS during the study period), so the underestimation is likely limited. Nonetheless, the overall comparison of risk between consumers of pasteurized and unpasteurized products should remain valid.

Estimates of the proportion of the population consuming dairy products were derived from the FoodNet population survey (*12*). We assumed that respondents who reported consumption of unpasteurized milk or cheese were not consuming pasteurized dairy. However, if unpasteurized milk or cheese only represented a fraction of their dairy consumption, the number of servings of unpasteurized dairy products could have been overestimated, and thus the risk for consumers of unpasteurized dairy products might have been underestimated. Also, the FoodNet population survey is based on a relatively small convenience sample and might therefore not be accurate. For example, the self-reported estimates of consumption of unpasteurized milk and cheese (3.2% and 1.6%, respectively) (*12*) might be underestimates or overestimates, potentially caused by consumers confusing the terms raw, organic, and natural (or other reasons). In addition, consumption might have changed since the 2007 FoodNet population survey (*12*), which might have resulted in an under- or overestimation of the risk from unpasteurized milk products. However, because the proportion of dairy consumers using unpasteurized products remains small, and the IRRs are very large, this overestimation is likely limited, and the trend for additional illnesses as unpasteurized dairy consumption grows remains valid. Similarly, estimates of the consumption of pasteurized cheese are underestimates: data available only provide estimates of the highest exposure to a single type of cheese, rather than to any type of cheese (*12*), potentially resulting in a risk overestimation for consumers of pasteurized dairy products. This is a limitation, notably for outbreaks linked to queso fresco and other Mexican-style soft cheeses. Despite these limitations, to the authors' knowledge, this study is based on the best available data and builds upon other well accepted risk attribution methods (*15*,*16*,*32*).

In conclusion, outbreaks linked to the consumption of cow's milk and cheese were estimated to cause on average 761 illnesses and 22 hospitalizations per year in the United States. Unpasteurized products are consumed by a small percentage of the US dairy consumers but cause 95% of illnesses; the risk for illness was found to be >800 times higher for consumers of unpasteurized milk or cheese than for consumers of pasteurized dairy products. Therefore, outbreak-related illnesses will increase steadily as unpasteurized dairy consumption grows, likely driven largely by salmonellosis and campylobacteriosis.

Acknowledgments

The authors thank collaborators E. Hovingh, D.R. Wolfgang, and H. Lysczek for their valuable input on milk production and consumption. We also thank the anonymous reviewers for their helpful suggestions.

This work was supported in part by a United States Department of Agriculture Special Research Grant (no. 2010-34163-21179) and the Pennsylvania Agricultural Experiment Station.

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a lesser prevalence of stage 1 and stage 2 CKD compared with using one urine test, resulting in more conservative estimates for CKD overall (11.0% versus 14.5%). Thus, CKD in this report might be overestimated (*4*). Third, the data are cross-sectional, not longitudinal, preventing assessment of whether risk factors caused or resulted from CKD. Finally, the number of persons with stages 3, 4, and 5 CKD is small, limiting the power of the analysis and precluding separate estimates for persons with stage 4 and stage 5 and comparison of estimates by demographic characteristic and risk factor.

New programs aimed at decreasing the number of CKD cases were established recently (*1,10*). The National Kidney Disease Education Program provides resources to the public, patients, and health-care professionals with the goal of reducing morbidity and mortality from kidney disease complications. World Kidney Day was instituted in 2006 to increase awareness of kidney disease and promote early detection. Continued surveillance of albuminuria and serum creatinine using NHANES can track the prevalence of CKD, monitor trends, and identify groups at high risk, enabling targeted programs. Finally, CDC is working with Johns Hopkins University and the University of Michigan to develop a comprehensive national surveillance system for CKD that will monitor early stages of the disease and its risk factors and the effects of CKD on the U.S. population.

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Escherichia coli O157:H7 Infection Associated with Drinking Raw Milk — Washington and Oregon, November–December 2005

During the week of December 5, 2005, public health officials in Clark County, Washington, were notified of four county residents with laboratory-confirmed *Escherichia coli* O157:H7 infection. All four residents reported having consumed raw (i.e., unpasteurized) milk obtained from a farm in neighboring Cowlitz County, Washington. The farm participated in a cow-share program, in which persons purchase interests in, or shares of, dairy cows in return for a portion of the milk produced.* The farm had five dairy cows and regularly provided raw milk to shareholders. Although the sale of raw milk and cow-share agreements are illegal in certain states, they are legal in Washington; however, Washington farms that provide raw milk to consumers must be licensed, meet state milk-production and processing standards, and pass health and sanitation inspections by the state department of agriculture (*1*). The Cowlitz County farm was not licensed. This report summarizes the investigation of *E. coli* O157:H7 cases associated with the farm and reinforces previous warnings about the health hazards of consuming raw milk.

The farm's shareholder list, obtained through a court order, was used to conduct a retrospective cohort study to identify risks for infection. During December 16–19, 2005, shareholders were interviewed by telephone using a standard questionnaire to collect information regarding their milk consumption since November 20, 2005. Forty-three of the 45 families who held shares in the dairy cows from the farm were interviewed; information regarding 157 persons was collected. A case was defined as either 1) laboratory-confirmed *E. coli* O157:H7 infection or 2) diarrhea with abdominal cramping or blood in a person with illness onset during November 20–December 13, 2005, who was a customer of the farm. Additional cases in the community were identified using faxed health alerts

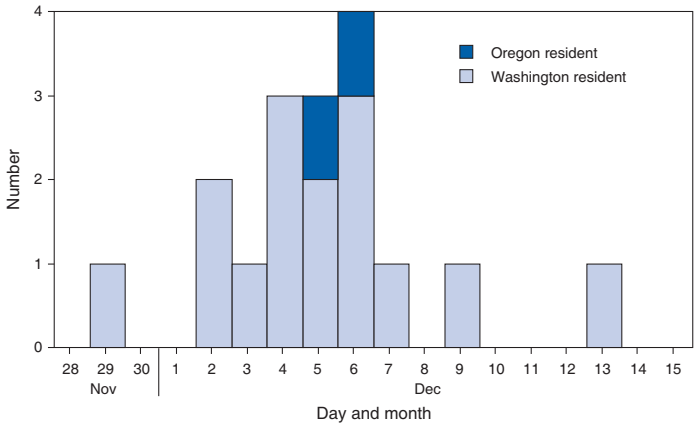
* In a cow-share agreement, a person who does not own, house, or care for the milking cow signs a contract or an agreement with the owner of the cow, pays an initial contract fee, and pays a monthly fee for the boarding and care of the cow. Depending on state law, the person might subsequently have partial ownership in the cow. In exchange for the fees, the person has the right to receive on a weekly basis a certain amount of unpasteurized milk, milk products, or both produced from the cow. The person can either pick up the unpasteurized milk at the farm or pay someone else to pick it up and deliver it or can pay a fee to the owner of the cow to have the products delivered.

and media releases to notify health-care providers, infection-control practitioners, neighboring public health agencies, and the public of the cluster of illnesses.

Eighteen cases were identified among the 43 families who were interviewed, and eight (44%) of these were laboratory confirmed. Dates of illness onset ranged from November 29 to December 13, 2005 (Figure). Patients were residents of two southwest Washington counties and one northwest Oregon county. The median age was 9 years (range: 1–47 years); nine (50%) were female. Among the 18 patients, 17 (94%) reported diarrhea, 13 (72%) bloody diarrhea, and 13 (72%) abdominal cramps. Five patients (28%), aged 1–13 years, were hospitalized; four of these had hemolytic uremic syndrome (HUS). Seventeen patients were farm shareholders or children of shareholders; one patient, a child aged 10 years, was a friend of a shareholder.

Of 140 persons who reported consuming raw milk from the farm, 18 (13%) became ill; among the 157 persons for whom information was obtained, no illness was reported among those who did not consume raw milk. Among 102 of 140 exposed persons who provided information about their raw milk consumption during November 20–December 13, the relative risk for illness increased with the average number of cups of milk consumed daily. The dose-response trend for average daily consumption was statistically significant (p=0.008 by expanded Mantel-Haenszel chi-square test), with attack rates of 3.6% for 0–0.9 cups of milk, 6.7% for 1–1.9 cups, 14.3% for 2–2.9 cups, and 37.5% for ≥3 cups. Visiting the farm and consumption of raw milk products from other sources were not associated with illness.

FIGURE. Number of persons reported with *Escherichia coli* O157:H7 infections who were customers of a Cowlitz County, Washington, farm, by date of illness onset and state of residence — Washington and Oregon, November–December 2005



* n = 17. Although 18 cases were identified during the investigation, for one patient who was asymptomatic, date of illness onset could not be established.

Pulsed-field gel electrophoresis (PFGE) was used to analyze *E. coli* O157:H7 isolates from stool samples from eight patients; seven (88.0%) isolates had PFGE patterns that were indistinguishable (pattern A), and one isolate from an Oregon patient had a PFGE pattern that differed from pattern A by one band.

E. coli O157:H7 also was isolated from raw milk samples obtained from the farm and one shareholder. In addition, *E. coli* O157:H7 was isolated from seven environmental samples collected from the floor of the farm milking parlor. All *E. coli* O157:H7 isolates from milk and environmental samples had PFGE pattern A. No *E. coli* O157:H7 was isolated from stool samples of any of the farm's five cows.

During inspections of the farm, officials from the Washington State Department of Agriculture (WSDA) noted mud and manure accumulation in the entrance to the milking parlor and on the rubber mats covering the dirt floors of the parlor. The bucket used for milk collection had direct contact with these surfaces. Inspectors also noted inadequate handwashing facilities and improper procedures for cleaning milking equipment and handling fresh milk.

On December 9, 2005, the farm contacted shareholders and advised them to discard any remaining raw milk. After a court order was obtained by the Cowlitz County Health Department and an embargo was placed by WSDA, the farm discontinued sales of raw milk on December 13, 2005. No additional reports of illness associated with the farm have been received.

Reported by: *M Bhat, MPH, J Denny, MD, Clark County Public Health, Vancouver; K MacDonald, PhD, J Hofmann, MD, Washington State Dept of Health. S Jain, MD, M Lynch, MD, Div of Foodborne, Bacterial, and Mycotic Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases (proposed), CDC.*

Editorial Note: *E. coli* O157:H7 causes an estimated 73,000 illnesses and 61 deaths annually in the United States (*2*). Approximately 8% of reported infections lead to HUS, particularly in children aged <5 years and older adults (*3*); 4% of patients with HUS die (*4*). Raw milk is an important vehicle of transmission of *E. coli* O157:H7 and other pathogens, including *Mycobacterium bovis*, *Listeria monocytogenes,* and *Campylobacter*, *Brucella*, and *Salmonella* species (*5,6*). During 1988–2005, a total of 33 outbreaks of *Campylobacter* species, *E. coli* O157:H7, and *Salmonella* species infections associated with raw milk consumption were reported to CDC (*7*).

Several findings from this investigation indicate that consumption of raw milk was the cause of the outbreak: 1) all ill persons drank raw milk; 2) the illness risk increased with the amount of milk consumed; 3) *E. coli* O157:H7 was isolated from raw milk samples and environmental samples collected

from the milking-parlor floor; and 4) PFGE patterns of isolates from patient, milk, and environmental samples were indistinguishable. Investigators found several factors that might have contributed to contamination of milk at the farm, although previous outbreaks have demonstrated that even raw milk collected using stringent hygiene methods might be contaminated with pathogens (*9*).

Although many consumers are aware that raw milk can contain pathogens, some believe that it has potential benefits (e.g., vitamins that are present naturally rather than added, enhanced fertility, and protection against tooth decay). However, the validity of any health or nutritional benefits from consuming raw milk has not been proven scientifically (*6*).

Raw milk is a well-documented cause of enteric infections and was first recognized as one approximately 100 years ago (*6*). Pathogens that infect humans, including *E. coli* O157:H7, are shed in the feces of cows and can contaminate milk during the milking process. Using standard hygiene practices during milking (e.g., washing hands, keeping equipment clean, and keeping the milking area separated from other areas) can reduce but not eliminate the risk for milk contamination. Pasteurization decreases the number of pathogenic organisms, prevents transmission of pathogens, and has been determined to improve the safety of raw milk more than other measures, including certification of raw milk (*8*). Because raw milk certification has failed to prevent many raw-milk–associated infections in the past, consumers should not assume that certified raw milk is free of pathogens (*9*). To prevent *E. coli* O157:H7 and other infections, consumers should not drink raw milk.

In Washington, cow-share programs and the regulated sale of raw milk are legal; however, the Cowlitz County farm was not licensed, and it did not follow applicable sanitation and public health safety regulations. As a result of this outbreak, WSDA revised regulations to help ensure that milk producers who sell pasteurized milk and those who sell raw milk through cow-share programs obtain the appropriate state licenses and comply with milk-processing sanitation and public health guidelines. As of February 2007, raw milk could be sold legally in 27 states, including Washington. During 1973–1992, a total of 40 (87%) of the 46 reported raw-milk–associated illness outbreaks occurred in states in which the intrastate sale of raw milk was legal (*5*). State milk regulations and methods for their enforcement should be reviewed and strengthened to minimize the hazards of raw milk.

Early in the 20th century, widespread adoption of the pasteurization process led to substantial reductions in milk-associated disease, a milestone in the history of food safety (*10*). In the 21st century, more effective consumer education regarding the hazards of drinking raw milk is needed to further reduce milk-associated diseases.

Acknowledgments

The findings in this report are based, in part, on contributions by M Fields, MD, H Gillette, MPH, Cowlitz County Health Dept; B Riehm, MN, Clark County Public Health; E Debess, DVM, Oregon Dept of Human Svcs; and C Coles, MS, Washington State Dept of Agriculture.

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Rates of Hospitalization Related to Traumatic Brain Injury — Nine States, 2003

Traumatic brain injury (TBI) is a major cause of morbidity and mortality in the United States. Each year, on average, TBIs are associated with an estimated 1.1 million emergency department visits, 235,000 hospitalizations, and 50,000 deaths in the United States (*1*). For 2002, the overall rate of TBI-related hospitalization reported by the 12 states in the CDC TBI surveillance system was 79.0 per 100,000 population (*2*); across these states, however, the rates varied substantially (from 50.6 in Nebraska to 96.9 in Arizona). To update results from the CDC TBI surveillance system, CDC analyzed data from 2003, the most recent year for which data were available. This report summarizes the results of that analysis, which indicated that an estimated 28,819 persons (87.9 per 100,000 population) were hospitalized with a TBI-related diagnosis in the nine states that reported data for 2003. For all age groups combined, rates were higher among males. Age-specific rates

Food Safety News
Breaking news for everyone's consumption

A Mom and a Dairyman Plead: Don't Feed Children Raw Milk

Kylee Young was a healthy two-year-old when she contracted an E. coli infection from drinking raw milk, an illness that caused a stroke and culminated in a kidney transplanted from her mom.

By Cookson Beecher | February 18, 2014

Two years ago, when Oregon parents Jill Brown and Jason Young met Brad and Tricia Salyers, the families had no idea that they would eventually be sharing in a tragedy that sickened four of the Salyers' children and left Brown and Young's youngest child, Kylee – 23 months old at the time – with such severe medical complications that she would need a kidney transplant from her mother.

All of that and more happened beginning in April 2012 when the children were among 19 people – 15 of them under the age of 19 — who fell ill with E. coli O157:H7, a potentially fatal foodborne pathogen. Soon after, Oregon health officials determined that the outbreak was caused by raw milk from Foundation Farm near Wilsonville in Western Oregon — the Salyers' family farm. Four of the sickened children were hospitalized with kidney failure.

Foundation Farm had been providing 48 families with raw milk. Raw milk is milk that hasn't been pasteurized to

kill harmful and sometimes deadly foodborne pathogens such as E. coli, Listeria, Salmonella and Campylobacter.

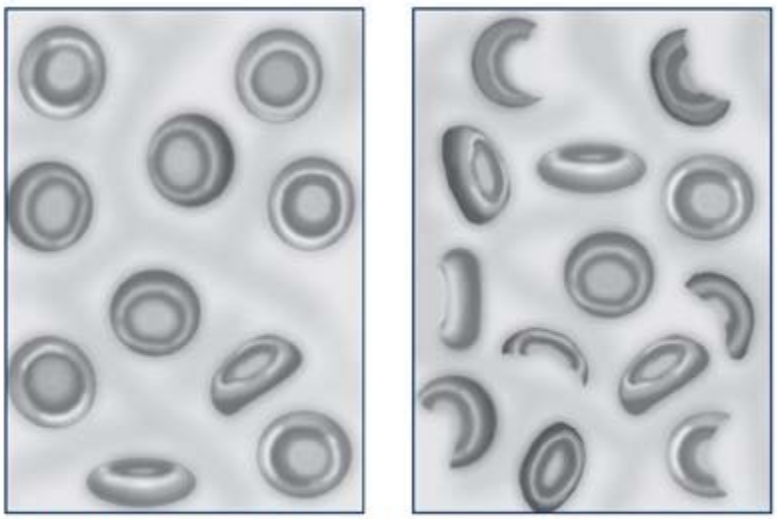
While many raw milk advocates say it has inherent nutritional advantages and even helps cure or ease the symptoms of ailments such as asthma and various allergies, most food-safety experts discount those claims as anecdotal, saying they're not based on science. They also warn of the serious risks to human health associated with drinking milk that hasn't been pasteurized.

The symptoms of E. coli O157:H7 infection typically include bloody diarrhea and other digestive-tract problems. In some people, this type of E. coli may also cause severe anemia or hemolytic uremic syndrome (HUS), a complication in which toxins destroy red blood cells, which are typically smooth and round. The misshapen or deformed blood cells can clog the tiny blood vessels in the kidneys, causing them to fail.

Statistics from the Centers for Disease Control and Prevention (CDC) underscore the potential dangers of raw milk. According to the agency, between 1998 and 2011, 148 outbreaks due to consumption of raw milk or raw milk products were reported. In those outbreaks, there were 2,384 illnesses, 284 hospitalizations and two deaths. Estimates from the agency put raw milk consumption at 3 percent of total milk consumption.

Currently, 29 states allow some form of on- or off-farm raw milk sales, but only a few allow sales in grocery stores. In Oregon, it is against the law to sell raw cow's milk, although there is an exemption for very small herds (no more than three cows on the premises, with no more than two of them being milked). Under that exemption, the milk must be sold on the farm and no advertising of the product is allowed. CDC has documented fewer illnesses and outbreaks from raw milk in states that prohibit sales.

Goals in common



Healthy red blood cells (left) are smooth and round, while blood cells damaged by E. coli toxins are misshapen and may clog the blood vessels in the kidney, causing HUS.

The irony of this story is that the two families shared a common goal to provide their children with nutritious food. Now they share another goal: to warn people that raw milk can be dangerous to drink, or even deadly. As parents, they want to let other parents know that they shouldn't feed raw milk to their children, no matter what some raw-milk farmers and advocacy organizations might say.

"There might be some benefits of raw milk, but there are huge risks," Jill Brown, Kylee's mother, told **Food Safety News**. "There needs to be more public awareness that this is a high-risk food. If I had known what I know now, I would never have fed it to my daughter."

Despite formerly selling raw milk, the Salyers agree.

"The people who bought our milk thought it was the healthiest choice for their kids," said Brad Salyers, co-owner of Foundation Farm. "But I see things differently now. By far, it's the most dangerous food you can feed them because of the chance it can be contaminated with E. coli or other harmful pathogens."

Knowing he fed raw milk to his children, Salyers' thoughts on the topic now veer into the emotional:

"It breaks my heart that anyone would give it to their children," he said. "What's even more troubling is that some of our friends who saw what our kids went through are still feeding raw milk to their children."

Salyers rankles at what he says is the proliferation of too much misinformation about raw milk's purported health benefits.

"It's duping people into thinking you can safely drink raw milk," he said.

The worst part of this, he added, is that children are especially vulnerable to contracting E. coli or other pathogens from raw milk, primarily because their immune systems are still developing.

According to a recently released statement from the American Academy of Pediatrics, the health claims related to drinking raw milk have not been verified by scientific evidence, and, therefore, do not outweigh the potential health risks that raw milk poses to pregnant women and children.

"Children depend on their parents," Salyers said. "They don't make the decision to drink or not to drink raw milk. They're at the mercy of their caretakers."

"We definitely want to get the word out about the dangers of raw milk," Tricia Salyers said.

Sold their cows

Once the Salyers saw what Brad Salyers refers to as the "devastation that HUS can cause in children," they immediately sold their cows.

"We didn't want to put kids at risk," Salyers said, pointing out that four of his family's five children came down with E. coli, with one of the four developing HUS.

"She fought for her life for 27 days," he said.

He objects to conspiracy theories that paint the government and food-safety scientists as "the enemy" when it comes to restrictive raw milk laws and the information they provide to customers (and farmers) about the potential dangers of raw milk.

"They're so cynical that they can't see straight," said Salyers. "They put their trust in some organizations with myopic agendas — places that glorify raw milk as 'miracle' food. That's nonsense. It's based on a lot of misinformation."

So why do people ignore warnings about the potential dangers of raw milk? According to a 2011 study that looked at what motivated people in Michigan to drink raw milk, cynicism about government surfaced. The study's authors told **Food Safety News** that they were surprised to find that only a small percentage of those surveyed trusted public health officials regarding which foods are safe to eat or drink.

The survey respondents also took issue with some of the survey's other statements, once again revealing sharp differences of opinion with official government views on the potential health hazards of drinking raw milk. For example, when asked if they agreed or disagreed with the statement that, "Drinking raw milk increases your risk of getting a foodborne disease," an average of 44 (or 78.6 percent) disagreed. Only six respondents agreed with

the statement, and another five (or 8.9 percent) respondents said they weren't sure.

As for those who think that "knowing your farmer" is safeguard enough, even raw-milk dairies with high sanitation standards and licensed and inspected by states that allow raw milk sales – California and Washington state are two of these – have been subject to recalls due to the presence of pathogens such as E. coli and Campylobacter in their milk. Those recalls are typically triggered by foodborne-illness outbreaks that have sickened people.

According to CDC, while adherence to good hygienic practices during milking can reduce contamination, it cannot eliminate it.

"The dairy farm environment is a reservoir for illness-causing germs," CDC says. "No matter what precautions farmers take, and even if their raw milk tests come back negative, they cannot guarantee that their milk, or the products made from their milk, are free of harmful germs."

Logistics come into the picture here. There's no way to test every part of every batch of milk 365 days a year. While testing will provide important clues about whether things are being done right, it doesn't ensure that all of the milk a farm produces will be safe.

Or, as Dr. Tim Jones, epidemiologist with the Tennessee Department of Health, puts it: "Those who consume raw milk are playing Russian roulette with their health; the glass they drink today may not have deadly microorganisms, but the one they drink tomorrow may cause serious health problems or even death."

Germs such as E.coli, Campylobacter and Salmonella can contaminate milk during the process of milking dairy animals, including cows, sheep and goats. Animals that carry these germs usually appear healthy.

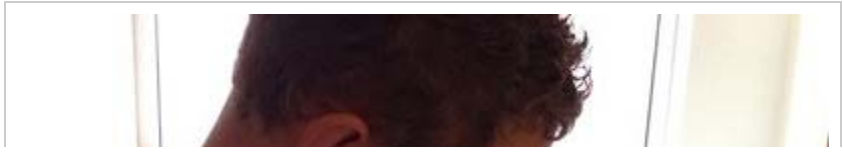
Brad Salyers said that a health official who visited his farm after the outbreak told him that it's not just about making sure the cow's udder is clean. Contamination could occur from something as simple as one drop of rain containing some E. coli O157:H7 bacteria picked up from the cow's hide trickling down the side of the cow. Not only are these germs extremely tiny, it takes only one or two of them to replicate inside the milk and make someone sick. And, unlike earlier strains of E. coli, this toxin-releasing strain, which wasn't identified as a cause of human illness until the 1980s, is far more virulent.

This chronology can confuse people. They don't understand how their grandparents who drank raw milk all of their lives never got sick from E. coli. But scientists believe E. coli didn't pick up the genes that cause human illness until late last century. Now that this disease-causing strain of the bacterium is commonly found in most cowherds, people can, and do, become ill from drinking contaminated milk.

Even more confusing for some is that cows that have this strain of E. coli in their systems generally don't show any signs of being infected with it. Then, too, it can come and go on a farm. It can be present in some of the cows or in water tanks or the soil for awhile and then disappear from one or all of these possible "harboring" places, only to return again.

What happened?

Like most mothers, Jill Brown wanted to feed her family the best food possible. For her, that meant growing a garden, buying as much food as she could from local farmers,



and eventually buying raw milk for her toddler, who was an avid milk drinker.

Her quest to find raw milk was in large part triggered by her desire to steer clear of "industrial agriculture" and buy from a local farm instead. She saw it as a good fit with the philosophy of the "local food movement," which her family and many of their friends embrace.

"I wanted to know where the milk I was buying was coming from," she said. "My research led me to believe that raw milk from a local farm would be healthier than the milk I bought at the store."

After finding Foundation Farm through an Internet search, Brown became a herd-share member. Under a herd-share arrangement, people can buy a share of the herd, or even an individual cow, with the understanding that they are not customers of the dairy but rather owners of the herd and the milk produced by the herd. Some refer to this arrangement as a "legal loophole." In Oregon, herd shares have not been challenged in court, according to information from the state's agriculture department.

Foundation Farm was providing raw milk to 48 households under a herd-share arrangement. On the legal front, the families couldn't sue the Salyers after the outbreak because the Salyers didn't have insurance, and they were leasing the land where they were farming. In short, they had no assets that could be taken and sold to raise money for the aggrieved families.

While it was a commitment to go to the farm once a week to get the milk, Brown believed it was well worth it, despite the inconvenience and additional cost.

"It felt good to know that we were getting 'real, actual milk,'" she said. "[The Salyers] seemed to be doing everything right."

In talking with them, she had learned that, before setting up a herd share, they had visited other raw-milk dairies and had improved on what they saw.

Even though, for the most part, no one in her family except Kylee drank milk, the toddler loved it and thrived on the raw milk from Foundation Farm. But it was short-lived. Brown said that Kylee probably only drank it for three months before things went wrong.

"It was pretty sudden," Brown said. "We went to the farm to get some milk on Friday, the last day of spring break."

The following Wednesday, Kylee was sick, an "exploding diaper" the first sign of problems to come. On Friday, her dad stayed home with her and took her to the pediatrician, who said she had a stomach bug.

By Saturday, she couldn't keep food down and was becoming dehydrated. They took her to the emergency room, where she was put on an IV, with oral rehydration administered every 10 minutes.

They chose to take her home that night, and, on Sunday, she was starting to feel better. But, on Monday night, they were called back to the hospital.

When Brown stood Kylee up, she was dismayed to see her walking backward, apparently disoriented. She rushed Kylee to the emergency room and was told that her kidneys had shut down. Kylee was admitted to the pediatric intensive care unit, and, the next day, she received the necessary set-up lines to start dialysis.

"That's when our whole life changed," Brown said. "From there, every step of the way, things got worse and worse. Each day brought more bad news."

Kylee developed edema, was having a hard time breathing, and her eyes were crossing.

"She had had a stroke," said Brown.

Once a happy, energetic toddler, Kylee now couldn't walk or say words, although for the first couple of days she did say "mama," "papa," and "no."

Even though test results from a stool sample submitted on Monday were not back yet, Kylee was diagnosed with HUS.

Brown went to work researching the medical problem.

"When you're Googling 'bloody stool or vomiting,' one of the top things that comes up is raw milk," she said.

Several days after Kylee had been admitted to the hospital, another child with E. coli was admitted. By April 21, a total of 19 people were confirmed ill with E. coli traced to raw milk from Foundation Farm. Of those, 15 were under the age of 19. Four of the Salyers' five children were among those ill, with one of them among four children suffering from HUS.

Kylee was on a ventilator, but she wasn't getting better. Before long, the other children who had been hospitalized were talking about going home. But that wasn't in store for Kylee.

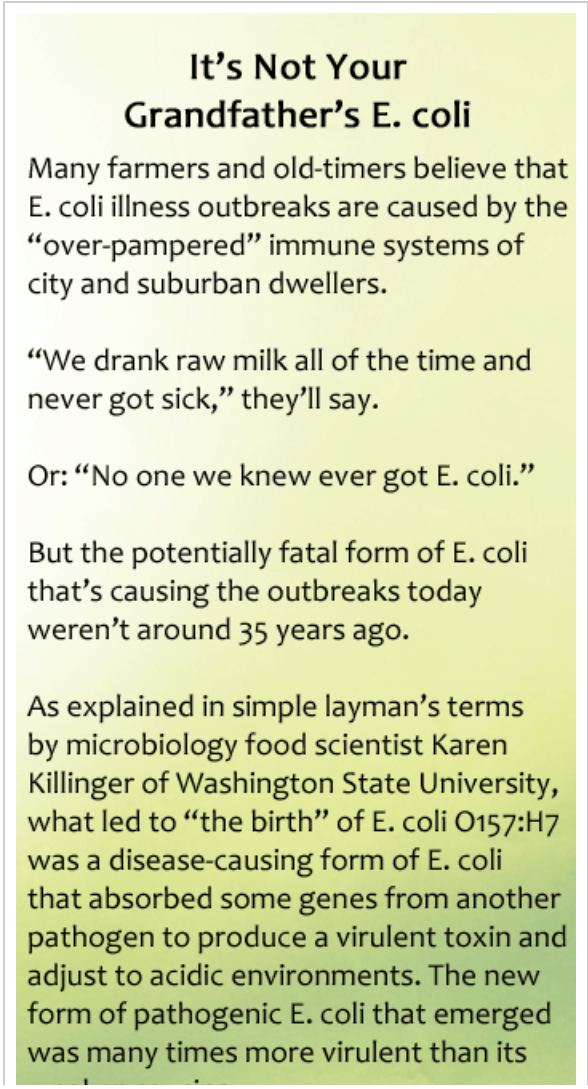
The lab results came back and showed that her bowels were necrotic and that she needed surgery. Her heart stopped while she was in surgery and she had to be brought back to life.

"That was probably the hardest part," said Brown.

But then suddenly, Kylee started doing much better. They took her off of dialysis in early June. She had been on dialysis for eight weeks.

After five weeks of rehab in the hospital, Kylee could go home, and Brown started going to work two days a week. November and December were good months. Kylee was getting stronger and sitting up on her own.

But then in January, lab tests came back that didn't look good. By February, the toddler had to go to the dialysis center in the



It's Not Your Grandfather's E. coli

Many farmers and old-timers believe that E. coli illness outbreaks are caused by the "over-pampered" immune systems of city and suburban dwellers.

"We drank raw milk all of the time and never got sick," they'll say.

Or: "No one we knew ever got E. coli."

But the potentially fatal form of E. coli that's causing the outbreaks today weren't around 35 years ago.

As explained in simple layman's terms by microbiology food scientist Karen Killinger of Washington State University, what led to "the birth" of E. coli O157:H7 was a disease-causing form of E. coli that absorbed some genes from another pathogen to produce a virulent toxin and adjust to acidic environments. The new form of pathogenic E. coli that emerged was many times more virulent than its

weaker cousins.

hospital three times a week for three hours a day. She was also admitted frequently throughout 2013 for multiple staph infections and other issues related to her kidneys.

Brown quit her job in May to stay home, finding it too hard to manage a household with two other children and be at the hospital for Kylee. In the meantime, Kylee struggled. Being on dialysis, she had only 15 percent kidney function and didn't have the energy for weekly physical therapy sessions.

The doctors decided that the toddler needed a kidney transplant. Brown and Young started the donor "work up" for a kidney transplant in June and July and were scheduled for the transplant on Sept. 9.

"She'll get 120 percent of her kidney function from this," Brown told **Food Safety News** several days before the surgery. "The hope is that she'll feel better and have the energy for therapy."

Kylee's father Jason Young told videographer Terry Tainter that when they realized that their toddler was going to need a kidney transplant, the word "now" took on new meaning.

"One of the biggest things that went through my mind at that point is that this is now," he said. "This is now a lifelong thing. There is no full recovery from this anymore. And there never will be. It's always going to have to be someone else's organ that keeps her alive."

People who have kidney transplants often have to have another in future years, something that both Brown and Young know.

All in all, the little girl has spent close to 200 days in the hospital since she was admitted in April 2012, with her mother by her side much of the time. The good news is that, as of mid-February 2014, the last time she had to be hospitalized was September 2013.

Before the transplant surgery, Tricia Salyers started a fundraiser. After the operation, she let Facebook readers know that Kylee was making "HUGE" strides forward in her recovery.

"What a miracle this transplant has been," she said, adding that all sorts of bills have been coming in from, among them, the insurance company, the hospital, and pharmacies. Salyers said that the $7,500 fundraising goal would get Brown and Young through the end of the year and pay off current medical debts.

On Jan. 26, Brown was happy to report that the goal was met, although medical bills will burden the family for years to come.

Through all of this, Brown and Tricia Salyers became friends.

"I'm so glad I chose to move on and forgive," Brown said. "It's so easy to blame the farmer. But they were just as much blindsided as we were. They fed all of their kids the milk. I do believe they thought they were doing things right."

Kylee will continue to need physical therapy and speech therapy for a long time, only part of which insurance will cover. But the family recently received some good news. The Wheel to Walk Foundation has approved Kylee for a grant to help cover the cost of her intensive therapy that insurance doesn't cover. Even so, there are still a lot of uncovered expenses, including medical equipment and medications such as immunosuppressants to prevent her system from rejecting her mother's kidney.

Although Kylee is for the most part stable medically, she still can't speak words, can't walk, uses a special table to stand, and eats through a special tube. Because she understands what's going on around her, she experiences a lot of frustration in not being able to express her thoughts and feelings in words.

With limited insurance and no chance of getting a settlement to help pay the bills, and with their two-story house no longer suitable for a child with Kylee's disabilities, Brown and Young have had to sell their home. The sale is expected to close in mid-March.

In another unforeseen bond tying the two families together, Tricia Salyers, who went into real estate after she and her husband sold the cows, handled the sale of Brown and Young's home.

The farmer's perspective

"We were foodie-type people," said Brad Salyers. "We felt the food system in this country was messed up. We were trying to get back to basics."

That led them to information that extolled the benefits of raw milk from grass-fed cows.

"We believed all the hype about its benefits," he said.

They started buying raw milk from a farm but eventually decided to buy their own cow, thinking they could improve on what they saw at the farm. Once they had their own cow, they quickly realized they were going to have a surplus of milk. Thinking that they could find people who would want it, the Salyers visited other farmers known for their dedication to cleanliness and learned from them.

"I felt I had enough information to put the necessary safeguards into place," Brad Salyers said. "I'm not one to take shortcuts or wing it."

Once they started making their raw milk available, demand grew and soon there was a waiting list.

"It snowballed," he said. "We got more cows. Before long, we had five and were milking three."

Now when he hears people talk about the safety of raw milk from grass-fed cows, he warns them not to jump to conclusions.

"Cows aren't like horses," he said. "Cows like to lie down a lot. Their udders and hides can be in manure. It's dangerous because that's where E. coli can be."

But he said he also thinks there can also be problems with an imbalance of nutrients and bacteria in their digestive system. He thinks that's what happened when he switched the cows from dry forage to pasture too quickly.

He called the vet because one of his cows wasn't acting quite right. When the vet came, he found an improper pH balance in the urine. He told Salyers he was pretty sure he'd find some bacteria.

David Smith, a veterinarian and professor at Mississippi State University College of Veterinary Science, told **Food Safety News** that it's possible that the switch in diet resulted in the cows' shedding E. coli O157:H7 in their manure, but he also said the diet change "did not make it appear out of nowhere."

"It was on the farm," he said, pointing out that this strain of E. coli is common to all beef and dairy herds and that it should be assumed that it is present in some cattle on all cattle farms.

It was while the vet was there that Tricia Salyers came out to the barn and told her husband that the doctors at the hospital had confirmed that Kylee was ill with E. coli O157:H7.

When Salyers walked back into the house, the phone was ringing. It was a state official asking him if they had informed their customers about the problem. Tricia, meanwhile, had already e-mailed their customers the information.

"It was the scariest time of our lives," he said.

Why did they do it?

"I blamed myself for the longest time," Brown said about the devastating effects raw milk had on her daughter. "But I know that I'm an amazing mom who was trying to do the best for my family."

When doing research on raw milk, she discovered that "it's a two-edged topic with no middle ground between. On one side are government and dairy industry representatives pointing to the inherent risks of raw milk. On the other hand are the raw-milk advocates who fervently believe that locally grown and produced foods, including raw milk, are healthier than foods produced on what they refer to as 'industrialized farms.'

"I do follow their philosophies about local foods, and since raw milk was part of what they believed in, I went along with it," Brown said.

The fact that she did still baffles her, especially since she considers herself to be levelheaded. She was on debate teams in high school and college and knows how important it is to gather objective information and not to be swayed by emotion.

"Debate is all about being well-researched," she said. "You learn to look at every side. That's why I get so frustrated about what I did. I know now that different choices could have been made."

It discourages her that despite continuing news about E. coli outbreaks caused by raw milk, so much of the information spread about raw milk praises its health benefits.

The Weston A. Price Foundation is a good example of one such information source. Its website shows a happy, healthy-looking family with this headline above the photo: "They're happy because they eat butter." Under the picture is some more information: "They also eat plenty of raw milk, cheese, eggs, liver, meat, cod liver oil, seafood, and other nutrient-dense foods that have nourished generations of healthy people worldwide."

Brown doesn't think that raw-milk dairy farmers are dishonest or "sleazy," and she thinks that they're trying to offer the community what they believe is a "valuable resource."

“But many of them are not educated enough,” she said. “Our farmer didn’t know the risk. I do believe that they thought they were doing it right.”

Like Brown, Brad Salyers also has misgivings about his experience with raw milk. Describing himself as a Christian, he said he trusted in the Lord to help him deal with what he describes as “the guilt and shame that was mentally devastating.”

“I had to believe that in my heart I was making the best decision for my children with the information I had,” he said.

Salyers said he would like to see farmers be more educated about raw milk. As a contractor, he had to take classes to get his license, and he believes something similar should be put in place for raw-milk producers.

He also believes that raw-milk producers should be required to carry liability insurance.

“It’s just part of running a business,” he said. “I don’t see why a farmer producing such a potentially dangerous product shouldn’t have to have insurance.”

In retrospect, he said he wouldn’t hesitate to support legislation that would safeguard children from raw milk, even though he knows it goes against the principle of “freedom of choice.”

“It’s just too dangerous for the children,” he said.

What about locally produced, ‘gently pasteurized’ milk?

Buying milk from a local farm conjures up scenes of contented cows grazing on lush green pastures, complete with a farm family dedicated to the health of the cows and the quality of the milk.

For the most part, but not always, this is “raw-milk country”— small-scale dairy farmers who can sell their milk at higher prices than milk sold in the stores. Those higher prices are based in part on the higher expenses that come with producing milk on such a small scale but also on the willingness of raw-milk customers to spend more money for what they consider to be a premium product.

Raw-milk farmers and raw-milk customers alike extoll this business model, saying it helps keep family-scale dairy farmers in business instead of being pushed off the map by ever-expanding dairy operations that depend on what’s referred to as “efficiency of scale” to stay in business.

“It used to be that the only alternative to conventional mass-produced milk was raw milk,” said Steve Judge, founder of Bob-White Systems and developer of the LiLi (Low Input-Low Impact) Pasteurizer. “But our goal is to give people the choice of either raw milk or farm-fresh ‘gently’ pasteurized milk.”

The LiLi pasteurizes the milk without homogenizing, separating or standardizing its nutritional value and farm-fresh flavor, according to the company’s website.

Judge said that in designing the LiLi Pasteurizer, he wanted a small machine that would allow small-scale farms to sell farm-fresh pasteurized milk direct to consumers.

With the LiLi Pasteurizer, the milk gets heated to 163 degrees F and held at that temperature for 15 seconds, after which it is immediately cooled to less than 60 degrees F. After the milk is pasteurized, it’s sent to a cooling tank

where it can be cooled to 38 degrees F in less than an hour. This allows for a pasteurization speed of two gallons a minute.

“I believe that the minimal damage done to milk by properly done, high-temperature, short-time pasteurization is a worthwhile compromise if it also expands the availability of locally produced farm fresh milk,” he said.

Although the LiLi can work for small dairies of four to 10 cows, Judge said it could handle milk from up to 100 cows. Bottom line, he said, “Anywhere you grow grass, you can do this.” Better yet, it meets all state and federal regulations.

While raw-milk proponents say that pasteurization kills many of the healthful components such as vitamins and enzymes, Judge said that he sent samples of raw milk and milk pasteurized with the LiLi to a food-safety lab for a comparison of 50 different nutrients. While there was a drop in lactic acid colonies and a slight drop in Vitamin B-12 in the pasteurized sample, other vitamins did just fine, including vitamins C and D.

“There was minimal damage,” he said.

That pretty much lines up with a recent rundown of a nutrient comparison between raw and pasteurized milk provided by the Purdue University Extension.

As for flavor, Judge said that one taste of milk pasteurized with the LiLi would convince anyone that it’s indistinguishable from raw milk. “It has a bright, clean, fresh flavor,” he said.

Other farms offer vat, or batch, pasteurized milk, which they also describe as “gently pasteurized.” In this method, the milk is heated to 145 degrees F and held at that temperature for 30 minutes and then cooled as quickly as possible. Proponents of this method also say that it provides a good option to raw milk.

In contrast, said Judge, most conventional milk bottlers use a method that heats milk to 170 degrees F and holds it at that temperature for no less than 15 seconds. Proponents of this method say that it destroys most bacterial pathogens, while largely protecting milk proteins from degradation.

“Ultra-pasteurized” refers to milk heated to at least 280°F for not less than two seconds.

Unfortunately, said Judge, as of yet, there is no association of dairy farms that produce “gently pasteurized milk,” although an Internet search will yield some farms in various locations that do.

Of course, for those whose main reason for buying raw milk is that they want to support local farms, there’s always the option of pasteurizing the milk at home.

What about those allergies?

Many parents who buy raw milk for their children do so because their children have allergic reactions to pasteurized milk. Many say that their children do better on raw milk. Some go so far as to say that raw milk can cure allergies, eczema, asthma and other ailments.

Like other raw-milk farmers, Brad Salyers said that many of his customers had children with allergies.

It's not surprising that milk comes into the picture. According to the U.S. Food and Drug Administration (FDA), milk is at the top of the list of the eight major food allergens that account for 90 percent of food-allergic reactions.

And, even though most food allergies cause relatively mild and minor symptoms, some food allergies can cause severe reactions and may even be life-threatening, says FDA.

Also, according to the agency's site, there is no cure for food allergies. And the agency recommends strict avoidance of food allergens and early recognition and management of allergic reactions to food.

Following this line of thinking, Mike Tringale, an official with the Asthma and Allergic Foundation of America, told **Food Safety News** that raw milk isn't a cure for an allergy to pasteurized milk.

"The milk protein in pasteurized milk is in raw milk, too, so anyone with a milk allergy would still be affected," he said. "Allergies in general are caused by a chronic disease of the immune system, and it's genetic – you inherit a hypersensitive immune system."

Interestingly enough, though, people don't inherit specific allergies. For example, a person's mother can be allergic to cats and the dad to dogs, yet the child can develop an allergy to peanuts, or other triggers.

Tringale describes allergies as "what happens when a person's body misinterprets the foods or pollens in his or her environment."

Speaking specifically about milk, he said that pasteurized or raw milk doesn't eliminate the allergenic protein in milk, which is what makes milk white.

He discounts assumptions such as the idea that getting back to simple agrarian life makes the body more defensive against allergies, calling them "old wives' tales."

He does say, however, that some research is turning up evidence that babies raised on farms or with cats and dogs may have a lower prevalence of allergies later in life.

"But the jury is still out on that," he said.

But when it comes to raw milk, he pointed out that it is not going to change your immune system.

"The thought that this can cure allergies is actually a dangerous thought," he said.

As for doing "their homework" on milk allergies, Tringale said that parents need to work with their doctor to make sure they're on the right path. If they don't do that, they haven't done their homework.

And, when all is said and done, it doesn't come down to deciding in favor of either pasteurized or raw milk.

"The real question is, 'How do I supply nutrition for my children if I can't feed them milk?'" he said.

Fortunately, said Tringale, this doesn't have to be hard – at least if a child has only one or two allergies. There are ways to make sure that children have nutritious diets. He recommends an interactive website, kidswithfoodallergies.org, which allows parents of kids with allergies to talk with one another for support, to find recipes and share ideas.

However, parents with children who have more than one or two allergies need to work with a nutritionist to make sure their children are getting all of the necessary nutrients.

"Getting as close to good health as possible is what people should be aiming for," he said. "It's important that in trying to do that, they're not making poor choices."

Updates on Kylee's progress can be found on her Facebook page.

Food Safety News *will feature a video interview with Kylee's parents on Wednesday, February 19.*

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