

The Raw Milk Beat Goes On: A Look at the Literature and the 60-Day Raw Milk Cheese Aging Rule

Introduction

Some say raw milk cheeses are being beat-up by US regulators this year. Indeed, if there was a Food Safety Zodiac, 2010 would be the Year of the Cheese (shell eggs a close second). Whatever the underlying explanation, the number of [cheese-related illnesses and recalls in 2010](#) appears unprecedented. While covering these events, my blog has been inundated with comments expressing outrage at FDA and state regulators for raw milk cheese “crackdowns.” The comments range from fringe screams about food Nazis and fascists to thoughtful and informative discussions about the microbiology of raw milk cheeses and implications for food safety and quality.

Tami Parr of the Pacific Northwest Cheese Association portended regulatory changes that may affect the fate of raw milk cheeses on [her blog](#) earlier last month. Interestingly, she links to a [1997 memo](#) that recommended FDA re-examine its 60-day aging process for hard cheeses made from raw milk. No changes were made to the rule at that time, but clearly the issue of aged raw milk cheeses and food safety is not new, as shown in the timeline below.

To look at the issue closer, this paper provides an overview of the historical context and timeline of raw milk cheese regulations in the US, and examines the state-of-the-science surrounding the 60-day aging rule established by FDA.

Historical Perspective

Timeline of Key Studies and Regulatory Changes for Cheeses Made from Raw Milk

- 1941-1944: Typhoid fever epidemics are linked to cheddar cheese made from raw milk in Canada; outbreak-related *Salmonella typhi* strains are recovered from 30-day-old cheese, but not from 48- or 63-day-old cheese resulting in Alberta, Canada halting the sale of raw milk cheese unless ripened for at least 90 days (Marth 1969).
- 1946: *Brucella abortus* is found to survive in cheddar cheese made from raw milk for up to 6 months depending on initial inoculation level, but the authors of the study conclude that cheddar cheese is not a proven carrier of undulant fever (the human disease caused by *B. abortus*). D’Amico (2008a) suggests that this study, combined with the earlier data on typhoid fever illnesses not attributed to cheese cured for more than 63 days, is the likely origin of the 60-day curing period in the US. However, subsequent reports in the 1940’s show extended survival of *Mycobacterium tuberculosis* (>100 days), *Salmonella typhi* (3-10 months), and hemolytic *Streptococcus* (>160 days) in cheddar cheese (D’Amico 2008a).

- 1950: FDA promulgates regulations (21 CFR Section 133) requiring that cheesemakers use pasteurized milk, or cure the cheese for no less than 60 days at a temperature greater than 35°F. According to D'Amico (2008a), there are over 30 natural cheeses that can be made legally from raw milk in the US under this rule.
- 1960's: Additional challenge studies show survival of pathogens including *Salmonella enterica* subtype Typhimurium beyond the 60 day curing period (Goepfert 1968); *Salmonella typhi* is found to survive in stirred curd granular cheddar cheese for 150-180 days when held at refrigeration temperatures (Hargrove 1969).
- 1987: Numerous foodborne illnesses are linked to commercial fluid raw milk including 22 deaths from *Salmonella* Dublin infections from 1971-1975 (Werner 1979). This prompts a Citizen's Petition and federal judge's ruling that orders the FDA to ban fluid raw milk and milk products from interstate commerce (21 CFR Section 1240.61). The regulations allowing cheesemakers to sell cheese made with raw milk if cured for 60 days at a temperature greater than 35°F remain in place (21 CFR Section 133).
- 1973-1992: CDC reviews reported outbreaks and illnesses from raw milk (Headrick 1998) and cheeses made from raw milk (Altekreuse 1998). During this time, there were 32 reported cheese-associated outbreaks and 58 deaths, but the authors conclude that "If current Food and Drug Administration sanitary requirements for cheesemaking had been met, these outbreaks would have been preventable." They go on to say: "Curing cheeses kills most bacteria present in cheeses; however, evidence from sources other than the CDC Foodborne Disease Outbreak Surveillance System suggests that curing alone may not be a sufficient pathogen control step to eliminate *Salmonella*, *Listeria*, and *E. coli* O157:H7 from cheese."
- 1996: Researchers at South Dakota State University publish a study showing that 60-day aging is largely ineffectual in reducing levels of *E. coli* O157:H7 in cheddar cheese. FDA then asks the National Advisory Committee for Microbiological Criteria for Food (NACMCF) to re-examine the literature on the efficacy of 60-day aging. [In a memo to FDA](#), the committee states: "the sixty-day aging process for hard cheese is questionable as an effective measure in support of the public's health."
- 2002: Health officials from Alberta, Canada report an outbreak of *E. coli* O157:H7 hemorrhagic colitis associated with Gouda cheese made from raw milk (Honish 2005). In their paper, the authors suggest that Canada re-evaluate the federal regulations for aging of hard cheeses made from raw milk.

- 2004: In an interview with Food Safety Magazine, FDA officials state that they are developing a “risk profile for raw milk cheeses, which will aid in the Agency’s assessment of the requirements for processing these cheeses,” based, in part, on the report by the NACMCF and other recent research suggesting that 60-day aging may be insufficient to protect the public’s health (Sheehan 2004).
- 2006: Schlessner and colleagues report results from a study of *E. coli* O157:H7 survival in cheddar cheese made from raw milk, and confirm previous reports questioning the efficacy of 60-day aging to eliminate *E. coli* O157:H7 during cheese ripening.
- 2008: D’Amico and colleagues determine that the 60-day aging requirement does not ensure safety of surface-mold-ripened soft cheeses manufactured from raw or pasteurized milk when *Listeria monocytogenes* is introduced as a postprocessing contaminant. The authors conclude that “the safety of cheeses of this type must be achieved through control strategies other than aging, and thus revision of current federal regulations is warranted.”
- 2010: [According to press quotes](#), FDA officials are conducting a nationwide survey of cheese safety with a focus on *Listeria monocytogenes* contamination. Notably, this survey encompasses both raw and pasteurized cheese products from large and small cheesemakers.

In November, the CDC reports 38 illnesses from Gouda cheese made from raw milk and aged for 60 days in accordance with regulations (CDC, 2010).

A study in the December 1, 2010 issue of the Journal of Food Protection documents survival of *E. coli* O157:H7 in aged Gouda and stirred-curd cheddar cheese (D’Amico 2010). The authors conclude that “the 60-day aging requirement is based on decades-old research indicating that *Brucella abortus* is eliminated in cheddar cheese alone is insufficient to completely eliminate levels of viable *E. coli* O157:H7 in Gouda or stirred-curd cheddar cheese manufactured from raw milk contaminated with low levels of this pathogen.”

Definitions

Before embarking on a discussion of the 60-day curing criteria for cheeses made from raw milk, it is important to understand the definition of cheese styles and differences in regulation.

Cheese was originally developed by human societies as a method to preserve milk. In the US, cheeses are usually made from cow’s, goat’s, sheep’s, or buffalo’s milk. Among 72 different cheese and cheese product types defined in 21 C.F.R. Part 133, the FDA allows only a limited number of cheese types to be made with raw milk so long as the cheese is cured at a temperature of not less than 35°F for not less than 60 days. The [Raw Milk Cheesemakers’ Association](#) adds an additional criteria for low-temperature (thermised) heat treatment of raw milk cheese: “Cheese produced from milk that, prior to setting the curd, has not been heated above the temperature of the milk (104°F, 40°C) at the time of milking and that the cheese

produced from that milk shall be aged for 60 days or longer at a temperature of not less than 35°F (2°C) in accordance with US FDA regulations.” Table 1 summarizes cheeses and cheese types subject to the 60-day aging rule.

Table 1. Cheese and Cheese Products in the US (adapted from The American Cheese Society).

Cheese Type	60-day aging rule allowed	Examples
Fresh cheeses	No	Italian style mascarpone and ricotta, chevre, feta, cream cheese, quark and cottage cheese, queso fresco and other Mexican-style fresh cheeses
Soft-ripened cheeses	Yes	brie and camembert styles, triple crèmes
Semi-soft cheeses	Yes	blue cheeses, colby, fontina styles, havarti and Monterey Jack, washed rind cheeses
Firm/hard cheeses	Yes	gouda styles, most cheddars, dry jack, Swiss (Emmentaler) styles, Gruyere styles, many “tomme” styles and Parmesan styles
Blue cheeses	Yes	French (roquefort), Italian (gorgonzola) and Danish blue styles
Pasta Filata cheeses	No	Italian style Mozzarella, Provolone, and Scamorza
Natural or washed rind cheeses	Yes	French Tomme de Savoie and Mimolette, as well as the English Stilton (also a blue), and Lancashire cheeses (natural); Epoisses, Livarot and Taleggio (washed)
Processed cheeses	Not applicable	American Cheese, processed cheese spreads, and “cheese flavored” spreads.

Regulation of Raw Milk Cheeses in Other Countries

Canada regulates cheeses made from raw milk similar to the US, except for Quebec where raw milk cheeses can be manufactured without 60-day aging if strict rules for milk quality and veterinary inspections of cattle herds are followed. In 1996, following an outbreak of *E. coli* O157:H7 linked to cured Gouda cheese, Health Canada proposed a ban on all raw milk cheeses, but the initiative was defeated by industry and consumer groups (Honish 2005).

The European Union has no aging rule, but their requirements for hygiene during milking, storing, and collection of milk for cheesemaking are likely much stricter than in the US. Additionally, requirements for both animal health and worker/personnel health help ensure safe raw milk cheese production. Cheeses made from raw milk in Europe must be labeled “Made with Raw Milk.”

The regulation of raw milk cheeses in Australia and New Zealand has been an area of intense controversy in recent years. Australia bans all domestic raw milk cheeses, but allows importation of certain cheeses—Roquefort, Gruyere, Sbrinz, Emmental—from Europe and Switzerland provided they are aged 90 days and meet European safety standards (Standard 4.2.4A). Domestic cheeses must be “thermised” by using a low temperature heat treatment followed by aging for 90-days.

Epidemiology

The epidemiology of cheese-related outbreaks has changed in the US since the 60-day aging rule was established in 1950. The studies conducted in the 1940’s that presumably provided the basis for the rule were based on diseases such as Typhoid fever, an infection transmitted by human carriers. Today, most of the cheese-linked illnesses are due to zoonotic enteric pathogens carried by ruminants including *Campylobacter*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*. *L. monocytogenes* is also a ubiquitous inhabitant of the dairy environment. Table 2 shows some of the major pathogens that may survive in cheese even after aging.

Internationally, dairy-related outbreaks are relatively uncommon in developed countries, but an estimated 11.8% are attributed to cheeses made from raw milk (FSANZ 2006). Foodborne disease outbreaks have been reported in all countries that allow raw milk cheese including France where raw milk cheeses are popular (Desenclos 1996; Desenclos 1996; DeValk 2000; Dominguez 2009; Haeghebaert 2003; Ostyn 2010). The most recent published review in the US examined reported cheese-related outbreaks and illnesses from 1973 – 1992 (Altekruse 1998). Fresh Mexican-style cheeses (for example, queso fresco) were the most frequently implicated vehicle and caused 56 of the 58 deaths described in the review; the other 2 deaths were linked to improper pasteurization of Mozzarella cheese.

Table 2. Bacterial pathogens that can survive in cheeses aged for 60 days.

Organism	Incubation	Duration of illness	Signs and symptoms	Comment
<i>Brucella</i> spp.	1-2 months or longer	May relapse for years	Fever, headache, joint pain, depression, weight loss	Cause of abortions in dairy animals
<i>Campylobacter</i>	2-5 days	2-7 days; some patients develop paralytic syndrome as a long-term complication	Diarrhea (sometimes bloody), cramps, fever, nausea, vomiting, muscle aches	Found in health dairy animals
<i>E. coli</i> O157 and other pathogenic <i>E. coli</i>	2-8 days	5-8 days; some patients develop kidney disease or other long-term complications	Diarrhea (often bloody), cramps, sometimes low-grade fever	Found in healthy dairy animals
<i>Listeria monocytogenes</i>	3 – 70 days (average 3 weeks)	Variable depending on susceptibility; Death rate in patients with meningitis as high as 80%; septicemia as high as 50%	Septicemia, meningitis, intra-uterine infections in pregnant women with spontaneous abortions and stillbirths	Found in healthy dairy animals and the dairy processing environment
<i>Mycobacterium bovis</i>	4 - 12 weeks to positive tuberculin test; 1-2 years for systemic infection	Years; may persist lifetime as latent infection	Pulmonary and extra-pulmonary disease	Systemic illness in cattle; transmitted through milk and aerosols
<i>Salmonella enterica</i>	6 – 48 hours	2-8 days; some patients develop long-term complications including arthritic disease	Diarrhea, nausea, vomiting, cramps fever	Some strains cause illness in dairy animals
<i>Salmonella typhi</i>	8 - 14 days	Variable; case fatality of 10-20% without	Fever, cramps, diarrhea, anorexia	Human carriers

		antibiotic treatment		
<i>Staphylococcus</i> enterotoxin	2-4 hours	1-3 days	Vomiting, nausea, cramping	Animal and human carriers; toxin produced following growth in a food

The problem with fresh, soft cheeses is ongoing and most often associated with use of inadequately pasteurized milk and cross-contamination in the processing environment (CDC 2000; CDC 2001; CDC 2008; CDC 2009; Cody 1999; MacDonald 2005; Villar 1999). *Listeria monocytogenes* and *Salmonella* are pathogens most often found in fresh Mexican-style soft cheeses as reviewed previously (Marler, 2009). Over the last decade, there have been only two deaths from cheese made with raw milk; both occurred in 2003, and were due to consumption of contaminated fresh (un-aged) queso fresco Mexican-style cheese (CDC OutbreakNet).

In contrast, outbreaks and illnesses linked to 60-day aged cheese are relatively rare despite microbiological evidence of pathogen survival in these cheeses (Altekruse 1998; D'Amico 2008b; D'Amico 2010; Donnelly 1990; Jaros 2008; Reitsma 1996; Schlessler 2006). Researchers from the University of Vermont have speculated that the relative paucity of outbreaks and illnesses associated with 60-day aged cheese may be due to 1) a low contamination level in milk used for cheesemaking or 2) alterations in virulence of pathogens within the cheese matrix (D'Amico 2010).

However, there are notable exceptions including *E. coli* O157:H7 outbreaks linked to cured Gouda cheese in Canada in 2002 (Honish 2005) and the US in 2010 (CDC 2010). In the latter, at least 38 cases have been linked to consumption of Gouda cheese made with raw milk and presumably aged for 60-days in accordance with FDA regulations. The CDC summarized findings from the ongoing investigation in a November 24, 2010 report: <http://www.cdc.gov/ecoli/2010/cheese0157/index.html>

The Appendix at the end of this report summarizes reported cheese outbreaks during 2010. Since February, there have been 14 cheese-related events including 7 aged raw milk cheese recalls (4 from the same cheesemaker) with 38 illnesses linked to one plant in California; 1 raw milk cheese embargo in Minnesota; 5 recalls in 4 states due to contaminated commercial queso fresco and other soft Mexican-style cheeses made using pasteurized milk including 5 illnesses linked to a cheesemaker in Washington state; 1 imported pasteurized cheese recall; and at least 3 sporadic illnesses due to illegal Mexican-style cheeses. Six pathogens have been involved including *Brucella*, *Campylobacter*, *E. coli* O157:H7, *Listeria monocytogenes*, non-O157 shiga toxin-producing *E. coli*, and *Staphylococcus aureus*.

Microbiology

Johnson (2001) reviewed the microbiology of cheese products and noted the complexity of the subject because of the great diversity in cheese manufacturing and ripening protocols, as well as composition of the different cheese types. The 60-day aging rule is based on the theory that pathogens, if present, will die-off to levels below the infectious dose during the aging process. However, the effectiveness of this system depends on the initial microbiological quality of the milk and other ingredients used, and the hygienic practices used during cheese processing (Donnelly 1990). No amount of curing or aging or even pasteurization will compensate for poor quality milk or lack of hygiene during manufacturing and storage.

The intrinsic properties of the cheesemaking process that affect pathogen survival and growth include:

- pH
- moisture
- salt content
- acidity
- temperature
- humidity
- redox potential
- cheese microbial flora including starter culture (microbial community)

Individually and in combination, these factors can have significant impacts on whether a foodborne pathogen survives or grows in cheese during curing. The effectiveness of these natural processes is ultimately dependent on the initial contamination level of the cheese. A high inoculum of a pathogen, especially one with a low infectious dose, will overwhelm these control systems. The soft and semi-soft surface-mold-ripened cheeses are at the greatest risk of contamination due to their higher pH and moisture content (D'Amico 2008a).

The presence of pathogens in milk used for production of raw milk cheeses represents a risk for consumers. Oliver (2009) reviewed the literature on pathogen prevalence in US bulk tank milk and found these levels.

- *Campylobacter*: 2 – 9.2%
- *E. coli* O157:H7: 0 - 0.75%
- *Listeria monocytogenes*: 2.8 - 7.0%
- *Salmonella* spp: 0 – 11%
- Shiga-toxin *E. coli*: 2.4 - 3.96%
- *Yersinia enterocolitica*: 1.2 – 6.1%

D'Amico (2008b and 2010) surveyed milk used to produce small-scale farmstead cheese in Vermont and found an overall low level of contamination, but documented variations from

farm-to-farm indicating that some operations practice strict hygienic controls while other need improvement in their food safety practices.

Experimental studies of the behavior of pathogens in aged cheese show mixed results (Park 1970; Park 1973; Frank 1977; Bachmann 1995; Back 1993; D'Amico 2008a; D'Amico 2008b; D'Amico 2010; Govaris 2002; Marth 1969; Reitsma 1996; Schlessner 2006). The studies are difficult to compare because of different experimental methods, and variations in how the cheese was manufactured for the experiments. For example, Reitsma (1996) found viable *E. coli* O157:H7 in cheddar cheese at 158 days, but used pasteurized milk in their comparisons. Schlessner (2006) inoculated cheddar cheese with a 5-strain *E. coli* O157:H7 cocktail and demonstrated an inadequate reduction at 60 days (1 log) and 120 days (2 logs); in contrast, heat treating the milk resulted in a 5-log reduction. D'Amico (2010) examined the behavior of *E. coli* O157:H7 in aged Gouda and stirred-cured cheddar cheeses manufactured from raw milk and was able to recover viable cells for more than 270 days in both cheese types using selective enrichment.

Listeria monocytogenes can be a pervasive problem in the dairy processing environment. There is evidence that *L. monocytogenes* can survive aging in both pasteurized and surface-mold-ripened cheeses if the pathogen is introduced post-processing (D'Amico 2008b). These findings underscore the importance of hygienic practices at cheesemaking facilities regardless of pasteurization status. D'Amico (2008a) provides a more comprehensive review of experimental studies using different pathogens and cheese types.

Producing Cheese Safely

Unlike fluid raw milk producers who have been the subject of intense conflict with regulators for many years, artisanal and specialty cheesemakers that use raw milk have maintained a relatively good relationship with state and FDA regulators in the US. According to their website, the [American Cheese Society](#) (ACS) shares resources to help producers adequately prepare for audits and inspections and work collaboratively with state regulators and the FDA. The recent increase in FDA inspections and *Listeria* testing of soft cheeses and cheesemaking facilities has no doubt caused tensions between cheesemakers and regulators. [The New York Times reports](#) that FDA inspectors visited 102 facilities beginning in April 2010, including both large and small cheesemakers. They found *Listeria* in the facilities of 24 cheesemakers and more than half were small, artisan-scale operations.

While these findings are a cause for concern and have resulted in at least one major recall, fortunately, cheesemaking associations such as the ACS have an infrastructure to address food safety. For example, the ACS advises their members to:

- take part in ongoing food safety education
- follow a HACCP plan

- regularly conduct their own product and environment testing
- maintain accurate and up-to-date records
- seek third party certification
- build relationships with local regulators

Conclusions

Artisanal raw milk cheeses are distributed around the world and revered by fans for their unique sensory characteristics, as well as the art and tradition of making these cheeses. Cheeses, especially fresh and soft or semi-soft styles, are susceptible to contamination with pathogens such as *Campylobacter*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*. Countries where raw milk cheeses are popular take different approaches in their regulations. Experimental and epidemiological evidence suggests that the 60-day aging rule used in the US and Canada is not a fail-safe approach to cheese safety, which has prompted the FDA to re-evaluate the efficacy of the rule and conduct a national survey of cheesemaking facilities.

There are at least four potential outcomes that may result from FDA's recent actions: 1) a ban on all cheeses made from raw milk, 2) an extension of the 60-day aging period to 90-days or longer depending on evidence from the literature, 3) adoption of a European-type approach with intense regulation of animal health and hygiene during processing, but no aging rule, or 4) no change in the 60-day aging rule in the US.

While the future of the 60-day aging rule for cheeses made from raw milk in the US remains to be determined, the openness of cheesemakers to working with state and federal regulatory agencies will hopefully foster a science-based approach to cheese safety that both protects the public's health and preserves the unique characteristics and tradition of artisanal cheeses.

APPENDIX

Outbreaks, illnesses and recalls linked to cheeses made from raw (unpasteurized) and pasteurized milk, United States, 2010 (through November 2010)

Year	Month	Location	Pathogen	Number ill	Vehicle*	Comment	Reference (click on link)
2010	Feb	WA	<i>Listeria monocytogenes</i>	5	Queso fresco cheese	Pasteurized milk used to make the cheese	FDA

2010	Feb	WA	<i>Listeria monocytogenes</i>	0	Various raw milk cheeses	60-day aged raw milk cheeses from Montesano plant	FDA
2010	Mar	WA	<i>Listeria monocytogenes</i>	0	Tomme raw milk cheese	Expanded recall of 60-day aged raw milk cheeses from Montesano plant	FDA
2010	Apr	WA	<i>Listeria monocytogenes</i>	0	Queso fresco cheese	Pasteurized milk used to make the cheese; recall with no illnesses reported	FDA
2010	May	NV	<i>Campylobacter</i>	1	Illegal Mexican-style cheese	Type of milk used to make the cheese unknown	Washoe
2010	May	MN	Shiga toxin-producing <i>E. coli</i>	0	Raw milk cheese	Non-O157 found in dairy's embargoed cheese during raw milk outbreak investigation	MDA/MDH

2010	Jun	DE	<i>Brucella</i> and <i>Listeria monocytogenes</i>	2	Raw dairy products including cheese	Two separate incidents	DE DHHS
2010	Jul	PA	<i>Staphylococcus aureus</i>	0	Raw milk hard cheddar cheese	60-day aged cheese; recall with no illnesses reported	PDA
2010	Jul	NY	<i>Listeria monocytogenes</i>	0	Queso fresco cheese	Pasteurized milk used to make the cheese; recall with no illnesses reported	NY AGMKT
2010	Aug	RI	<i>Listeria monocytogenes</i>	0	Queso fresco cheese	Pasteurized milk used to make the cheese; recall with no illnesses reported	RI DOH
2010	Aug	Multiple	<i>Listeria monocytogenes</i> and <i>Staphylococcus aureus</i>	0	Raw milk Cheese	60-day aged raw milk cheese from plant in Missouri; recall with no illnesses	MO AG

2010	Sep	WA	<i>Listeria monocytogenes</i>	0	Raw milk cheeses	Expanded recall of 60-day aged raw milk cheeses from Montesano plant	FDA
2010	Oct	WA	<i>Listeria monocytogenes</i>	0	Raw milk cheeses	Expanded recall of 60-day aged raw milk cheeses from Montesano plant	US AG
2010	Nov	AZ, CA, CO, NM, NV	<i>E. coli</i> O157:H7 and <i>Listeria monocytogenes</i>	38	Raw gouda cheese; other cheeses	60-day aged gouda; <i>E. coli</i> outbreak linked to Costco "Cheese Road Show;" recall expanded to all company cheeses on 11/17/10; no <i>Listeria</i> illnesses reported	CDC

2010	Nov	CO	<i>E. coli</i> O157:H7	0	Gorgonzola cheese	Cheese imported from Italy, made from pasteurized milk; no illnesses reported	FDA
2010	Nov	WA	<i>Listeria monocytogenes</i>	0	Fresh (Queso and ricotta) Mexican-style cheeses	Made from pasteurized milk; no illnesses reported (previous recall from same plant in April 2010)	FDA

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