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**Unpasteurized Milk and Soft Cheese Outbreaks:
An Overview of Consumer Safety**

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ABSTRACT

Unpasteurized (also called raw or farm-fresh) milk is currently banned in more than half of all U.S. states. There is substantial controversy over whether unpasteurized milk is safe for human consumption. Although less than 1% of the total U.S. population is known to consume these products, proponents of raw milk claim that unpasteurized milk and soft cheeses are more nutritive than pasteurized milk and soft cheeses. However, there have been a multitude of disease outbreaks linked to raw milk and soft cheese consumption, which involved pathogens including *Escherichia coli*, *Salmonella*, and *Listeria monocytogenes*. While some believe an outright ban would help abate the incidence of unpasteurized milk and cheese outbreaks, many believe imposing a ban on such products is an infringement on one's freedom of choice. If a ban were imposed, it would pose a variety of problems for key stakeholders, such as state agriculture departments, dairy farmers, and raw milk and cheese consumers. Given these considerations, providing education to dairy producers and consumers and implementing the use of warning labels on unpasteurized milk and soft cheeses are the most effective ways for the state agriculture departments to decrease the consumption of these products and thus prevent illness.

CONTEXT

In the U.S., raw milk is typically consumed and/or distributed directly on the premises of farms, through milk clubs, cow-sharing (or cow-leasing) programs, boarding agreements or as pet food. Currently, less than half of all U.S. states have legalized the sale of raw milk for human consumption (Figure 1) (13). Four states (Arkansas, Kentucky, Mississippi, Rhode Island) prohibit consumption of raw cows' milk, but permit consumption of raw goats' milk. There is substantial evidence that raw milk serves a source of pathogens that cause disease in humans.

UNPASTEURIZED (RAW, FARM-FRESH) MILK AND SOFT CHEESES: AN OVERVIEW

As dairy farms became more industrialized in the late nineteenth century, milkborne diseases became more common as a result of poor sanitation measures, improper handling procedures, and diseased dairy cows. In 1886, Franz Ritter von Soxhlet suggested pasteurizing milk, which involved heating it to 161°F for fifteen seconds to destroy viruses and harmful organisms such as bacteria, protozoa, molds, and yeasts (86). In the early twentieth century, the Illinois and Wisconsin Supreme Courts were among the first courts to see legal cases that highlighted the potential harmful effects of unpasteurized milk. Unpasteurized milk is milk from cows, sheep, and goats that has not been pasteurized or homogenized (pumped under pressure to render it uniform in consistency by emulsifying the fat content) (57, 58). Milk produced in cities where cows were kept in tight, unhygienic quarters led to contamination of milk and milk products. As a result of poor hygiene and lack of pasteurization, numerous city dwellers

and children fell ill and some died after consuming contaminated, unpasteurized milk (104).

During this time, unpasteurized milk increasingly grew in public health significance. By 1938, approximately 25% of all disease outbreaks from contaminated food and water were attributed to milk (71). Unpasteurized cow's milk was noted to contain many pathogens capable of causing disease in humans, including bovine tuberculosis, diphtheria, severe streptococcal infections, and typhoid fever. However, many feared that the nutritional value of milk would be diminished by this treatment, so pasteurization was not widely adopted (77).

In order to prevent infections from drinking unpasteurized milk, others improved the sanitary conditions and health of the animals going through the milk production process. Regardless, there were continued outbreaks of illness and, as a result, the Public Health Service Standard Milk Ordinance of 1927 was enacted. This new regulation sought to grade milk based on a range of sanitation measures and to pasteurize only Grade A milk (4). Since the promotion of pasteurization techniques in milk during the late 1940's, the incidence rate of milk-borne outbreaks has diminished to less than 1% (91).

The Food and Drug Administration (FDA) states that soft raw-milk cheeses are capable of causing serious infectious diseases including listeriosis, brucellosis, salmonellosis and tuberculosis. As a result, a law was enacted in 1944 mandating that all raw-milk cheeses (including all imported cheeses, since 1951) must be aged at least 60 days. The aging process allows for a combination of factors, which include pH levels, salt content, and water activity to render cheeses microbiologically safe for consumption (43).

Presently, there is no law requiring all milk to be pasteurized, though numerous educational, regulatory, and public health organizations have issued statements regarding the hazards of unpasteurized milk consumption (Table 1) (12). In *Public Citizen v. Heckler*, the U.S. District Court stated that the FDA had garnered enough evidence to show that raw milk is not safe for human consumption (98). Despite this decision, the FDA did not impose a federal ban of unpasteurized milk and milk products. The FDA believed that this would not be an effective measure for a variety of reasons, including the fact that most unpasteurized milk and milk products are marketed in intrastate commerce. They also believed that problems created by unpasteurized milk and milk products are best managed at the state and local level (98).

In 1987, the FDA banned the shipment of raw milk in interstate commerce as part of the Public Health Service Act (24). Currently, the majority of milk consumed in the United States is Grade A and pasteurized (54). The National Conference on Interstate Milk Shipments “Grade A” milk program oversees proper pasteurization. The standards in the program are based on those set by the FDA’s Pasteurized Milk Ordinance (PMO) that gives states the option of adopting these regulations. Raw milk and raw milk cheeses are not labeled “Grade A” since they are not pasteurized and do not meet the requirements covered in the PMO.

OPPOSING VIEWS

According to the Centers for Disease Control and Prevention, more than 800 people in the United States have gotten sick from consuming raw milk or cheese products made from unpasteurized milk since 1998 (10). Raw milk proponents believe that

pasteurization of milk diminishes the nutritive value of milk, causes pathogens to multiply, destroys immunoglobulin G antibodies, and causes lactose intolerance (85). They also maintain that pasteurization destroys enzymes, including lactoferrin, xanthine oxidase, lactoperoxidase, lysozyme, and nisin, some of which are necessary for calcium absorption (15, 44). There are also claims that the pasteurization process causes allergic reactions, kills beneficial bacteria, and is associated with the development of arthritis (15, 44). Moreover, they praise the unpasteurized milk's richer flavor and claim that it is more nutritious and that it leads to stronger immune and digestive systems than pasteurized milk (15, 44).

Review of the scientific literature has shown that there are no significant differences between pasteurized and raw milk (59). Milk is a nutritive source of lactose, proteins (casein and whey), vitamins (thiamine, folate, B-12, riboflavin), minerals (calcium, iron, etc.), enzymes, gases and acids (Figures 2 and 3) (99, 101). The bovine enzymes that are naturally present in milk are reduced by pasteurization, yet these enzymes are not used by humans to aid calcium and nutrient metabolism; enzymes naturally present in humans are used to digest and metabolize milk. At present, there is no scientific evidence to substantiate the claim that there is an anti-arthritis factor present in raw milk or that it enhances resistance against diseases. Vitamin D, used to aid in the body's absorption of calcium, is added to pasteurized milk, but is found in only limited amounts in raw milk (85). The creamier flavor of raw milk can be attributed to the higher butterfat content as the fat particles have not been homogenized (broken up).

Raw milk advocates have also claimed that two types of spore-forming bacteria (termed "heat-resistant pathogens" by raw milk advocates), *Bacillus cereus* and

Clostridium botulinum, survive the pasteurization process. *Bacillus cereus* can be eliminated through pasteurization at temperatures above 212°F, and the growth of *Clostridium botulinum* in milk, though possible, is rare since milk is too aerobic to allow growth (100).

Lactoperoxidase and bovine milk lysozyme, enzymes key to limiting microbial growth and spoilage, are described as being inactivated by pasteurization.

Lactoperoxidase is not destroyed by minimum pasteurization standards (85). Griffiths has also reported that bovine milk lysozyme survives pasteurization (50).

Some raw milk advocates have stated that drinking unpasteurized milk on the farm during childhood can help abate allergic symptoms, such as allergic rhinitis and asthma. In a study by Perkin, farmers' children who drank unpasteurized milk showed decreased asthma symptoms (OR = 0.67, 95% CI 0.49 – 0.91), seasonal allergic rhinitis (OR = 0.50, 95% CI 0.33 – 0.77), eczema (OR = 0.59, 95% CI 0.40 – 0.87), and atopic symptoms (OR = 0.24, 95% CI 0.10 – 0.53) compared to non-farmers' children (75). However, the generalizability of this study is questionable; there may have been unidentified confounding factors in the farm environment that were responsible for the reduction of these symptoms. Furthermore, this was a cross-sectional study which makes it difficult to determine a causal relationship due to the lack of a time component.

Assertions regarding the destruction by pasteurization of immunoglobulin G (IgG) - a protein found in blood and other bodily fluids of vertebrates that is used by the immune system to identify and neutralize foreign bacteria and viruses - are refuted by Kulczycki. Kulczycki states that the receptor-binding ability of IgG is not destroyed, but enhanced by pasteurization of milk (66). Another source of contention is whether

unpasteurized milk causes lactose intolerance. Bifidobacteria are claimed to aid in alleviating these symptoms. Raw milk consumers are not protected against developing lactose intolerance as this condition is caused by innate lactase deficiency, low levels of lactase after childhood, or a variety of illnesses, including Crohn's disease, celiac sprue, or Whipple's syndrome (16, 79). Raw milk proponents claim that it is probiotic, or contains beneficial bacteria. However, raw milk is not considered a probiotic food according to Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food (9). In order for the term "probiotic" to be applied to a particular food, it must meet certain requirements, such as a safety assessment, which has not been conducted for raw milk.

Research regarding over reduction of proteins, vitamins, and minerals by pasteurization have revealed that there are minimal reductions of these components of milk. The major milk proteins, caseins, are essentially unaffected by pasteurization (6). Pasteurization reduces B-complex vitamins (thiamine, folate, and riboflavin) and Vitamin C by no more than 10% (20). Most of the Vitamin C losses occur while milk is in storage irrespective of whether it is pasteurized. Moreover, pasteurization is not known to cause considerable reductions of fat-soluble vitamins (A, D, E and K). Lastly, minerals such as manganese, potassium, and sodium are not significantly reduced by pasteurization (107). In a study performed on both pasteurized and unpasteurized bovine and caprine milk, no differences in calcium levels existed (68).

PREVALENCE OF RAW MILK CONSUMPTION

In 1997, Headrick et al. (55) showed that 3.2% of the population surveyed in California consumed raw milk. This study also showed an association between education and a person's choice to consume raw milk; those with less than a high school education were more likely to consume raw milk than those who had completed high school. According to Mark McAfee, owner of Organic Pastures Dairy Company, California's largest producer of raw milk, approximately 100,000 California residents drink raw milk each week (51). In a survey conducted by Jayarao and colleagues in Pennsylvania, they concluded that dairy producers residing on dairy farms were approximately three-fold more likely to consume raw milk compared to those living elsewhere (59). Furthermore, they noted that merely 42.3% of dairy producers in Pennsylvania were aware of pathogens in raw milk.

THE RISKS

Those who oppose the consumption of raw milk believe that unpasteurized milk is inherently unsafe and may expose the public to potentially infectious pathogens that include Enterotoxigenic *Staphylococcus aureus*, *C. jejuni*, *Salmonella* species, Enterohemorrhagic *Escherichia coli* (*E. coli* O157H:7), Enterotoxigenic *E. coli* - ETEC, *Listeria monocytogenes*, *Mycobacterium tuberculosis*, *Mycobacterium bovis*, *Brucella* species (*B. abortus* is mainly associated with cattle and *B. melitensis* is mainly associated with goats), *Yersinia enterocolitica*, *Coxiella burnetii* and the Rabies virus (84). As a result, there are a range of tests to ensure the safety of unpasteurized milk (Table 2) (61). Five pathogens, *Salmonella*, *E. coli* O157H:7 and other forms of Shiga toxin-producing *Escherichia coli*, *Campylobacter*, *Listeria*, and *Toxoplasma*, account for most of the

severe illnesses and can be contracted through raw milk consumption (91). These disease-causing organisms cause an estimated 3.5 million infections, 33,000 hospitalizations, and 1,600 deaths each year (91). Outbreaks have affected European countries as well; between 1992 and 2000, 52% of all foodborne outbreaks in England and Wales were attributable to consumption of raw milk (48). Lastly, the economic burden of foodborne infections is substantial, costing the U.S. approximately \$6.7 billion annually (91).

THE EVIDENCE: RAW MILK OUTBREAKS

Salmonellosis. An estimated 1.4 million of the 76 million annual foodborne illnesses in the U.S. are caused by *Salmonella* spp. and result in roughly 16,000 hospitalizations and 580 deaths (54). From 1972 to 2000, 17 (29%) of the 58 raw milk-associated outbreaks were directly attributable to *Salmonella* spp (54). Between 2000-2005, there were 191 illnesses traced to *Salmonella* spp. infected raw milk. An outbreak occurred in Illinois, Indiana, Ohio, and Tennessee where *Salmonella* Typhimurim infected 62 people (54). 87.1% of patients reported signs and symptoms of illness which included diarrhea (96.3%), abdominal cramps (75.9%), and emesis (44.4%) (54). Approximately 81% of the cases reported more than one symptom (54). In a case-control study, 37 (94.9%) of the 39 people who drank the unpasteurized milk (cases) and 16 (29.1%) of the 55 people who did not (controls) became ill (OR = 45.1, 95% CI = 8.8 – 311.9) (32).

In 2007, 29 cases of diarrhea caused by *Salmonella* Typhimurium were directly linked to consumption of raw milk and raw milk products in Pennsylvania (36). During this time, the Pennsylvania Department of Agriculture estimated that the dairy that was

implicated in this outbreak was selling approximately 200-300 gallons of raw milk on a weekly basis to 275 regular customers (36). No deaths were reported, but two of the 29 patients were hospitalized (36). One-hundred and five people were also infected with *Salmonella* Typhimurium in Montana after drinking raw milk from a particular farm (27). In Vermont, *Salmonella* Derby infection occurred in eight persons, resulting in symptoms of diarrhea, abdominal cramps, and fever (96). The unpasteurized milk was traced back to a single dairy.

Werner and colleagues indicated that the mean annual incidence of *Salmonella* Dublin infections increased more than five-fold in the period between 1971 and 1975 in California (102). Forty-four cases out of 113 drank unpasteurized milk; 35 consumed the raw milk from a single dairy (102). There were 89 hospitalizations (79%) and 22 (20%) fatalities were reported (102). Most of the cases that were infected were immunocompromised due to diseases such as leukemia and lymphoma. The authors concluded that the public, particularly infants, the elderly, and the immunocompromised, should be the most informed of the potential danger of drinking unpasteurized milk (102).

Campylobacteriosis. *Campylobacter jejuni* infection, commonly characterized by gastritis (inflammation of the stomach) and enterocolitis (inflammation of both the small and large intestine), can also lead to more serious diseases which include Guillain-Barré syndrome and reactive arthritis (73, 82). In the U.S., campylobacteriosis is one of the most frequently reported bacterial causes of foodborne illness (45). *C. jejuni* is commonly found in approximately 1% to 12% of raw milk samples (78). In 1981, an outbreak in Arizona left approximately 200 persons with *C. jejuni* enteritis after the consumption of one brand of unpasteurized milk (92). A cohort study showed that those

who drank unpasteurized milk had diarrheal illness (RR = 4.7, 95% CI 1.79 – 12.33, p = 0.003) at a significantly higher frequency than those who did not consume unpasteurized milk (RR = 3.85, 95% CI 1.68 – 8.81, p = 0.001) (92). Fecal samples containing the bacterium were found in higher quantities in the cattle that produced the unpasteurized milk compared to the control cattle. In Chittenden County, Vermont, Vogt and colleagues also traced fifteen cases of *C. jejuni*-associated gastroenteritis to a commercial dairy (97).

In Oregon, a college retreat to a farm left nineteen of 31 students with acute gastrointestinal illness secondary to unpasteurized milk consumption (19). These students showed high levels of *C. jejuni*-specific antibodies compared to the unexposed population (19). Of the 25 students who consumed the raw milk for the first time, 22 were infected, whereas neither of the two students who did not consume the raw milk were infected (19). Though *C. jejuni* is more commonly found in unpasteurized cows' milk, goats' milk has also been documented as a source of infection; in Washington State, it was identified as the source of *C. jejuni* enteritis among six patients (52). Though the organism was not recovered from the milk, it was isolated from the intestinal tract of three goats from one dairy and other *C. jejuni* isolates were obtained from goats at another dairy (52).

An outbreak of *C. jejuni* enteritis in Utah occurred at a high school athletic-team dinner where unpasteurized milk was served. In this case-control study, all cases (those experiencing illness) reported diarrhea, abdominal pains, nausea, vomiting, body aches, chills, and headaches four days after the team dinner compared to controls (those not

suffering from any illness). The consumption of unpasteurized milk was significantly associated with *C. jejuni* enteritis (OR = 30.0, 95% CI 1.58 – 153, p = .0072) (76).

Escherichia coli. *E. coli* and Shiga-toxin producing *E. coli* have been found in 0.87% to 10% of bulk tank samples of unpasteurized milk in Minnesota, Ontario, Pennsylvania, South Dakota and Wisconsin (59, 74, 88). Sixteen cases of *E. coli* infection caused by raw milk consumption were reported in Oregon where four of the 132 animals of the herd tested positive for the organism (63). The infection led to gastrointestinal symptoms in those affected. Interestingly, despite new labeling requirements, increased monitoring of dairy sales from the implicated dairy farm, and public health efforts to warn the public of hazards associated with raw milk consumption, retail sales continued and illnesses ensued (63). In 2005, an outbreak of *E. coli* resulted in illness among eighteen people in Washington State, most of whom were children. The relative risk for illness steadily increased with the average number of cups of raw milk consumed on a daily basis. The average daily consumption dose-response trend was highly statistically significant (p=0.008), with disease 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 (35).

Shiga toxin producing strains of *E. coli* is also known to cause hemolytic uremic syndrome (HUS), a potentially fatal disease occurring mostly among children and infants (94). A majority of cases experience acute renal failure (97%) and gastroenteritis (83%). In 1997, four cases of HUS were reported in children living in the Czech Republic after consumption of raw goat's milk. The levels of anti-O157 LPS antibodies (can be associated with *E. coli* infection) were found to be significantly higher among those who regularly consumed a particular farm's goat milk (33%; 5 of 15 regular drinkers)

compared to a control population (0%; 0 of 45) ($p = 0.0005$) (18). In Austria, enterohemorrhagic *E. coli* O26:H infection was also linked to the consumption of raw cows' and goats' milk in two children, both less than three years of age (3). Both children had severe, bloody diarrhea and one child developed HUS.

Other diseases. In 1996 and 1998, two separate incidents in Massachusetts involving the consumption of unpasteurized milk from rabid cows led to mass rabies post-exposure prophylaxis (PEP) of 80 people (29). The median cost of this treatment in Massachusetts was \$2376 per person during the period of 1991-1995 (65). In 2005, the milk of a rabid cow in Oklahoma was mixed with that of approximately 70 other cows and, as a result, hundreds of consumers were potentially exposed (34). Sixty-two consumers received PEP at an estimated cost of \$186,000. No humans were reported to have contracted rabies through ingestion of unpasteurized milk from any of rabid cows. Though rabies-infected unpasteurized milk has not been described in the literature, it is theoretically possible; rabies transmission through ingestion of milk from rabid animals has been reported (2). Pasteurization, however, inactivates the rabies virus (89).

Other organisms present in raw milk have been implicated in disease onset. Globally, milk and milk products are the primary mechanisms by which human brucellosis infection occurs. Approximately 10% of all cases in the U.S. are attributed to consumption of unpasteurized milk and milk products (105). Several studies have suggested that unpasteurized milk consumption has been a source of *Coxiella burnetii*, the causative agent of Q fever (38, 41, 93). Hatchette and colleagues noted 37% of those affected by a goat-associated Q fever outbreak in Newfoundland had antibody titers to phase II *C. burnetii* antigen >1:64, suggesting infection (53). Consumption of

unpasteurized milk contaminated with *Listeria monocytogenes* in pregnant women is also known to cause miscarriage, fetal death, or illness or death of a newborn (28). Infections caused by *Toxoplasma gondii* and *Corynebacterium pseudotuberculosis* have also developed illness in persons who have consumed unpasteurized milk (77, 80).

THE EVIDENCE

Cow-shares. Cow-share programs involve a farm co-operative in which members lease cows from a dairy farm and then sell shares in the herd to each co-operative member. Typically, a member pays an annual fee and, as a result, is given purchasing rights to the herd's milk. In turn, the dairy farmer uses the annual fee in the form of a boarding fee for the cows. Outbreaks of foodborne illness have been linked to raw milk purchased through cow-sharing programs (31). In 2005, eighteen cases of *E. coli* O157:H7 were associated with raw milk consumption among shareholders of a cow-share program in Oregon (33). Five patients, all younger than fourteen years of age, required hospitalization and four developed hemolytic uremic syndrome (33).

Pasteurized milk outbreaks. The rare outbreaks attributed to pasteurized milk can be generally traced to post-pasteurization hygiene, namely inadequate pasteurization and contamination after pasteurization (47). In 1983, an outbreak of *Listeria monocytogenes* in Massachusetts affected 42 immunocompromised adults and seven fetuses or infants (47). Fourteen of these patients died due to disease-related meningitis, septicemia, or spontaneous abortion (47). In this outbreak, two case-control studies (one matched by neighborhood, one matched by underlying disease) showed that illness was strongly associated with consumption of pasteurized whole or 2% milk (OR = 9.0,

p<0.01 for neighborhood-matched study; OR = 11.5, p<0.001 for illness-matched study) (47). After inspection of the dairy plant from which the outbreak occurred, neither improper pasteurization nor a source of contamination after pasteurization was identified. After further epidemiologic study, it was determined that this vulnerable population had in fact consumed raw milk that was contaminated after processing (47).

Yersinia enterocolitica O:8 infections have the potential of being transmitted through pasteurized milk because the bacterium is capable of surviving refrigeration (62). In 1976, 38 schoolchildren became ill secondary to yersiniosis infection by way of contaminated chocolate milk. The bacterium introduced into the milk through improper handling of chocolate syrup, which was hand-mixed with pasteurized milk. A large multistate outbreak of this disease also occurred in Tennessee, Arkansas, and Mississippi, where three different case-control studies indicated that milk consumption from a specific plant was statistically associated with illness characterized by enteritis involving fever, diarrhea, and abdominal pain (90). Inspection of the plant did not reveal a source or mechanism of contamination. However, an outbreak of yersiniosis in 10 residents of the Upper Valley of Vermont and New Hampshire was linked to consumption of bottled pasteurized milk (1). The contamination likely occurred when milk bottles were rinsed with untreated well water after being handled by workers caring for pigs.

Salmonella Typhimurium outbreaks were also linked to poor pasteurization techniques (12). The largest outbreak of salmonellosis in U.S. history can be attributed to two brands of pasteurized 2% milk taken from a single dairy plant in Kentucky. At least sixteen cases of gastroenteritis occurred due to improperly pasteurized milk. People who

consumed the milk were approximately six times more likely to develop illness ($p = 0.01$) compared to those who did not consume the milk (26).

Unpasteurized soft cheese outbreaks. Unpasteurized milk is preferred by cheese makers because pasteurization can decrease flavor and lengthen the ripening time of cheese (23). However, the United States Department of Agriculture regulations require that cheeses made from unpasteurized milk must be aged for greater than 60 days as stated in the Standards of Identity in the U.S. Code of Federal Regulations CFR, section 7 CFR 58.439. The FDA permits the manufacture and interstate sale of unpasteurized milk cheeses that are aged for a minimum of 60 days at a temperature greater than 35°F.

Soft cheeses tend to be high in moisture. Unpasteurized soft cheeses implicated in disease outbreaks include Brie, Camembert, Vacherin, and homemade, soft, and unripened cheeses (106). A variety of pathogens have been implicated in raw soft cheese outbreaks (106). During the cheese-making process, some pathogens are inactivated depending on the temperature and pH during production and ripening, yet many survive this aging process. Ripened soft cheeses present a greater risk for growth and survival compared to aged hard cheeses (43).

The raw milk soft cheeses of greatest concern to public health are “queso fresco” style cheeses, which are typically soft and white and imported from Mexico and Central American countries (5). They are typically made at home, sold from door-to-door, illegally imported, or sold in local markets and restaurants. In the United States, a variety of raw milk cheese outbreaks have occurred (5).

In 1983, sixteen cases of Group C Streptococcal infections in New Mexico were linked to “queso blanco,” a homemade white cheese (5). In North Carolina, there was

also an outbreak of listeriosis associated with homemade Mexican-style cheese in which ten pregnant women infected with *L. monocytogenes* resulted in five stillbirths, three premature deliveries, and two infected newborns (87). A case-control study showed that cases had a seven times greater odds of having ingested queso fresco compared to controls (OR = 7.3, 95% CI 1.4 - 37.5) (30). In another case-control study, *Salmonella* Typhimurium DT104 was also shown to have caused queso fresco- associated illness due to raw milk cheese ingestion where isolates were drawn from seventy-nine people (37). Lastly, a comparison of patients with neighborhood controls linked *Salmonella* Typhimurium with eating raw milk queso fresco of an outbreak in Washington State (matched OR = 32.3, 95% CI 3.0 – 874.6) (95).

In France, where many of the world's raw milk soft cheeses are produced, several outbreaks have occurred. Desenclos and colleagues identified an outbreak in 273 people in France who consumed raw goats' milk cheese where the organism implicated was *Salmonella enterica* serotype *paratyphi* B infection (42). Brie de Meaux cheese made from raw cows' milk was the source of *Listeria monocytogenes* infection among 20 people in France (49). Eleven pregnant women were affected; two suffered spontaneous abortions, two stillbirths, and five premature births (49). A case-control study linked four cases of acute hemolytic uremic syndrome that occurred in four children in a French village to a cheese made with unpasteurized mixed cows' and goats' milk ($p = 0.006$) (41). All four patients had fever, diarrhea, acute renal failure, anemia, schistocytosis, and thrombocytopenia (41).

Interestingly, a risk assessment performed by Sanaa and colleagues revealed that the predicted probability of contracting severe listeriosis after consumption of both Brie

de Meaux cheese and Camembert of Normandy made from raw milk is lower than after consumption of soft cheeses made from pasteurized milk (81, 103). The incidence rate of severe listeriosis after consuming one of these two cheeses was 10^{-3} per year (81). In 1997, a community-wide outbreak of *Salmonella enterica* serotype Typhimurium infection secondary to raw milk Morbier cheese consumption occurred in thirty-three of forty cases compared to 23 of 42 controls matched on age and area of residence (OR = 6.5, 95% CI 1.4 – 28.8) (39). All cases suffered from fever and/or diarrhea during the investigation period. Lastly, a cluster of four cases of bloody diarrhea and hemolytic uremic syndrome in 1994 was traced to consumption of fromage frais made from raw cows' and goats' milk (7).

An outbreak of Q fever caused by *Coxiella burnetii* occurred among support staff and patients in a psychiatric hospital in southern France who also worked on a dairy farm near the hospital (46). A serologic survey performed among suspected cases - those with exposure to goats and their unpasteurized dairy products - revealed that 66% had elevated *C. burnetii* titers. Seropositive rates were significantly higher among persons who worked on the farm and consumed unpasteurized milk products (69%, 22 of 32, $p = 0.007$), suspected cases who only had worked on the farm (75%, 9 of 12, $p = 0.009$), and those who only had consumed unpasteurized milk products (75%, 9 of 12, $p = 0.009$) compared with those who had neither worked with the goats nor consumed unpasteurized goat milk products (0 of 5) (46).

Other European countries have also had raw soft milk cheese-associated outbreaks. In Malta, a soft cheese made from unpasteurized goats' and sheeps' milk affected 135 people as a result of *Brucella melitensis* infection (22). Cheeses made from

unpasteurized cows' milk led to food poisoning in England and Wales; 42 people who consumed Irish soft cheese were infected with *Salmonella* Dublin (69). In Spain, 81 cases of brucellosis were associated with consumption of fresh unpasteurized cottage cheese (OR = 311.9, 95% CI 41.28 – 12,735) (25). Consumption of fresh, unpasteurized goat cheese in a local dairy farm in Finland led six people to develop septicemia and one person to develop purulent arthritis secondary to *Streptococcus equi* subspecies *zooepidemicus* infection (67).

Fresh, unpasteurized cheese curds are also a potential source of infection. In Wisconsin, 55 patients contracted *E. coli* infection after eating fresh cheese curds (8). Furthermore, more than 40 people had symptoms of abdominal cramping, bloody diarrhea, fever, vomiting, and nausea after the ingestion of white cheese curds produced in Wisconsin (8). The cheese curds tested positive for *Campylobacter jejuni* and, as a result, all dairy manufacturing activity was terminated (64).

Unpasteurized hard cheese. From 1948 to 1988, six outbreaks implicated hard cheeses produced in the United States (60). Several reports have called the existing 60-day aging period in the manufacture of hard cheeses made with unpasteurized milk into question due to safety concerns, suggesting that all cheeses should be made from pasteurized milk (83). The FDA's Center for Food Safety and Applied Nutrition has also begun examining the safety of all raw milk cheeses and plans to conduct a full risk profile of each type of cheese (83). Thirteen cases of *E. coli* hemorrhagic colitis associated with unpasteurized Gouda cheese in Canada led Honish and colleagues to suggest that Canadian authorities question current federal legislation that permits sale and consumption of unpasteurized milk cheeses aged over 60 days (56). After consuming

Stilton cheese, 155 people were thought to have been infected with *Staphylococcus aureus* enterotoxin (69). In 2008, several hard raw milk cheeses were recalled in Indiana due to high levels of *Staphylococcus aureus* in Colby cheese, jalapeño natural cheese, garlic pepper cheese, and Monterey Jack cheese (21). There was also a recall of Berkshire Blue Cheese, a cheese made in Massachusetts, after routine FDA sampling discovered elevated levels of *Listeria monocytogenes* (14). There is limited information in the scientific literature concerning pasteurized milk cheese disease outbreaks.

THE EUROPEAN SOLUTION

Europe has a rich tradition of producing unpasteurized milk products (mainly cheese), the safety of which is regulated by the European Commission (EC). The EC requires that these products meet process hygiene, food safety, and microbiological standards. It also regulates the production and labeling of raw milk products (72). Countries of the European Union must then create their own laws and regulations in compliance with EC regulations. Products made with unpasteurized milk must bear the label ‘made with raw milk (72).’ For instance, in England, the sale of raw milk is legal provided that the containers have a green top (40).

RECOMMENDATIONS

Given the evidence, it is clear that unpasteurized milk and cheese have the potential to pose a risk to one’s health. While some purport that an outright ban may help abate the incidence of unpasteurized milk and cheese outbreaks, many believe that imposing a ban on such products is an infringement on one’s freedom of choice. If a ban

were imposed, it would pose a variety of problems for key stakeholders, such as the state agricultural departments, dairy farmers, and raw milk and cheese consumers. The time, energy, and resources needed to enact in a ban would overstrain state agricultural departments. Furthermore, surveillance and regulation of sales is impractical due to labor and costs and may not be completely effective in preventing the illegal production and sale of these products. Illegal production and sale would also most likely continue.

A ban on unpasteurized milk cheeses would also cause a great deal of economic concern for states as many cheeses in cheese-producing states are made using unpasteurized milk and a large portion of state agricultural revenue may come from milk and milk products, particularly in states like Vermont.

A successful intervention called The Abuela Project has shown how effective safe cheese workshops encouraging the use of pasteurized milk can reduce the incidence of *Salmonella* Typhimurium outbreaks (17). The intervention focused on the use of pasteurized milk in the preparation of queso fresco among a Hispanic community in Washington State (17). Two-hundred and twenty-five attendees reported an acceptance of a new recipe and, as a result, educators began conducting more workshops throughout the state.

The success of the Abuela Project suggests a public health campaign informing potential raw milk consumers and producers about the safety of raw milk products would be beneficial. This may be accomplished in a variety of ways which includes information sessions, community meetings, and dissemination of brochures. Public health measures to help improve the pasteurization process include the use of a recording thermometer

and air space heater, pasteurization at appropriate temperatures and time intervals, and regular phosphatase and bacteriologic testing.

Another alternative is to require warning labels on raw milk. This allows consumers to make informed choices. This would help reduce rates of infection, especially among the most vulnerable populations. Moreover, if a disease outbreak occurs, the contaminated products could be traced easily to the source. The downsides of this approach include limited public health benefits, costs associated with labeling, and inaction among consumers after reading labels. Currently, 12 out of the 22 states where it is legal to sell raw milk for human consumption require warning labels (Figure 4) (15). In Washington State, all retail raw milk products must bear the following label (11):

“WARNING: *This product has not been pasteurized and may contain harmful bacteria. Pregnant women, children, the elderly and persons with lowered resistance to disease have the highest risk of harm from use of this product.”*

States could use a warning such as this to properly inform all producers and potential consumers about associated hazards of raw milk and raw milk cheese consumption. A measure such as this is feasible and not without precedent. Given these considerations, providing education to dairy producers and consumers and implementing the use of warning labels on unpasteurized milk and soft cheeses are the most effective ways for the state agricultural departments to decrease the consumption of these products, prevent illness, and thus ensure public safety.

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LIST OF FIGURES

Figure 1. U.S. states that have legalized the sale of raw milk for human consumption (shaded).

Figure 2. Average Milk Composition As Percent of Total Volume.

Figure 3. Composition of Non-fat Solids in Milk.

Figure 4. U.S. states that have legalized the sale of raw milk for human consumption, but require warning labels (shaded).

Table 1. Organizations with Formal Statements Regarding the Hazards of
Consumption of Unpasteurized Milk.

American Academy of Pediatrics

American Medical Association

American Public Health Association

International Association for Food Protection

National Environmental Health Association

The Centers for Disease Control and Prevention

U.S. Animal Health Association

U.S. Department of Agriculture

U.S. Food and Drug Administration

World Health Organization

Table 2. Tests Commonly Performed on Raw Milk Samples.

Specific Pathogens	<p>Tests for certain pathogens considered to be the most dangerous, which include <i>Salmonella</i> spp., <i>E. coli</i> O157:H7, <i>Staphylococcus aureus</i>, and <i>Listeria monocytogenes</i>.</p> <p>Cattle are also vaccinated against brucellosis and tested for tuberculosis and Johne's disease (paratuberculosis).</p>
Somatic Cell Count	<p>Presence of leukocytes (white blood cells) in milk which is an indication of whether the dairy herd is infected.</p>
Coliforms	<p>Should be equal to or less than 200,000 cells/mL.</p> <p>Indication of unsanitary production practices and/or mastitis.</p>
Standard Plate Count	<p>A count of less than 100 cfu/mL is considered acceptable.</p> <p>An indication of overall cleanliness of milking equipment of bacteria in 1 mL of milk incubated at 90°F for 48 hours.</p>
Drug or Antibiotic Residues	<p>Standard plate count equal to or less than 5,000 cfu/mL</p> <p>Used for treatment of mastitis and for disease therapy, but can be shed in milk.</p> <p>Commonly used drugs/antibiotics include penicillin, oxytetracycline, cephalosporin, amoxicillin, cloxacillin, and gentamicin.</p>
Preliminary Incubation	<p>Cattle should be 100% drug/antibiotic residue-free.</p> <p>Best measure of raw milk keeping quality and sanitation practices on farms.</p>
Lab Pasteurized Count	<p>Preliminary incubation count should be equal to or less than 10,000 cfu/mL.</p>
Sanitation Inspection of Milking System	<p>Levels in raw milk should be less than 250-300 cfu/mL</p>
Monthly bulk tank cultures	<p>Commonly performed every 6 months.</p> <p>Identification of equipment bacteria, mastitis, and potential environmental contamination.</p>
Sediment count	

Acceptable levels are less than 1.5 mg./gal. milk

**Freezing Point
(Cryoscope)**

Reading should be equal to or less than $-.530^{\circ}$ Horvet.

Rancidity

Acid degree value should not exceed 1.0.

*Mastitis, an inflammation of the mammary glands, caused by bacterial infection, trauma, or injury to the udder. Globally, it remains the most common and most expensive disease affecting dairy cattle.

**cfu indicates colony-forming units.

