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| Citation | Origins of the Regulation of Raw Milk Cheeses In the United States (2005 Third Year Paper) |
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Origins of the Regulation of Raw Milk Cheeses

In the United States

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Class of 2005

April 26, 2005

**This paper is submitted in satisfaction of the Food and Drug Law course paper and the
Written Work Requirement at Harvard Law School.**

ABSTRACT

Artisanal cheese constitutes a subcategory of specialty cheese whose manufacture is characterized by its small scale, limited volume production, and individualistic producers. In recent years, artisanal cheese has been the fastest growing sector of the dairy products industry. This value-added product enables small dairy farmers to survive in the modern economy. The industry's success has been limited by federal regulations which essentially require the use of pasteurized milk in all cheeses that are not aged for 60 days at temperatures not less than 35 degrees Fahrenheit. Although states retain the authority to permit all raw milk cheeses to be sold in intrastate commerce, very few have chosen to do so. As a result, U.S. artisanal cheese-makers, unlike their European counterparts, cannot sell fresh raw milk cheeses and have been confined to making hard, aged cheeses. At present, the Food and Drug Administration is reviewing the safety of raw milk aged cheeses, threatening to halt the growth of the entire industry. This paper explores the origins of federal and state regulations affecting cheese in order to demonstrate that they were devised to suit the needs of large-scale manufacture rather than artisanal production. It explains the success of artisanal cheese movement in terms of postmodern consumer theory and recommends that state governments should act to protect and encourage the production of raw milk cheeses for intrastate sale.

INTRODUCTION

There are currently at least 350 artisanal cheese-makers in the United States. Virtually all have appeared since 1980.¹ Artisanal cheese constitutes a subcategory of specialty cheese whose manufacture is characterized by its small scale, limited volume production, and individualistic producers. In contrast, so-called specialty cheese can be produced by large-scale manufacture in industrial creameries, of which Cabot Creamery Cooperative is the most famous example in the United States. One out of every ten pounds of cheese eaten nationally is specialty cheese, and production of specialty cheese in the United States has grown five times faster than total cheese production in recent years.² Although it is difficult to estimate the dollar value of the U.S. market for artisanal cheese, there is no doubt that it is a small, yet growing, sector of the dairy products industry.

According to shop owners who sell specialty cheese, the shift away from more industrialized products is partly due to the fact that [p]eople like to know they're supporting small farmers.³ The small dairies which produce artisanal cheese, and often also raise the animals which provide the milk, are located across the country.⁴ Existing cheese centers such as California and Vermont are not alone in enjoying this new micro-industry – for example, cheese has recently been called Kansas' newest value-added product...one of its fastest growing, bringing in revenue not only from sales of cheese but from agritourism as well.⁵ Moreover, the growing interest in artisanal cheese must be compared to the American wine revolution a few decades

¹Colman Andrews, *In Praise of American Cheese*, SAVEUR, Apr. 2005, at 49. If there were any true artisanal cheese producers in American prior to 1980, though, they operated on such a small scale as to be all but invisible. *Id.*

²Roberta Strickler, *Indulge; Artisan Cheese (Handcrafted and Made in Small Batches) Offers Smooth, Deep Flavor*, LANCASTER INTELLIGENCER JOURNAL, Mar. 16, 2003 (citing California Milk Advisory Board).

³Ann Hackworth, *Cheese Course*, ROANOKE TIMES, Feb. 25, 2005, at Extra 1.

⁴Andrews, *supra* note 1, at 68.

⁵Phyllis J. Griekspoor, *State Churns Out More Cheese – Two Cheesemaking Factories, In Potwin and Alma Are Seeing Their Business Grow*, THE WICHITA EAGLE, Dec. 5, 2004, at C1.

ago. Artisanal cheese has a similar appeal to fine wine in that its taste is determined by a host of natural variables and a plethora of traditional production methods.⁶

Are American consumers prepared to pay a premium for domestically produced artisanal cheese? They certainly appear to be. And, with many European cheeses exceeding \$30 per pound (an exorbitance only exacerbated by the current exchange rates), domestic producers have little trouble keeping their prices competitive with comparable products.⁷

In the United States, artisanal cheese production is subject to exactly the same federal regulations which affect massive, industrial manufacture in factories owned by Cabot or Kraft. Since 1949, the Food and Drug Administration (FDA) has employed standards of identity (codified at 21 C.F.R. §133) which effectively prevent the manufacture, for sale in interstate commerce, of any cheese made from unpasteurized milk (i.e. raw milk), unless such cheese has been aged for at least 60 days at temperatures not less than 35° F.⁸ In 1987, the FDA reiterated the ban on the interstate sale of all unpasteurized milk products (including cheese) which do not comply with the aging requirement of 21 C.F.R. §133, and declined to extend the prohibition to intrastate sales of milk products because it was deemed unnecessary to effect the interstate ban of 21 C.F.R. §1240.61.⁹ Laws and regulations governing intrastate cheese sales and manufacturing were gradually adopted during the second half of the 20th century, and states have almost uniformly chosen to follow federal guidelines.

⁶Hackworth, *supra* note 3, at Extra 1.

⁷Janet Fletcher, *Cheddar on the Cheap Tastes That Much Better*, SAN FRANCISCO CHRONICLE, Sept. 16, 2004, at F3.

⁸21 C.F.R. §133 (1949).

⁹21 C.F.R. §1240.61 (1987).

As a result of federal and state regulations, the United States artisanal cheese industry has grown through production of (1) soft cheeses made from pasteurized milk and (2) hard, aged cheeses made from raw milk. Hard, aged American cheeses are now of such fine quality that cheese expert Steve Jenkins has asserted that 100 percent of the time customers will choose the American artisanal cheese when it is contrasted with the European counterpart.¹⁰ The trouble, however, is that American soft artisanal cheeses must be made from pasteurized milk, and, as expert Max McCalman maintains, the process eliminates most of the desirable flavors, textures, and aromas.¹¹

The use of raw milk, however, comes with safety concerns which have been greatly debated in the United States and in Europe in recent years. Pasteurization kills bacteria which may be present in milk prior to the manufacture of cheese, although the process does nothing to ensure that cheese will not thereafter become contaminated. On March 14, 2005, the FDA issued a health advisory concerning consumption of soft, unaged cheeses made from raw milk.¹² Although these cheeses are illegal and cannot be imported into the United States, one infant has died and dozens of New Yorkers have contracted tuberculosis from 2001 through 2004 by eating queso fresco received from family and friends who traveled to Mexico.¹³ These cheeses were contaminated with *Mycobacterium bovis*, a tuberculosis organism primarily found in cattle.¹⁴ In the case of the dangerous queso fresco, diseased cattle produced milk which was used in unaged cheese. If the milk had been pasteurized prior to curdling, the final product would have been safe, assuming no later contamination by another pathogen. If the milk had not been pasteurized but instead had been used to produce an aged

¹⁰Andrews, *supra* note 1, at 51 (quoting Steve Jenkins, author of *Cheese Primer* and cheese purchaser for New York City's Fairway market).

¹¹MAX MCCALMAN & DAVID GIBBONS, *THE CHEESE PLATE* 4 (2002). McCalman is the *maitre fromager* for the restaurants Picholine and Artisanal in New York City.

¹²FDA Statement, *FDA Issues Health Advisory About Certain Soft Cheese Made From Raw Milk*, March 14, 2005, at 1, available at <http://www.fda.gov/bbs/topics/news/2005/NEW01165.html> (last visited Apr. 18, 2005).

¹³Marc Santora, *Tuberculosis Cases Prompt Warning on Raw-Milk Cheese*, *THE NEW YORK TIMES*, Mar. 16, 2005, at B4.

¹⁴*Id.*

cheese, the final product would have been safe because pathogens would have died over time. Although *Mycobacterium bovis* and many other pathogens have largely been eradicated from U.S. cattle,¹⁵ the FDA advises that there is some risk of infection from a number of pathogenic bacteria from anyone who eats raw milk soft cheese from any source.¹⁶

Many Europeans disagree. In the European Union, producers are free to sell both fresh and aged raw milk cheeses, and safety is assured through stringent sanitation standards and dairy inspections. These are administered by each Member State along the principles of Hazard Analysis and Control Points (HACCP) – ironically, a set of principles developed by the United States.

This paper explores how economic, regulatory, and cultural forces in the United States have shaped the artisanal cheese industry over the course of the 20th century. Part I explains the science and history of pasteurization techniques and presents empirical evidence of differences in taste and smell of cheeses made from pasteurized and from raw milk. Part II explores the history behind municipal and state regulation of pasteurization of fluid milk in order to show how the real threat of fluid raw milk attached a cultural importance to pasteurization in America which was later extended to cheese production. This section then presents a regulatory history of cheese production in the United States at the federal and state levels, aimed at demonstrating that regulations were adopted at times when there was no actual production of artisanal cheese in this country. As a result, current regulations reflect the legitimate safety concerns associated with large-scale manufacturers such as Cabot and Kraft, rather than the different concerns which should exist for

¹⁵Id.

¹⁶FDA Statement March 14, 2005, *supra* note 12 at 1.

small artisanal producers. Part II finishes with a summary of recent challenges to existing regulations which have resulted in the FDA's ongoing study of whether a 60-day aging requirement for unpasteurized cheeses is adequate to protect consumers. This government research threatens the future imposition of a total ban on raw milk cheese production. Part III examines trends in cheese consumption in the United States over the past century and analyses the growing market for artisanal raw milk cheese as a phenomenon of postmodern consumerism. This part also offers a description of the French cheese economy and shows how raw milk and pasteurized-milk cheeses can coexist as components of an industry which thrives both domestically and in export markets. Part III finishes with a summary of the European Union's debate over the safety of raw milk cheese. In conclusion, this paper offers substantive recommendations for state and federal regulators who have meaningful control over the expansion and direction of a small but viable industry.

The purpose of this paper is not to advocate the use of pasteurized or unpasteurized milk in the production of cheese, or to debate the safety of raw milk products. Instead, it demonstrates that existing U.S. regulations are largely the result of historical accident and do not reflect detailed federal or state analyses of the safety risk associated with raw milk cheese. This paper explores the growing market for raw milk cheese products and argues that the potential for the re-emergence of small dairy farmers and artisanal cheese producers at least justifies the government expense of a cost-benefit analysis concerning the safety of all raw milk cheeses. In the words of Paul S. Kindstedt, professor of Nutrition and Food Sciences at the University of Vermont, [r]aw milk cheeses are worth saving. They are a distinct value-added product niche. Because they provide a high return on investment, they are able to sustain agriculture in a form that is rapidly disappearing – the small farm.¹⁷

¹⁷Id. at 38 (quoting Paul Kindstedt).

PART I

What is pasteurization?

It is hard to ignore the irony that France, the country which produces the greatest variety of raw milk cheeses and is most vocal in advocating their safety, was also home to Louis Pasteur (1822-1895), creator of the pasteurization process. The irony is less terrible when one remembers that the immediate application of Pasteur's work in microbiology was to improve the preservation of beer, wine, and vinegar.¹⁸ Nonetheless, this French genius became the father of microbiology and developed the pasteurization technique which now dominates American production of cheese.

Pasteur's research began with the question: *what does fermentation consist of?*¹⁹ Almost immediately, Pasteur realized that fermentation was a term that had been loosely applied to three different processes: (1) *alcoholic fermentation* – the production of alcohol, such as during the manufacture of liquors such as wine, beer, or cider; (2) *acetic fermentation* – the transformation of an alcoholic liquor into vinegar; and (3) *lactic fermentation* – the conversion of the sugar in milk into acids.²⁰ This last process results in the souring of milk. Until Pasteur proved otherwise, scientific opinion concurred that lactic fermentation was a purely chemical reaction without any biological explanation.

¹⁸HILAIRE CUNY, LOUIS PASTEUR: THE MAN AND HIS THEORIES 19 (1963).

¹⁹Id. at 74.

²⁰Id. at 77-78.

In its most simple form, Pasteur's theory was that the transformations of organic matter are carried out through the agency of microorganisms.²¹ He found that all forms of fermentation rely on the help of microorganisms which are responsible for the secretion of certain enzymes. Enzymes are biocatalysts, meaning that these substances can accelerate (or initiate) chemical reactions without affecting the nature of the products resulting from the reaction and without being changed themselves.²² In the case of milk, the chemical reaction is the breakdown of sugar molecules and the microorganisms responsible are lactic acid bacteria, the most important of which is *Lactobacillus lactis*.²³

Entries in Pasteur's notebook indicate that he had begun research into fermentation as early as 1855.²⁴ Although he would focus the majority of his attention on alcoholic fermentation, his first paper on fermentation, presented to the scientific community in August 1857, dealt with lactic fermentation.²⁵ Historians have explained Pasteur's initial focus on lactic fermentation as a necessary first battle against the established theory that all fermentations were purely chemical.²⁶ Although earlier scientists had considered the presence of yeast in alcoholic fermentation, they had incorrectly concluded that this living organism was not responsible for the transformation into liquor because yeast was not present in the other two types of fermentation. If Pasteur could demonstrate that lactic fermentation resulted from the agency of another microorganism, he could collaterally attack conventional wisdom and reopen scientific debate on the causes of alcoholic fermentation.²⁷

²¹RENÉ J. DUBOS, LOUIS PASTEUR: FREE LANCE OF SCIENCE 158 (1950).

²²CUNY, *supra* note 18, at 75-76.

²³Other bacteria which aid in the production of lactic acid include: *Leuconostoc mesenteroides*, *Pediococcus cerevisiae*, *Streptococcus lactis*, and *Bifidobacterium bifidus*.

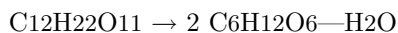
²⁴DUBOS, *supra* note 21, at 125.

²⁵*Id.*

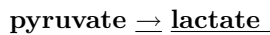
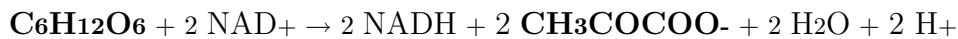
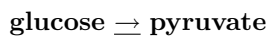
²⁶*Id.* at 126.

²⁷*Id.*

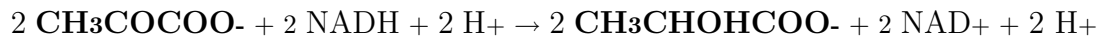
Furthermore, lactic fermentation is the simplest form of fermentation. Like the other two forms, the process is rather counter-intuitively named for its product – lactic acid. Fermentation begins with lactose, the sugar which makes up 2-8% of the solids in milk. Lactose (C₁₂H₂₂O₁₁) is a disaccharide consisting of two subunits, a glucose and a galactose linked together. Glucose (C₆H₁₂O₆) and galactose (C₆H₁₂O₆) are molecularly identical except in the position of an OH- ion on the fourth carbon atom. As a result, lactose chemically reacts as two glucose molecules:



The breakdown of glucose is generally known as glycolysis, and fermentation is termed anaerobic glycolysis because the breakdown occurs without the presence of molecular oxygen. During the process of fermentation, each glucose molecule is broken down into two molecules of pyruvate, which are then converted to two molecules of lactate.



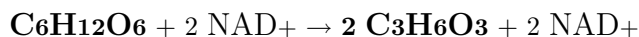
(enzyme = lactate dehydrogenase)



Nicotinamide adenine dinucleotide (NAD⁺) is present at both ends of the reaction because it acts as an intracellular oxidizing agent (i.e. as an electron acceptor).²⁸ The enzyme, lactate dehydrogenase (LDH), catalyzes the conversion of pyruvate and lactate along with the co-enzyme NAD⁺. Strains of *Lactobacilli* and other lactic acid bacteria are responsible for the secretion of the enzyme lactate dehydrogenase. The final product is lactic acid, shown in the equation above as lactate molecules held in solution with hydrogen ions.

²⁸Basically, NAD⁺ is converted to NADH in the formation of lactate and then reconverted to NAD⁺:
 NAD⁺ + 2 H⁺ + 2 e⁻ → NADH + H⁺ (e⁻ is an electron)
 ... followed by ...
 lactate + NADH → lactic acid + NAD⁺

The two-step conversion of milk sugar into lactic acid can be summarized in one equation as follows:



Lactic acid itself is a syrupy, colorless fluid with a sour taste and strong acid reaction. The protein in milk (mostly casein) is coagulated by lactic acid; this curdling permits the extraction of solids from whey in the process of cheese-making.

Pasteur's discovery that bacteria played a role in the production of lactic acid held important implications for food science. The presence of anaerobic life suggested that the speed of the fermentation process could be controlled by affecting the functioning of the microorganisms – in order to preserve fluid milk, curdling could be slowed by killing bacteria, and in order to produce cheese, curdling could be hastened by introducing bacteria cultures.

Heating milk proved to be the most effective technique for killing bacteria. When every particle of milk is heated to at least 145° Fahrenheit for not less than 30 minutes and then promptly cooled, virtually all bacteria contained in milk are destroyed.²⁹ This technique is termed pasteurization, and the FDA has prescribed higher temperatures to which milk may be heated for shorter periods of time.³⁰ Even with a drastically

²⁹International Dairy Foods Association, Pasteur, available at <http://www.idfa.org/facts/milk/pasteur.cfm> (last visited Apr. 20, 2005).

³⁰21 C.F.R. §1240.61(b) (1987).

reduced bacteria population, some small amounts of the enzyme lactate dehydrogenase will be secreted over time, and lactic acid fermentation will eventually occur in milk. Furthermore, although pathogenic bacteria are killed during pasteurization, recontamination of treated milk remains a danger. Refrigeration helps to slow curdling as well as to slow the growth of any pathogens which reach the product after pasteurization. Only ultra-pasteurization (heating to at least 280°F. for not less than 2 seconds) followed by immediate vacuum sealing can create a product with a shelf life of many weeks, and even ultra-pasteurized milk must be refrigerated once opened.³¹

How does pasteurization affect cheese production?

In the United States, where cheese must be made from pasteurized milk unless it is aged for more than 60 days at temperatures not less than 35° F., consumers cannot legally obtain soft, fresh cheeses such as brie or camembert which are made from raw milk and not aged. In contrast, hard cheeses such as cheddar and asiago can be prepared from raw milk and aged by methods identical to those used throughout Europe. The effect of requiring pasteurization of milk used in soft cheese is that lactic acid fermentation takes place after pasteurization. Nearly all the bacteria – both harmless and pathogenic, if any – present in the raw milk are killed, and starter bacterial cultures must be introduced post-pasteurization to induce curdling. In large-scale factory production of cheese, this is desirable because it permits a high level of control over the timing and degree of curdling, ensuring homogeneity among batches of cheese (i.e. quality consistency).

³¹As an interesting irony is that in France, where raw milk cheese is so popular, almost all milk for sale in a supermarket is ultra-pasteurized.

There are several negative effects of pasteurization. First, the bacterial cultures introduced post-pasteurization may not reflect the diversity of microorganisms naturally occurring in the milk. Microbial diversity will depend on factors such as climate, environment, and animal diet – these will vary with time of year, locations, and an infinite array of other factors. Second, if milk is left unpasteurized, the lactic acid produced by the breakdown of milk sugar automatically kills most varieties of pathogenic bacteria. Although the advantage of pasteurization is that it indiscriminately kills *all* varieties of bacteria (pathogenic or not), the death of non-lactic acid bacteria during fermentation of raw milk affects the nature of the curdling process. Third, heat denatures certain proteins and amino acids found in raw milk, and this effect cannot be repaired post-pasteurization. In Europe, food scientists debate whether these three undeniable effects alter the flavor and odor of fresh or unaged cheeses.

How does pasteurization affect organoleptic properties of cheese?

Cheese enthusiasts often resort to anecdotal evidence in describing the difference between the taste and smell of pasteurized and unpasteurized cheeses. In a *New Yorker* article, writer Burkhard Bilger depicted in colorful terms his comparison tasting experience alongside expert Max McCalman:

McCalman reached over and cut wedges from two Reblochon-style cheeses, one of pasteurized milk, the other of raw. We had done a few of these comparisons already, with the pasteurized invariably tasting milder, gummier, and less complex. But this time the difference was more elemental. The pasteurized version wasn't bad, with its musty orange rind and rich ivory pate. But the raw-milk Reblochon seemed to bypass the taste buds and tap directly into the brain, its sweet, nutty, earthy notes rising and expanding from register to register, echoing in the upper palate as though in a sound chamber. I thought of something one of the founders of the Cheese of Choice Coalition had said when I asked her what difference raw milk could possibly make: One is a cheese; the other is an aria by Maria Callas.³²

Even outside the realm of overblown literary depictions in magazines, there is abundant empirical, albeit European, evidence of how pasteurization affects the taste of cheese.

In 1998, six European laboratories across Switzerland, France, Sweden, Norway, and the United Kingdom collaborated to test the differences in the chemical, sensory, and microbiological properties of model cheeses produced from pasteurized and unpasteurized milk.³³ The experiments revealed that pasteurization, which reduces the natural milk flora and indigenous enzymes of raw milk, influenced “the microbial flora, extent of proteolysis, levels of D-lactate, some volatile fatty acids, and the sensory properties of the mature model cheese.”³⁴ Furthermore, the post-pasteurization addition of *Lactobacillus casei* to pasteurized milk cheese did not restore the properties of a raw milk cheese.³⁵ A later study by unaffiliated researchers confirmed these results, and extended the trials to significantly older model cheeses (aged over 120 days).³⁶ It was found that pasteurization generally resulted in lower amounts of D-lactate, lower amounts of some volatile fatty acids, and higher amounts of certain amino acids.³⁷ The researchers concluded:

It has been shown that the microbial flora of cheese made from raw milk comprises activities that were different from those in the cheese from pasteurized or microfiltered milk by analysis of biochemical components during ripening. . . The results clearly indicated a relationship between the activities of the microbial flora, the biochemical composition, and the flavor intensity. Flavor intensity was greater in cheeses from raw milk for the notes animal, lactic sour, and spicy.³⁸

In 2002, research by yet another unaffiliated group revealed similar differences among model cheeses prepared from pasteurized and unpasteurized *goat* milk, demonstrating that the effects of pasteurization on chemical

³³H.P. Bachmann et al., *Interlaboratory Comparison of Cheese Making Trials: Model Cheeses Made From Raw, Pasteurized and Microfiltered Milks*, *LEBENSMITTEL-WISSENSCHAFT UND-TECHNOLOGIE*, Volume 31, 585-93 (1998).

³⁴*Id.* at 586.

³⁵*Id.*

³⁶Siv Skeie & Yla Ardo, *Influence From Raw Milk Flora on Cheese Ripening Studied by Different Treatments of Milk to Model Cheese*, *LEBENSMITTEL-WISSENSCHAFT UND-TECHNOLOGIE*, Volume 33, 499-505 (2000).

³⁷*Id.* at 500-02.

and microbial composition were not unique to cow cheeses.³⁹ Although it does not appear that comparable research has been performed with *sheep* milk, there is little scientific basis to expect that pasteurization does not produce the same changes that are relevant to cheese-making.

In conclusion, the anecdotal testimony of cheese enthusiasts is supported by scientific literature examining the microbial and biochemical effects of pasteurization on flavor and odor. The mere fact that the major studies in this area are European reflects the relative cultural importance placed on raw milk cheese and stronger economic dependence on the artisanal cheese industry. The phenomena of differences in taste and smell, however, are not generally denied in the United States. Max McCalman, who selects cheeses for the restaurants Picholine and Artisanal in New York City, says that when diners at his restaurants ask him for brie, he politely informs them that he does not carry it because the only versions legally available in the United States are made from pasteurized milk.⁴⁰ In response to such complaints, the FDA produces a rather cagey cost-benefit analysis relating safety to the value of having lactic acid fermentation occur naturally:

[P]asteurization will destroy some bacteria that may be helpful in the fermentation of milk into products such as cheese and yogurt, but the benefit of destroying the harmful bacteria vastly outweighs the supposed benefits of retaining those helpful microorganisms. Plus, by adding the microorganisms that we need for fermentation, we can assure a consistently high quality product.⁴¹

In short, the FDA offers the response that consumers should make do with pasteurized-milk cheeses because they are safer. In doing so, the agency cannot resist lending credence to the Kraft cheese mentality that consistency is a virtue surpassing variety.

³⁹Martin Buffa, Buenaventura Guamis, Jordi Saldo & Antonio J. Trujillo, “Changes in Organic Acids During Ripening of Cheeses Made From Raw, Pasteurized, or High-Pressure Treated Goats’ Milk,” *LEBENSMITTEL-WISSENSCHAFT UND-TECHNOLOGIE*, Volume 37, 247-253 (2004).

⁴⁰McCalman, *supra* note [], at 71.

PART II

The rise of pasteurization of fluid milk

Current American attitudes toward the manufacture of cheese can only be fully understood against the historical background of how pasteurization virtually eliminated the death and disease resulting from fluid milk contamination. The well deserved priority given to the elimination of pathogens in fluid milk meant that state and federal regulators addressed this issue decades before they turned to regulations affecting cheese. As a result, the limited inquiry into the risks and benefits of raw milk cheese production partly reflect the comfort and appreciation which Americans attached to pasteurization in general.

Industrial pasteurization equipment became available after 1895.⁴² Because milk came from small producers and prices were often regulated, there were at first few financial incentives to purchase the apparatus necessary to improve consumer safety. It was not until the early 1920s that most large cities required that all except specially certified milk be pasteurized before sale.⁴³ As a result, in many parts of the country, small dairy farmers avoided the expense of the new machinery for another two decades.

For example, in 1912, *The Minneapolis Tribune* published an exposé of bacterial contamination in the city's milk supply and offered numerous suggestions for improvement – without even mentioning the possibility of pasteurization!⁴⁴ Unsafe milk was generally attributed to [l]aziness on the part of dairymen and their desire

⁴²International Dairy Foods Association, Dairy Facts 2003 Edition, at 4.

⁴³U.S. Department of Agriculture, *Milk and Its Uses in The Home*, FARMERS' BULLETIN 1207 (Aug. 1921), at 16

⁴⁴*Clean Milk*, THE MINNEAPOLIS TRIBUNE, Oct. 28, 1912, at 3.

to increase profits by cutting down operating expenses.⁴⁵ The remedy was imagined to be greater attention to cleanliness and sanitation, promising that [i]t is possible to prevent impurities getting to milk simply by exercising care.⁴⁶ Cleanliness was perceived of as a complete, and low-cost, solution:

Not one case [of disease] is unavoidable. If milk is handled in a sanitary manner, no such results will follow, and the complaint from some dairymen, that proper sanitation would put them out of business, is unfounded.⁴⁷

The motivation behind *The Minneapolis Tribune's* exposé was the city's municipal health ordinance, which addressed the cleanliness of distribution procedures within city limits but could not reach the country farmer. While the city could regulate the use of clean, capped, and labeled bottles to distribute milk, it could not ensure that the milk contained therein would be uncontaminated from the point of production. This demonstrated that without mandatory pasteurization ordinances, cities were unable to ensure the safety of their milk supply. In 1908, Chicago was the first city to require that all milk sold within its limits be pasteurized.⁴⁸

In cities which took longer to institute mandatory pasteurization, consumer advocates became suspicious of dairies which used pasteurization because the technique sometimes served as a way to forego safety and cleanliness in production.⁴⁹ Larger dairies were the first to afford pasteurization equipment – however, larger dairies also incurred greater costs in monitoring safe handling, exposed the milk to more human infectious sources, and derived their final product from a greater number of animals. As a result of simple economic forces, the dairies which first undertook the expense of pasteurization were often those which could not

⁴⁵Id.

⁴⁶Id. at 5.

⁴⁸International Dairy Foods Association, Dairy Facts 2003 Edition, at 4.

⁴⁹Mrs. William Lowell Putnam, The Women's Municipal League of Boston, *Care of Milk by the Consumer*, Jul. 10, 1923, at 1.

obtain state or municipal certification as clean establishments.

In Boston, prior to mandatory pasteurization, there existed such a divide between smaller, city-certified dairies which produced more expensive milk, and larger farms which pasteurized their cheaper product as an alternative to certified production.⁵⁰ In 1923, the Women's Municipal League of Boston instructed housewives to pasteurize all of their milk at home unless purchased from a state certified producer.⁵¹ This is much safer than buying pasteurized milk, for the pasteurization not only may not have been thoroughly done, but the milk may also have been kept too long afterwards.⁵² Far from being viewed as a safeguard of public health, pasteurization was viewed as a cost-cutting measure for dairies which avoided the stringent cleanliness requirements and inspections of certified producers.

Pasteurization was also treated with initial suspicion because one of its major purposes prior to 1910 was as a commercial expedient for preserving milk containing an excessive number of bacteria for a sufficient length of time to allow its transportation and sale.⁵³ The milk was not given true pasteurization because it was only expos[ed] to a momentary application of heat which varied from 120 degrees to 180 degrees Fahrenheit with no system of control.⁵⁴ This so-called flash pasteurization (also known as commercial pasteurization) destroyed lactic acid organisms and prevented souring, eliminating any signs of poor handling otherwise visible to any consumer without meaningfully ensuring safety:

⁵⁰Id.

⁵¹Id.

⁵²Id. at 5.

⁵³Russell Sturgis, Department of Health of the City of New York, *The Role of Dairy Inspection in Safeguarding a City's Milk Supply*, Jun. 1915, at 7.

⁵⁴Id.

Many mothers are cheated into the belief that they are getting a safe milk when they buy what is described as commercially pasteurized milk. Such milk should be labeled NOT Pasteurized. It is a humbug and a fraud, for it has not been pasteurized at all, but has been treated by a process that merely preserves the milk and keeps it from souring; it does not kill the disease germs. It does more harm than good, for it enables dealers to keep bad milk and to market it when it is old and stale.⁵⁵

Therefore, before 1910, partial pasteurization often served as a way to cut costs on by slowing down distribution and decreasing cooling during shipment, at the expense of consumer safety.⁵⁶

By the early 1920s, most cities came to the realization that control of the milk supply required both inspection of dairies and standardized, effective pasteurization. In 1915, the Department of Health of the City of New York wrote that pasteurization was necessary as an additional feature of prime importance [to inspection].⁵⁷ Nonetheless, in 1921, the federal government considered milk to be so dangerous that it continued to advise home pasteurization of *all* milk:

While efficient pasteurization destroys disease germs such as those of tuberculosis, diphtheria typhoid fever, and pathogenic streptococci, it should not be regarded as an insurance against future contamination, and as great care should be taken of pasteurized as of unpasteurized milk.⁵⁸

This warning reflected the reality that contamination of pasteurized milk remained a major threat during shipment, distribution, and even home storage.

As a result, in a 1921 pamphlet on the home pasteurization and safe storage of fluid milk, the U.S. Department of Agriculture recommended that Americans increase their consumption of cheese:

⁵⁶Cooling during shipment in this era was done by packing the milk with blocks of ice. See Sturgis, *supra* note 53, at 7.

⁵⁷*Id.* at 3.

Cheese, containing, as it does, almost all the protein and often most of the fat of the milk from which it is made, and having a comparatively low water content, is a very nutritious food, and the cheaper kinds may well be used more abundantly than is commonly the case in this country as part of the regular diet and not simply as a condiment at the end of a hearty meal.⁵⁹

The federal government's pamphlet on milk safety failed to mention whether cheese was such a safe substitute because it was made from pasteurized milk. At this time period, however, cheese was overwhelmingly made from pasteurized milk in the United States because production occurred in large factories. Since cheese-making was done in large batches, hundreds of gallons of milk had to be assembled at once before each round of production could begin. This practical consideration was simply incompatible with the use of unpasteurized milk coming from dozens of suppliers. The sheer quantity of milk mixed together meant that contamination by a single source would spread to vast quantities of otherwise safe milk.

Economic forces also conspired to dictate the pasteurization of milk used in cheese. As more cities adopted mandatory pasteurization for fluid milk and/or cleanliness inspections, dairy farmers who could not afford pasteurization equipment or were unable to comply with sanitation standards lost a market for their fluid product and were forced to sell to cheese and butter factories. In 1915, the Department of Health of the City of New York noted the unpleasant side effect of its own inspection and pasteurization program:

[T]here usually exists some nearby outlet as is offered by cheese or butter factories or even creameries shipping to cities with no inspection service whereby the excluded dairyman is able to obtain a market for his filthy and often dangerous product.⁶⁰

As a result, the increasing safety requirements for fluid milk meant that the milk shipped to factories for cheese production was of lesser quality. The incentive to pasteurize milk used to make cheese was therefore partly an economic side effect of regulatory pressure on dairies in the early 20th century. This subtle factor, combined with the obvious American gratitude for the virtual elimination of health risks from fluid milk,

help explain the nature of the regulations affecting cheese which emerged after 1949.

A regulatory history of cheese production

Until 1949, the United States did not regulate the pasteurization or aging of any variety of cheese.⁶¹ In fact, the FDA had promulgated standards of identity for only three varieties of cheese – cheddar, colby, and washed curd and soaked curd cheese.⁶² These few preexisting standards were essentially quality control measures dictating milkfat content and production methods and contained no reference to pasteurization or aging.⁶³ Historians disagree as to the motivation behind the sudden change in regulatory agenda that resulted in the modern requirement that cheeses either be produced from pasteurized milk or aged for not less than 60 days at temperatures not less than 35° F.⁶⁴ This section examines the U.S. regulatory history at the state and federal level. It concludes that because federal regulations affecting cheese were adopted in 1949 when there was no meaningful production of raw milk cheese in this country, the FDA conducted no actual assessment of the safety risks posed by raw milk cheese, or of alternate methods of safe production which could still avoid pasteurization. Subsequently, over the remainder of the 20th century, states largely followed the federal guidelines with no critical examination of the safety issue.

⁶¹Cheeses, Processed Cheeses, Cheese Foods, Cheese Spreads, and Related Foods; Definitions and Standards of Identity, Notice of Proposed Rule Making, 12 F.R. 1960, 1960 (Apr. 22, 1949) (to be codified at 21 C.F.R. § 19); Standards of Identity for Cheeses, Processed Cheeses, Cheese Foods, Cheese Spreads, and Related Foods, Notice of Hearing 12 F.R. 1191, 1192 (Feb. 21, 1947).

⁶²12 F.R. 1191 at 1192 and 1194.

⁶³Id.

⁶⁴Compare Corby Kummer, *Craftsman Cheese*, THE ATLANTIC MONTHLY, Dec. 1, 2000, at 109; Martha Ingram, *Raw Deal: Trade Implications of the U.S. Food and Drug Administration's Pending Review of Unpasteurized Cheeses*, 12 MINN. J. GLOBAL TRADE 461, 465 (2003); Andrews, *supra* note 1, at 49.

One historical interpretation is that the FDA's lack of concern prior to 1949 reflected the small scale of pre-World War II cheese manufacturing.⁶⁵ It has been claimed that prior to the wartime mobilization of the American food industry, cheese production resembled European practices in that manufacture was confined to smaller farms which drew on local milk supplies. According to this line of historical thought, pasteurization simply seemed unnecessary to U.S. authorities because the milk-safety dangers of mass industrialization – namely, exposure during interstate shipment and commingling of milk sources – did not yet exist. Once cheese manufacturing became a large-scale industrial process, the FDA instituted pasteurization and aging requirements to accommodate the new risks within the industry.

This simple and attractive historical explanation imagines the FDA as a highly responsive authority, acting swiftly to defeat the new safety risk presented by industrial manufacturing methods. This story has persisted among many cheese historians and enthusiasts. Unfortunately, the more accurate historical interpretation maintains that mass-produced, industrialized cheese was the American norm by 1900, indicating that the federal government waited through 50 years of factory production before regulating the cheese industry.

The real history of American cheese manufacturing reveals that by the turn of the twentieth century, “commercial farm production of cheese had all but died out.”⁶⁶ The dominance of farmstead cheese, manufactured on a farm from milk drawn from its livestock, declined rapidly after the Civil War.⁶⁷ The demise of farm production of cheese was so complete that the 1904 census only bothered to report factory output.⁶⁸ This development did not result from a newfound cultural aversion to farmstead cheese, but rather was an eco-

⁶⁵Kummer, *supra* note 64, at 109; Ingram, *supra* note 64, at 465.

⁶⁶Andrews, *supra* note 1, at 49. Andrews' sources for this conclusion were drawn from the U.S. Department of Agriculture's National Agricultural Library.

⁶⁷*Id.*

⁶⁸International Dairy Foods Association, Dairy Facts 2003 Edition, available at www.idfa.org/facts/cheese.cfm.

conomic effect of the technological advance of the railroad. Britain experienced precisely the same effect on its cheese industry: “Milk could now be delivered to . . . big-city markets in less than a day, meaning that farmers could dispense with the labor-intensive cheesemaking process and simply dispose of all their milk fresh for immediate consumption.”⁶⁹ Thus, the economic force of an emerging milk commodity market made the farmstead production of cheese unprofitable during the second half of the nineteenth century, and mass-produced, industrialized cheese was the norm by the beginning of the twentieth.⁷⁰ In fact, America shifted so quickly and effectively to industrial manufacture of cheese that Britain actually became a net importer of the cheaper American product during the nineteenth century.⁷¹ If indeed, the United States had adopted large-scale, industrial cheese production by 1900, why did the federal government wait until 1949 to institute pasteurization requirements?

One answer is that the federal government left regulation of the *milk* industry to the prerogative of state legislatures until the 1970s. Pasteurizing machines were introduced in 1895, and the first compulsory milk pasteurization law was enacted by the city of Chicago in 1908.⁷² By 1921, most large cities required that all except specially certified milk be pasteurized before sale.⁷³ In 1924, the United States Public Health Service developed the Standard Milk Ordinance (now called the Pasteurized Milk Ordinance), which served as a model regulation for states that wished to prevent the transmission of milk borne disease.⁷⁴ The federal pasteurization requirement for all milk traded in interstate commerce languished until 1973 (certified raw milk was finally banned in 1987).⁷⁵ The introduction of mandatory pasteurization in 1973 as part of the

⁶⁹MCCALMAN, *supra* note 11, at 11.

⁷⁰*Id.*

⁷¹*Id.*

⁷²International Dairy Foods Association, *Dairy Facts* 2003 Edition, at 4.

⁷³FARMERS’ BULLETIN, *supra* note 43, at 16.

⁷⁴To date, forty-six of the fifty states have adopted most or all of the Pasteurized Milk Ordinance, and the states which did not adopt it (California, Pennsylvania, New York, and Maryland) passed their own similar laws.

⁷⁵See Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 54 F.R. 22340, 22342 (Jun. 11,

revised standards of identity for milk and cream was almost an afterthought following the real debate over vitamin fortification, additives, and quality control – but only because state law already adequately addressed the health risk.⁷⁶

In contrast to the regulation of milk, the pasteurization and aging requirements for cheese originated with the federal government's standards of identity in 1949, and similar laws and regulations affecting intrastate commerce were gradually introduced throughout the remainder of the twentieth century. As noted above, until 1949, the FDA's regulation of the entire cheese industry was contained in three standards of identity – for cheddar, colby, and washed curd and soaked cheese – none of which required either pasteurization or aging.⁷⁷ On February 21, 1947, the FDA first revealed its concern for pasteurization and aging in a Notice of Hearing for the adoption of several dozen new standards of identity.⁷⁸ Without discussing its reasons, the agency proposed to modify the three existing standards and to have all of the new standards require either aging or the use of pasteurized milk in manufacturing. The only exceptions were for cheeses to be used in further manufacturing where the end product itself would be pasteurized. The final rulemaking release from April 22, 1949, offered the FDA's rationale for the standards of identity which survive to this day:

1987) (to be codified at 21 C.F.R. §1240). When the FDA issued its final rule requiring pasteurization on December 5, 1974, the agency stayed the requirement with respect to certified raw milk transported in interstate commerce in order to perform further research. The FDA's research progressed slowly, and ultimately, the Health Research Group of Public Citizens obtained a court order requiring the Secretary of the Department of Health and Human Services to promulgate a regulation banning *all* interstate sales of raw milk. *Public Citizen v. Heckler*, 602 F. Supp. 611 (D.D.C. 1985).

⁷⁶Milk and Cream: Proposed Revision of Existing Standards and Establishment of New Identity Standards, 37 F.R. 18392, 18392 (Sept. 9, 1972) (to be codified at 21 C.F.R. Part 18); Milk and Cream, 38 F.R. 27924, 27924 (Oct. 10, 1973) (to be codified at 21 C.F.R. Part 18).

⁷⁷See *supra* note 62.

⁷⁸12 F.R. 1192, *supra* note 61, at 1192.

Consumers expect, and have a right to expect, that manufacturers of cheese shall take reasonable precautions to render the finished cheese safe for human consumption. Under present conditions reasonable caution on the part of manufacturers of cheese intended for human consumption without further processing requires that the milk used be pasteurized, or in the alternative that such cheese, after manufacturing, be held for a period whereby it can reasonably be expected that it will be safe for human consumption. It will promote honesty and fair dealing in the interest of consumers to include in the definition and standards of identity of the different varieties and classes of cheese requirements that the milk used be pasteurized or the cheese held for a period whereby it may be reasonably expected that the cheese will be rendered safe. Based on the best evidence available now it is reasonable to require that when the milk used in manufacturing cheese is not pasteurized the cheese be held after it is manufactured for not less than 60 days at temperatures of not less than 35° F.⁷⁹

The FDA's strong concern for consumer expectations of safety led it to set the aging requirement at 60 days with very little scientific evidence to support such a specific duration regardless of cheese variety.⁸⁰ In its rule-making release, the agency admitted as much:

Viable pathogenic microorganisms in cheese, even when present to such an extent as to be capable of causing disease in humans, tend to die when the cheese is held for some time at temperatures above 35° F. It is not known with certainty how long cheeses must be held before they become safe. . . . *No outbreak has been reported from cheese held 60 days or more.*⁸¹

The release in the Federal Register reveals two fundamental agency attitudes toward protection of consumers: (1) that aging requirements should be as long as necessary to replicate the safety provided by pasteurization of milk, and (2) that pasteurization of milk provided a complete promise of consumer safety. This first attitude is reflected in the last excerpt from the release, while the second is clearly revealed as follows:

⁸⁰Some cheeses have standards of identity which require longer aging periods, but these reflect quality control measures to protect cheeses which are aged for flavor (e.g. gruyère or gorgonzola).

Milk obtained from infected animals may and often does contain microorganisms capable of causing disease in humans. At present it is practically impossible to insure the use in cheese making of milk free from such microorganisms. Milk may also become contaminated with pathogenic microorganisms from persons handling it. *Pasteurization of the milk destroys such microorganisms.* Milk is pasteurized if it is held at a temperature of 143° F. for not less than 30 minutes, or at a time and temperature equivalent thereto in phosphatase destruction. Sufficiently high temperatures are not reached in cheese manufacturing, and any present in the milk are usually carried over into the cheese. Such cheese may transmit infections to consumers. . . .Milk contains an enzyme, known as phosphatase, which is destroyed when the milk is sufficiently heated. The extent of the destruction of phosphatase depends on the time and temperature of heating. *When milk is pasteurized the destruction of phosphatase is practically complete.* Cheeses made from properly pasteurized milk contain practically no phosphatase. Chemical tests for determining the amount of phosphatase in milk and in products made from milk have been devised.⁸²

The ability to test milk and finished cheese products reinforced the promise that pasteurization would provide complete consumer safety, and the FDA’s rule prescribed standards for such testing. Reading the final rule release suggests that the FDA regarded pasteurization as a complete guarantee of safety to consumers. The aging requirement was set at 60 days in order to replicate this guarantee for cheeses made from unpasteurized milk.

The 1949 standards of identity have remained virtually without change to the present day. The following table tracks the requirements for each variety of cheese subject to regulation.

Table 1 – Evolving Standards of Identity For Cheeses

| Standard of Identity | Prior to 1949 (NS = no standard of identity) | April 22, 1949 Final rule published in Federal Register (14 F.R. 1960) | Present day requirements |
|-----------------------------|--|--|---------------------------------|
|-----------------------------|--|--|---------------------------------|

| | | | |
|-------------------------------------|----|---|---|
| Asiago fresh and asiago soft cheese | NS | Cheese must be aged > 60 days, pasteurized milk optional | Cheese must be aged > 60 days, pasteurized milk optional |
| Asiago medium cheese | NS | Cheese must be aged > 6 months, pasteurized milk optional | Cheese must be aged > 6 months, pasteurized milk optional |
| Asiago old cheese | NS | Cheese must be aged > 1 year, pasteurized milk optional | Cheese must be aged > 1 year, pasteurized milk optional |
| Blue cheese | NS | Cheese must be aged > 60 days, pasteurized milk optional | Cheese must be aged > 60 days, pasteurized milk optional |
| Brick cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Brick cheese for manufacturing | NS | Milk is not pasteurized, cheese is not aged ⁸³ | Milk is not pasteurized, cheese is not aged |

⁸³Cheeses which are “for manufacturing” do not need to be pasteurized or aged because they will be used in a manufacturing process that necessarily involves pasteurization.

| | | | |
|---|--|---|---|
| Caciocavallo siciliano cheese | NS | NS | Cheese must be aged > 60 days, pasteurized milk optional |
| Cheddar cheese | No pasteurization or aging requirement | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Cheddar cheese for manufacturing | NS | Milk is not pasteurized, cheese is not aged | Milk is not pasteurized, cheese is not aged |
| Low sodium cheddar cheese | NS | NS | Milk must be pasteurized or cheese must be aged > 60 days |
| Colby cheese | No pasteurization or aging requirement | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Colby cheese for manufacturing | NS | Milk is not pasteurized, cheese is not aged | Milk is not pasteurized, cheese is not aged |
| Low sodium Colby cheese | NS | NS | Milk must be pasteurized or cheese must be aged > 60 days |
| Cold-pack and club cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Cold-pack cheese food | NS | NS | Milk must be pasteurized or cheese must be aged > 60 days |
| Cold-pack cheese food with fruits, vegetables, or meats | NS | NS | Milk must be pasteurized or cheese must be aged > 60 days |
| Cook cheese, koch kaese | NS | Milk does not need to be pasteurized ⁸⁴ | Milk does not need to be pasteurized |
| Cottage cheese | NS | NS | Creaming mixture must be pasteurized |
| Dry curd cottage cheese | NS | NS | Creaming mixture must be pasteurized |

⁸⁴Cook cheese, or koch kaese, is a variety of soft cheese made from cottage cheese curd. "Due to the heating of the curd for the purpose of melting it, in the manufacture of cook cheese, it can reasonably be expected that pathogenic organisms are destroyed and that it is safe for consumption." 14 F.R. 1960, supra note 61, at 1972.

| | | | |
|--------------------------------------|--|---|---|
| Cream cheese | NS | NS | All dairy ingredients used must be pasteurized |
| Cream cheese with other foods | NS | NS | All dairy ingredients used must be pasteurized |
| Washed curd and soaked curd cheese | No pasteurization or aging requirement | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Washed curd cheese for manufacturing | NS | Milk is not pasteurized, cheese is not aged | Milk is not pasteurized, cheese is not aged |
| Edam cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Gammelost cheese | NS | Milk does not need to be pasteurized ⁸⁵ | Milk does not need to be pasteurized |
| Gorgonzola cheese | NS | Cheese must be aged > 90 days, pasteurized milk optional | Cheese must be aged > 90 days, pasteurized milk optional |
| Gouda cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Granular and stirred curd cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Granular cheese for manufacturing | NS | Milk is not pasteurized, cheese is not aged | Milk is not pasteurized, cheese is not aged |
| Grated cheeses | NS | NS | Milk must be pasteurized or cheese must be aged > 60 days |
| Grated American cheese food | NS | NS | Milk must be pasteurized or cheese must be aged > 60 days |
| Hard grating cheeses | NS | Cheese must be aged > 6 months, pasteurized milk optional | Cheese must be aged > 6 months, pasteurized milk optional |

⁸⁵Gammelost cheese is manufactured in such a way that the cheese itself is heated to 145 degrees Fahrenheit for at least 30 minutes during the production process. Hence no pasteurization of the raw milk itself is required.

| | | | |
|--|----|---|---|
| Gruyere cheese | NS | Cheese must be aged > 90 days, pasteurized milk optional | Cheese must be aged > 90 days, pasteurized milk optional |
| Hard cheeses | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Limburger cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Monterey cheese and Monterey jack cheese | NS | Milk must be pasteurized | Milk must be pasteurized |

High-moisture jack cheese

NS

Milk must be pasteurized

Milk must be pasteurized

| | | | |
|--|----|--|--|
| Mozzarella cheese and scamorza cheese | NS | NS | Milk must be pasteurized |
| Low-moisture mozzarella and scamorza cheese | NS | NS | Milk must be pasteurized |
| Part-skim mozzarella and scamorza cheese | NS | NS | Milk must be pasteurized |
| Low-moisture, part-skim mozzarella and scamorza cheese | NS | NS | Milk must be pasteurized |
| Muenster and munster cheese | NS | Milk must be pasteurized | Milk must be pasteurized |
| Muenster and munster cheese for manufacturing | NS | NS | Milk is not pasteurized, cheese is not aged |
| Neufchatel cheese | NS | NS | Milk must be pasteurized |
| Nuworld cheese | NS | NS | Cheese must be aged > 60 days, pasteurized milk optional |
| Parmesan and reggiano cheese | NS | Cheese must be aged > 14 months, pasteurized milk optional | Cheese must be aged > 10 months, pasteurized milk optional |
| Pasteurized blended cheese | NS | NS | Cheese itself must be pasteurized |
| Pasteurized blended cheese with fruits, vegetables, or meats | NS | NS | Cheese itself must be pasteurized |
| Pasteurized process cheese | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |

| | | | |
|---|----|---|---|
| Pasteurized process cheese with fruits, vegetables, or meats | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized process pimento cheese | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized process cheese food | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized process cheese food with fruits, vegetables, or meats | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized cheese spread | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized cheese spread with fruits, vegetables, or meats | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized neufchatel cheese spread with other foods | NS | Cheese itself must be pasteurized | Cheese itself must be pasteurized |
| Pasteurized process cheese spread | NS | NS | Cheese itself must be pasteurized |
| Pasteurized process cheese spread with fruits, vegetables, or meats | NS | NS | Cheese itself must be pasteurized |
| Provolone cheese | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Soft ripened cheeses | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Romano cheese | NS | Cheese must be aged > 5 months, pasteurized milk optional | Cheese must be aged > 5 months, pasteurized milk optional |

| | | | |
|--|----|---|--|
| Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk | NS | Cheese must be aged > 60 days, pasteurized milk optional | Cheese must be aged > 60 days, pasteurized milk optional |
| Samsøe cheese | NS | NS | Cheese must be aged > 60 days, pasteurized milk optional |
| Sap sago cheese | NS | Cheese must be aged > 5 months, pasteurized milk optional | Cheese must be aged > 5 months, pasteurized milk optional |
| Semisoft cheeses | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Semisoft part-skim cheeses | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Skim milk cheese for manufacturing | NS | Milk may be pasteurized | Milk may be pasteurized |
| Spiced cheeses | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Part-skim spiced cheeses | NS | Milk must be pasteurized or cheese must be aged > 60 days | Milk must be pasteurized or cheese must be aged > 60 days |
| Spiced, flavored standardized cheeses | NS | NS | Conforms to standard of identity for the specific natural cheese variety which is spiced or flavored |
| Swiss and emmentaler cheese | NS | Cheese must be aged > 60 days, pasteurized milk optional | Cheese must be aged > 60 days, pasteurized milk optional |
| Swiss cheese for manufacturing | NS | Cheese must be aged > 60 days, pasteurized milk optional | Cheese must be aged > 60 days, pasteurized milk optional |

Although there are far more cheeses for sale in the United States than are subject to prescribed standards

of identity under 21 C.F.R. §133, the federal regulation effectively reaches every variety of cheese through the use of standards for soft ripened cheeses, semisoft cheeses, and hard cheeses. All conceivable cheeses are included in these broad categories.⁸⁶ As a result, although the federal government did not forbid the interstate distribution of all unpasteurized, unaged milk products until 1987, such a comprehensive ban has existed de facto since 1949.

When the FDA eventually decided to add a redundant ban on interstate distribution to the existing regulatory framework of standards of identity, the agency did not pause to reconsider the necessity of pasteurization or aging to the safety of the cheese consumer. On June 11, 1987, the FDA proposed a rule requiring mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.⁸⁷ The relevant portion of the rule was promulgated as originally proposed and is contained today in 12 C.F.R. §1240.61:

No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk *or milk product* in final package form for direct human consumption that has not been pasteurized *except where alternative procedures are provided by regulation, such as Part 133 of this chapter for curing of certain cheese varieties.*⁸⁸

The regulation applies to cheese as it applies to any other milk product and incorporates the standards of identity in 12 C.F.R. §133 for purposes of allowing certain cheeses to be aged at least 60 days instead of made from pasteurized milk.

In promulgating 12 C.F.R. §1240.61, the FDA was not motivated by concern over cheese made from raw

⁸⁶This logical inference is confirmed by Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, Proposed Rule, 52 F.R. 22340-01, 22343 (Jun. 11, 1987) (to be codified at 21 C.F.R. Part 1240):

The standards of identity currently in effect for milk and milk products marketed in interstate commerce require that all standardized products other than certified raw [milk] (and other than certain cheese products that are aged rather than pasteurized) be pasteurized.

⁸⁷Id. at 22340.

milk because such products were already covered by the standards of identity of 12 C.F.R. §133. Instead, the agency was responding to a court order which required it to publish a proposed rule banning the interstate sale of certified raw milk.⁸⁹ In 1987, certified raw milk remained unregulated although the FDA's standards of identity for fluid milk had required pasteurization since 1973.⁹⁰ The agency had stayed the pasteurization requirement with respect to certified raw milk for further consideration pending a hearing.⁹¹ Although the hearing took place, the FDA spent the next decade studying the health risks posed by certified raw milk without making a decision.

Finally, on April 10, 1984, the Health Research Group of Public of Public Citizen petitioned the Secretary of the Department of Health and Human Services to promulgate a regulation banning all sales, interstate and intrastate, of raw milk and milk products in the United States.⁹² After a few months, the citizens' group then filed suit in federal district court to compel HHS to promulgate such a rule.⁹³ The court ordered HHS to respond to the petition, finding that there had been unreasonable delay.⁹⁴ The Commissioner of Food and Drugs then denied the petition, forcing the Health Research Group to seek judicial review. This time, its request for relief also challenged the agency's failure to terminate the stay of the 1973 regulation which had required pasteurization of fluid milk products through standards of identity.⁹⁵ In *Public Citizen v. Heckler*, the court ruled that the denial of the petition had been arbitrary and capricious, and ordered the FDA to institute rule-making procedures for a regulation banning the interstate sale of all raw milk and

⁸⁹52 F.R. 22340-01, *supra* note 86, at 22340.

⁹⁰Milk and Cream, 38 F.R. 27924, 27924 (Oct. 10, 1973) (to be codified at 21 C.F.R. Part 18):

While raw milk produced under carefully controlled conditions is relatively safe, pasteurization assumes the destruction of pathogenic bacteria that may be present. The Commissioner concludes that it is reasonable to require that fluid milk products moving in interstate commerce be pasteurized.

⁹¹Milk and Cream; Identity Standards for Milk and Cream; Order Staying Certain Provisions, 39 F.R. 42351, 42351 (Dec. 5, 1974).

⁹²52 F.R. 22340-01, *supra* note 86, at 22341.

⁹³See *Public Citizen v. Heckler*, 602 F.Supp. 611 (D.D.C. 1985).

⁹⁴*Id.*

⁹⁵See *Public Citizen v. Heckler*, 653 F.Supp. 1229 (D.D.C. 1986).

milk products.⁹⁶ Ultimately, on August 10, 1987, the final rule was released, and 12 C.F.R. §1240.61 has endured essentially unaltered until present day.⁹⁷

Significantly, the court in *Public Citizen v. Heckler* declined to order the FDA to propose a rule banning the *intrastate* sales of raw milk:

Public Citizen asks this Court to compel the agency to promulgate a rule banning both interstate and intrastate sales of raw milk. While we must agree that a rule banning the interstate sale of raw milk is appropriate, at this time there is no indication that a rule banning the intrastate sale of raw milk is necessary to effectuate the interstate ban. Accordingly, the Court declines to order the promulgation of a rule banning intrastate sales of raw milk. Assuming the interstate ban is effective without an intrastate ban, it is up to the individual states to decide on such matters of purely local concern. Should it appear that the interstate sale of raw milk continues, it is within HHS's authority at that time to institute an intrastate ban as well.⁹⁸

Although the court's opinion, and indeed, the entire case, concerned the sale of certified raw milk and had no practical effect on cheese, this excerpt explains the current status of intrastate sales of unaged, raw milk cheese.

The FDA has acknowledged that the standards of identity in effect for milk and milk products (including cheese) do not apply to products marketed only in intrastate commerce.⁹⁹ When it proposed 12 C.F.R. §1240.61, the FDA noted that neither FDA nor HHS has adequate legal authority, based on the facts available at this time, to prohibit the intrastate marketing of unpasteurized milk and milk products.¹⁰⁰

This was because there was no evidence that an intrastate ban would be necessary to effect the interstate

⁹⁶Id.

⁹⁷7 C.F.R. §58.439 (1997) also states that [c]heese made from unpasteurized milk shall be cured for a period of 60 days at a temperature not less than 35° F., but this is merely a restatement of the law contained in 21 C.F.R. §1240.61 (1987) and the standards of identity in 21 C.F.R. §133 (1949).

⁹⁹52 F.R. 22340-01, *supra* note 86, at 22343.

¹⁰⁰Id.

prohibition. Moreover, the agency maintained that even assuming that FDA and HHS have such authority, the problems created by unpasteurized milk and milk products are most appropriately dealt with at the State and local level.¹⁰¹ It is relatively clear that the FDA was considering the limited nature of the interstate market for certified raw milk, because there was no cheese made from certified raw milk at the time. As the FDA pointed out, the regulation of the *fluid milk industry* has historically been a matter in which States have exercised primary responsibility.¹⁰² Because there already [existed] a pervasive system of State regulation and because an intrastate ban would not be necessary to effect an interstate ban, the FDA chose to leave purely intrastate sales to the legal authority of individual states.

In 1987, when the FDA chose not to reinforce its interstate ban with an intrastate ban, only 26 states prohibited the sale of unpasteurized milk and milk products.¹⁰³ Today, because of the activism of raw milk advocates, only 22 states fully prohibit the sale of *fluid* raw milk.¹⁰⁴ Many states which permit the sale of fluid raw milk, however, do so under tightly restricted circumstances. Furthermore, states which permit the sale of fluid raw milk do not generally allow the distribution of raw milk cheese. The following table illustrates this surprising phenomenon.¹⁰⁵

¹⁰¹Id.

¹⁰²Id.

¹⁰³Id.

¹⁰⁴What's Happening With Real Milk? Available at <http://www.realmilk.com/happening.html> (last visited Apr. 9, 2005).

¹⁰⁵The table is incomplete because some states have delegated rule-making authority to state departments of agriculture, and some state regulatory authorities have not addressed the issue or have not done so with sufficient clarity for information to be included in this chart. Many state agencies, however, were extremely helpful and responsive to emails and phone calls inquiring about their regulation of cheese.

Table 2 – Survey of State Laws Relating to Sale and Manufacture of Cheese

| State | Provision(s) Relating to Sale and Manufacture of Unpasteurized Cheese | Effect of Provisions | Date ¹⁰⁶ | Fluid Raw Milk Sales? ¹⁰⁷ |
|------------|---|---|---------------------|--------------------------------------|
| Alabama | | | | No |
| Alaska | | | | No |
| Arizona | A.R.S. § 3-624 | Cheese must be made from pasteurized milk or aged > 60 days. | 1951 | Yes |
| Arkansas | A.C.A. § 20-59-227 | Cheese must be made from pasteurized milk, unless it is sold by a dairy farmer who produces a majority of the milk he uses. | 1941 | No |
| California | Cal.Food & Agric.Code § 32920.5 | Incorporates federal standards by reference. | 2001 | Yes |
| Colorado | C.R.S.A. § 25-5.5-101 | Incorporates federal standards by reference. | 1985 | Yes |

¹⁰⁶Note that the date enacted corresponds to the date of the original statute. This is not necessarily the date of enactment of the provision relating to unpasteurized cheese.

¹⁰⁷Note that states which permit only sales of *goat* milk to individuals with prescriptions from a physician have been counted as not permitting the sale of raw milk.

| | | | | | |
|-------------|------------------------------------|--|--------------|-----|--|
| Connecticut | | | | Yes | |
| Delaware | | | | No | |
| Florida | F.S.A. § 502.091 | Cheese must be made from pasteurized milk. | 1931 | No | |
| Georgia | | | | No | |
| Hawaii | | | | No | |
| Idaho | I.C. § 37-334a | Incorporates federal standards by reference. | 1985 | Yes | |
| Illinois | 410 ILCS 620/2.35 | Incorporates federal standards by reference. | 1967 | Yes | |
| Indiana | IC 15-2.1-23-8.5 | Cheese must be made from pasteurized milk or aged > 60 days. | | No | |
| Iowa | | | | No | |
| Kansas | K.S.A. § 65-784 K.S.A. § 65-771 | On-farm retail sales of cheese made from unpasteurized milk permitted. Incorporates federal standards by reference for all other sales. | 2001 2001 | Yes | |
| Kentucky | | | | No | |
| Louisiana | | | | No | |

| | | | | | |
|-------|--|--|--------------|-----|--|
| Maine | 7 M.R.S.A. § 2902- B 7 M.R.S.A. § 2904- A | Cheese made from un- pas- teur- ized milk must be la- beled not pas- teur- ized. Such cheese may not be sold at any eat- ing es- tab- lish- ment. State de- part- ment may is- sue per- mit for man- u- fac- ture of un- aged farm cheese from un- pas- teur- ized milk. | 1954 1997 | Yes | |
|-------|--|--|--------------|-----|--|

| | | | | |
|---------------|------------------------------------|--|--------------|-----|
| Maryland | | | | No |
| Massachusetts | M.G.L.A. 94 § 13 | Incorporates federal standards by reference. State regulators authorized to adopt more stringent standards. | 1933 | Yes |
| Michigan | M.C.L.A. 288.698 | Incorporates federal standards by reference. | 1947 | No |
| Minnesota | M.S.A. § 32.482 M.S.A. § 32.486 | Cheese must be made from pasteurized milk or aged > 60 days. State commissioner may issue permits to farms to produce unaged Minnesota farmstead cheese from unpasteurized milk. | 1959 1977 | Yes |
| Mississippi | | | | No |
| Missouri | V.A.M.S. 196.530 | Incorporates federal standards by reference. State regulators authorized to adopt more stringent standards. | 1939 | Yes |

| | | | | | |
|---------|--------------------------|--|------|----|--|
| Montana | MCA 81- 22- 413 | Cheese must be made from pas- teur- ized milk or aged > 60 days. If aged > 60 days, must also be la- beled made from raw or un- pas- teur- ized milk or un- pas- teur- ized cream. | 1971 | No | |
|---------|--------------------------|--|------|----|--|

| | | | | | |
|----------------|----------------------------|--|------|-----|--|
| Nebraska | Neb.Rev.St. § 2-3903 | Cheese produced by farmers for sale at the farm directly to customers for consumption and not for resale does not need to be made from pasteurized milk or aged. | 1980 | Yes | |
| Nevada | N.R.S. 584.208 | Cheese made from certified raw milk may be sold. County milk commissions responsible for certification. | 1979 | Yes | |
| New Hampshire | N.H. Rev. Stat. § 184:30-a | Cheese must be made from pasteurized milk or aged > 60 days. | 1961 | Yes | |
| New Jersey | N.J.S.A. 24:10-57.18 | Cheese must be made from pasteurized milk or aged > 60 days. | 1964 | No | |
| New Mexico | | | | Yes | |
| New York | NY AGRI & MKTS § 67-b | Cheese must be made from pasteurized milk or aged > 60 days. | 1955 | Yes | |
| North Carolina | | | | Yes | |

| | | | | | |
|-----------------|--|--|--------------------|----|--|
| North Dakota | NDCC, 4- 30- 33 | Incorporates fed- eral stan- dards by ref- er- ence. State reg- u- la- tors au- tho- rized to adopt more strin- gent stan- dards. | 1963 | No | |
| Ohio | Ohio Administrative Rule 901:3-12-25 | Incorporates federal standards by reference. | N/A ¹⁰⁸ | No | |

¹⁰⁸There is no date of enactment listed where the state has used an administrative regulation, rather than a statute, to regulate the pasteurization of cheese.

| | | | | | |
|-------------------|--------------------------------------|---|--------------|-----|--|
| Oklahoma | 2 Okl.St. Ann. § 7- 404 | Incorporates federal standards by reference. State regulators authorized to adopt more stringent standards. | 2003 | Yes | |
| Oregon | O.R.S. § 621.116 O.R.S. § 621.012 | Cheese must be made from pasteurized milk. Farmer may sell cheese from unpasteurized milk under small farm exception if he does not advertise, sells directly to consumer from farm, and owns fewer than two cows (or nine sheep/goats). | 2003 2003 | Yes | |
| Pennsylvania | | | | Yes | |
| Rhode Island | Gen.Laws, § 21-2-2 | Cheese must be made from pasteurized milk. | 1956 | Yes | |
| South Carolina | | | | Yes | |
| South Dakota | | | | Yes | |
| Tennessee | | | | No | |
| Texas | | | | Yes | |

| | | | | | |
|------------------|---|--|------|-----|--|
| Utah | | | | Yes | |
| Vermont | 6 V.S.A., § 2672 (25) | Incorporates federal standards by reference. | 1950 | Yes | |
| Virginia | | | | No | |
| Washington | RCWA 15.36.021 | Incorporates federal standards by reference. | 1989 | Yes | |
| West Virginia | W. Va. Code, § 19-11D-2 | Cheese must be made from pasteurized milk, except that traditional cheese production allows sale of raw milk cheese aged > 60 days if made from milk of West Virginian cows and sold in local small businesses or restaurants. | 1999 | No | |
| Wisconsin | Administrative Rule ATCP 80.41 | Incorporates federal standards by reference. | N/A | Yes | |
| Wyoming | | | | No | |

As seen from this survey, there is virtually no correlation between a state's willingness to allow sales of fluid raw milk and its willingness to permit sales of cheese made from raw milk. Of the 20 states which permit

sales of fluid raw milk (for which there is data available on regulation of cheese), only 6 allow the sale of cheese made from raw milk. And, of the 8 which permit sales of cheese made from raw milk, only 6 allow the sale of fluid raw milk.

What explains this inconsistency? The simple explanation appears from the fact that virtually every state addresses fluid milk and raw milk cheese production in different subsections of their code chapters on dairy products. The generally applicable legislative history is that states adopted their first milk laws in the 1920s and 1930s. By contrast, states adopted laws and promulgated regulations on raw milk cheese throughout the remainder of the 20th century. Many state laws and regulations which prohibit the sale of raw milk cheese were adopted shortly after the FDA's 1949 standards of identity or after its redundant 1987 interstate ban. This strongly suggests that state laws and regulations were not the result of careful research and were adopted as each state noticed the gap in its regulatory regime for dairy products. This interpretation is only supported by the fact that almost all laws affecting the sale of unaged raw milk cheese predated the gradual growth of the artisanal cheese industry from the 1980s onward. Although the federal government has left open the possibility for states to permit intrastate sale of all raw milk cheeses, including fresh cheeses which cannot be imported because of the federal regulations, relatively few states have seized this opportunity on behalf of their small local dairy farmers.

The current threat to aged raw milk cheeses

In 1995, academic researchers in South Dakota demonstrated that *E. coli* O157:H7 (*E. coli*) bacteria

could survive the 60-day aging period.¹⁰⁹ Prior studies in Europe had shown that salmonella and listeria could similarly persist.¹¹⁰ These results suggested that existing regulations were insufficient to protect consumers from pathogens. In 1998, a trade group comprising large-scale manufacturers (of both specialty cheeses and process cheeses) compiled such studies and contacted the FDA to suggest that all cheese, whether fresh or aged over 60 days, should be made from pasteurized milk.¹¹¹ In the fall of 1998, the FDA announced that it would research whether pathogenic bacteria contained in raw milk cheese could survive the 60-day aging period. Such a discovery would justify a complete ban on interstate sales of raw milk cheese, far surpassing the restrictiveness of current regulations.

The FDA's studies were funded by former President Clinton's Food Safety Initiative and conducted by government researchers at the National Center of Food Safety and Technology in Chicago.¹¹² The project's anticipated impact on existing regulations was summarized as follows:

In the event that 60-day aging is found to be inadequate to provide the appropriate level of public health protection, an evaluation of alternative control measures would assist the agency in the development of policy in this area. Validation of the effectiveness of current or alternative process control measures used in the manufacture of aged hard cheese would result in a greater assurance of a safe food supply and enhanced public confidence in these products.¹¹³

Although the government hesitated to revise regulations which had existed for half a century, the future of aged raw milk cheeses clearly was in jeopardy.

In response, the American Cheese Society, a group representing artisanal cheese makers, and Oldways Preser-

¹⁰⁹Christine J. Reitsma & David R. Henning, *Escherichia coli O157:H7 in Experimental Cheddar Cheese*, 59 J. FOOD PROT. 460 (1995).

¹¹⁰Judith Weinraub, *Why the Cheeses You Enjoy Today Could Be Gone Tomorrow*, THE WASHINGTON POST, Sept. 6, 2000, at F7.

¹¹¹Id.; see also Kummer, *supra* note 64, at 109-10.

¹¹²Weinraub, *supra* note 110, at F7.

vation & Exchange Trust, an activist group promoting sustainable agriculture and traditional foods, formed the Cheese of Choice Coalition to oppose mandatory pasteurization.¹¹⁴ The group contacted Catherine W. Donnelly, a professor in food microbiology at the University of Vermont, to conduct an independent review of the ongoing FDA study and the 1995 South Dakota study which had sparked the controversy over a 50-year old regulation. Donnelly found two critical flaws in the design of the 1995 South Dakota study of *E. coli*: (1) the researchers had injected strains of *E. coli* into cheddar samples made from pasteurized milk, and (2) the samples were injected with several thousand times more bacteria than could realistically enter cheese during the manufacturing process.¹¹⁵ The first design flaw meant that *E. coli* bacteria were never exposed to lactic acid during fermentation, as would normally happen in manufacture of cheese from raw milk. High acidity helps kill pathogens. The second design flaw meant that the South Dakota study might have produced overly pessimistic and alarmist results.¹¹⁶ Although the FDA's research properly used samples created from raw milk, thereby eliminating one of the flaws of the South Dakota study, the government continued to inject samples with unrealistic concentrations of *E. coli*.¹¹⁷

Publication of Donnelly's independent research and activism by the Cheese of Choice Coalition produced sufficiently negative publicity that the FDA's review lost its priority status in 2002.¹¹⁸ The FDA's results, scheduled for release in September of 2002,¹¹⁹ have not been released to-date, despite the fact that the FDA had publicly stated in 2000 that [p]reliminary results appear to confirm what was in the scientific literature – that these organisms do indeed survive past 60 days.¹²⁰ Had the FDA pursued its study and concluded

¹¹⁴Id. at 110.

¹¹⁵Catherine W. Donnelly, *Factors Associated With Hygienic Control and Quality of Cheeses Prepared From Raw Milk: A Review*, 369 BULL. OF THE INT'L DAIRY FED'N 16, 16-17 (2001).

¹¹⁶Id.

¹¹⁷Id.

¹¹⁸Martha Ingram, *Raw Deal: Trade Implications of the U.S. Food and Drug Administration's Pending Review of Unpasteurized Cheese*, 12 MINN. J. GLOBAL TRADE 461, 466 (2003).

¹¹⁹Project No. 13, *supra* note 113, at 1.

¹²⁰Weinraub, *supra* note 110, at F7.

that all raw milk cheeses should be banned, the most popular affected varieties of raw milk cheeses would be: comte, cheddar, Cheshire, emmentaler, gruyère, morbier, parmigiano reggiano, pecorino romana, reblochon, Roquefort, salers, tome de savoie, and Vermont shepherd.¹²¹ These popular artisanal cheeses would only be available as products of pasteurized milk.

As of October 2004, it appears that the study continues and that the FDA may eventually conclude that aged raw milk cheeses should be banned, or the aging period increased. In a consumer advice article concerning fluid raw milk, the agency stated:

The FDA allows the manufacture and interstate sale of raw milk cheeses that are aged for at least 60 days at a temperature not less than 35 degrees Fahrenheit. However, recent research calls into question the effectiveness of 60-day aging as a means of pathogen reduction, says [John Sheehan, director of the FDA's Division of Dairy and Egg Safety]. The FDA's Center for Food Safety and Applied Nutrition (CFSAN) is currently examining the safety of raw milk cheeses and plans to develop a risk profile for these cheeses. This information will help FDA risk managers make future decisions regarding the regulation of these products to protect public health.¹²²

Therefore, as of the date of this paper, aged raw milk cheeses are in danger of the total ban which currently affects fresh raw milk cheeses.¹²³ Although the U.S. artisanal cheese economy has never been legally able to create fresh raw milk cheeses, it has relied heavily on the production of aged raw milk cheeses. While a forced wholesale shift to pasteurized milk cheeses might not destroy the artisanal industry, it would require massive changes in many producers' methods (which have been refined over the course of many years). It would also make it more difficult for artisanal producers to distinguish their product from factory-made specialty cheeses, and would alienate a small portion of artisanal cheese consumers who actively seek out raw milk cheese for the same reasons they seek out fluid raw milk.

¹²¹Id.

¹²³In addition, importers of raw milk cheeses have reported increased FDA scrutiny of shipments to the United States in the wake of September 11, 2001. See Janet Fletcher, *Slice Up This Reasonable Substitute For a Beloved Oozer*, SAN FRANCISCO CHRONICLE, Jan. 20, 2005, at F4.

The Cheese of Choice Coalition, which opposes any increased ban on the use of raw milk, has expressed its interest in protecting the current regulation in the following language:

We believe that raw milk cheeses should not be made extinct because:

A. American consumers want the choice. Clearly, they demand and are entitled to safe products. Informed correctly, we, the American public, should be able to eat what we want, because the freedom of choice is ingrained in the very fabric of our beings.

B. There is a growing market in the U.S. for raw milk cheeses. In recent years, the increased sophistication of the American consumer has called for a larger variety of unique, distinctive, hand-crafted cheeses. This has prompted specialty food stores and farmers' markets throughout the country to expand their cheese offerings.

C. Raw milk cheeses belong in the high end of the specialty market, thus providing a high return to the farmer and making it viable to sustain agriculture on a small farm.

In forming the Cheese of Choice Coalition, the American Cheese Society and Oldways Preservations & Exchange Trust aim to unite organizations and individuals that will share information and resources and concentrate the power to stand up to the international governmental organizations that want to prohibit the production of raw milk cheeses.¹²⁴

One of the most desirable aspects of the artisanal cheese industry is that it can exist in virtually any state.

As between the dual purposes of providing choice to educated consumers and enabling the economic viability of small dairies, the more compelling argument is probably the importance of maintaining growing, value-added small businesses on farms in rural areas. Nonetheless, the following Part addresses the consumer's interest in artisanal and raw milk cheeses.

PART III

The changing importance of cheese in the American diet

One cannot overstate the dramatic change in American consumption of dairy products over the past century. In 1899, only 4.50% of total raw milk by volume was used for the production of cheese.¹²⁵ By 1919, consumption patterns had barely changed: only 4.65% of milk was used in the production of cheese.¹²⁶ During the period 1953-1960, the percentage had climbed to 11.65%.¹²⁷ The truly amazing increase, however, is that ever since the 1990s, *more than one third of all milk produced* by volume in the United States has been used to manufacture cheese.¹²⁸

These numbers reflect three main trends over the course of the 20th century. First, there has been a decline in the consumption of butter due to the new use of margarine and butter substitutes.¹²⁹ Second, consumption of fluid milk with high fat content, and consumption of cream, has declined much more than consumption of fluid milk as a category.¹³⁰ The government has generally attributed these developments to a conscious effort at weight control by consumers.¹³¹ The third trend, a major increase in per capita cheese consumption, is bizarrely at odds with the weight control explanation for the declining use of butter, cream, and whole milk. Undoubtedly, the American consumer has become increasingly aware of cheese as a desirable food product.

¹²⁵FEDERAL TRADE COMMISSION, REPORT ON MILK AND MILK PRODUCTS: 1914-1918 184 (1921).

¹²⁶Id.

¹²⁷U.S. TARIFF COMMISSION, BLUE-MOLD AND CHEDDAR CHEESES, REPORT TO THE PRESIDENT ON INVESTIGATION NO. 22-6 (SUPPLEMENTAL) UNDER SECTION 22 OF THE AGRICULTURAL ADJUSTMENT ACT, AS AMENDED 32 (1961).

¹²⁸International Dairy Foods Association, Dairy Facts 2003 Edition, at 4.

¹²⁹BLUE-MOLD AND CHEDDAR CHEESES, *supra* note 127, at 14.

¹³⁰Id. at 13.

¹³¹Id.

The increase in cheese consumption from the end of World War II until 1960 was primarily due to the rising popularity of pizzas, cheese-burgers, cheese dips, and cheese spreads – a development which [was] actively promoted by cheese producers.¹³² The further increase in cheese consumption from 1960 until the present day can probably attributed to a similar further expansion of the role of cheese in the American diet.

The fact remains that per capita cheese consumption climbed steadily throughout the 20th century: in 1960, the average American consumed 8.4 pounds of cheese, whereas in 2003, he (or she) consumed 30.58 pounds.¹³³ In 1961, the federal government correctly noted that the cheese industry itself had driven this increase.¹³⁴ Throughout the 1940s, Kraft Cheese Company published a rather self-congratulatory history of cheese in America, which confirms the role of the large-scale cheese manufacturer in promoting the expanded use of its product:

Cheese is not only a tid-bit, an enhancer of other foods, but is an integral part of many dishes. There are cheese fondues, soufflés, cheese and vegetable combinations, cheese with noodles and with rice or macaroni. And there are cheese dishes for luncheon, dinner, and supper. The simple, sophisticated custom of serving a variety of cheese with a fruit dessert, a beverage and crackers is one which is growing more and more popular. . .

Considered from the standpoint of food value, flavor, easy assimilation and economy, cheese is an excellent food. To gain the full value of it in the diet, we must consider it from the standpoint of its rightful place in a well-balanced meal, rather than as a condiment for flavor only. *Cheese should be used often as the main dish of the meal.*¹³⁵

Kraft, however, maintained that the federal government itself had contributed to the rising position of cheese as a staple of the American diet:

¹³²Id. at 24.

¹³³BLUE-MOLD AND CHEDDAR CHEESES, *supra* note 127, at 24; International Dairy Foods Association, Dairy Facts 2003 Edition, at 102. The Americans are hardly alone: French per capita per annum cheese consumption grew from 18.4 pounds in 1958 to 54.0 pounds in 2001. See BRITISH EMBASSY, THE FRENCH MARKET FOR CHEESE 1 (2003).

¹³⁴Id.

Long recognized by nutritionists for its highly concentrated food values, cheese came sharply into the limelight in the critical days of 1941, as one of the basic foods necessary to help win the [Second World] war. . . the U.S. Department of Agriculture early in 1941 asked the dairy industry of the United States to increase the nation's cheese production beyond all previous limits.¹³⁶

In promoting its product, Kraft attempted to simultaneously celebrate its use of modern technology to produce cheese of consistent quality and its production of traditional European cheeses by new American factory methods. The photographs in its history of cheese reveal stainless steel vats and workers dressed in white laboratory coats, and Kraft's description of the making of process cheese reveals a similar pride:

Skilled blenders examine the cheese in each carefully identified lot in order to determine its exact flavor and texture. . . The skill of the blender, backed by laboratory tests, makes it possible to produce a cheese of uniformly fine flavor, texture and consistency, by combining just the right proportion of the various lots. . . the cheese is then shredded and pasteurized by automatic machines and packed in sealed containers. Practically the entire process is performed by automatic machinery, down to the folding of the wrapper on the top of each package in its final sealing.¹³⁷

At the same time that it congratulated itself on automation of the cheese-making process and consistency of taste, Kraft's slogan in the 1940s was a variety to suit every taste. Indeed, during this period, the company manufactured (from pasteurized milk, of course) versions of many European cheeses, such as brie, camembert, edam, gorgonzola, limburger, neufchatel, port du salut, and stilton. Far from glorifying Velveeta (already one of its most successful brands in the 1940s), the company wanted to highlight its role in Americanizing *European* cheeses:

Camembert, one of the most tempting and delicious of all varieties, is of French origin. . . Originally an imported connoisseur's item, it is now made to perfection in America and is achieving wide favor as a dessert cheese.¹³⁸

Today, consumers identify Kraft almost entirely with pasteurized blended cheeses, pasteurized process cheese, and pasteurized process cheese food. In the 1940s, however, Kraft optimistically believed it could appeal

to consumers by democratizing traditional European cheeses, *and* by manufacturing truly American cheese products.

Why was Kraft incorrect? Although American factory-made versions of European cheeses have increased in popularity, today Kraft's only mock-European brand is Athenos, which makes pasteurized-milk feta.¹³⁹ Kraft's other natural cheeses, such as cheddar, are not marketed as specialty products. The answer is that the appeal of specialty cheese to present-day consumers is generally incompatible with Kraft's pride over factory production and consistency in flavor. Furthermore, the cultural developments which have driven the popularity of specialty cheese logically predict an expanding market for artisanal cheese and raw milk artisanal cheese.

The postmodern consumer theory and artisanal cheese

Sociological studies of consumer preference have found that the rising market share of specialty cheese is consistent with the theory of postmodern consumerism.¹⁴⁰ This theory speculates that postmodern purchasing involves a reversal of consumption and production in which "the products alter and influence consumers through their consumption experiences to produce a 'new' type of consumer."¹⁴¹ The postmodern consumer approach is characterized by a "hostility toward generalization" in which plurality, diversity, and

¹³⁹Kraft's natural cheeses are marketed under the following brands: Athenos, Churny, Cracker Barrel, Di-Giorno, Handi-Snacks, Harvest Moon, Hoffman's, and Polly-O. See Kraft, North American Brands, available at <http://www.kraft.com/brands/namerica/us.html#Anchor-Cheese-11481> (last visited Apr. 17, 2005).

¹⁴⁰Beata Kupiec & Brian Revell, *Speciality and Artisanal Cheese Today: The Product and the Consumer*, BRITISH FOOD JOURNAL, at 236 (1998).

¹⁴¹Id. at 238. "This is seen as the process of merging the subject and the object." For an overview of postmodern consumerism, see ELIZABETH C. HIRSCHMAN & MORRIS B. HOLBROOK, POSTMODERN CONSUMER RESEARCH: THE STUDY OF CONSUMPTION AS TEXT (1992).

originality of products create value for a purchaser whose identity is forged by the act of exercising choice and by the development of connoisseur skills.¹⁴² Such a conceptual framework goes far in explaining Kraft's incentive behind marketing "Isle of Orkney Reserve Cracker Barrel," and even farther in explaining the rising success of artisanal cheese as a subcategory of specialty cheese.

The theory of postmodern consumerism explains the value that a consumer derives from a wide selection of artisanal cheese:

Artisanal cheese consumers focus on the unique characteristics of the products and their distinctive character in relation to mass-produced industrial cheeses. Price and functional properties of artisanal cheeses are less important in the consumer purchase decision. Artisanal cheese consumers are characterized by 'variety seeking' behavior. This is stimulated by the broad range of available flavors, tastes, and cheese types and suggests a low degree of brand or even cheese-type loyalty among such consumers.¹⁴³

The lack of loyalty to brand or cheese type explains that while specialty cheese may offer partial consumer satisfaction, artisanal cheese represents the ultimate postmodern product. The consumer values a host of "distinctive features...created by physical, sensory, and aesthetic attributes such as raw material quality, the technology used, presentation and packaging, organoleptic properties, identification and association of geographic origin with product image, and by selection of distribution channels."¹⁴⁴ Such values are totally incompatible with Kraft's emphasis on *consistency* of product quality. Artisanal cheese fulfills every postmodern expectation by providing a dizzying selection of unique and often scarce products that are manufactured according to diverse and often historically or regionally traditional methods. Furthermore, the experience of purchasing artisanal cheese typically involves interaction with specialists at grocery stores, small shopkeepers, or even artisanal producers, thereby encouraging the purchaser to develop "connoisseur"

¹⁴²KUPIEC & REVELL, *supra* note 140, at 238.

¹⁴⁴*Id.*

skills.

Surveys have examined why artisanal cheese consumers choose their purchase. “Quality,” “flavor,” “superiority,” and “difference from industrial cheeses” were identified as the most important cheese properties, while the least important aspects were functional aspects: “shelf life,” “packaging,” “health,” “appearance,” “price,” and “origin.”¹⁴⁵ The unimportance of “health” to artisanal cheese consumers was clearly demonstrated by retailer surveys following a 1995 *Listeria monocytogenes* scare in Scotland. Humphrey Errington, a producer of Lanark Blue Cheese, was accused by officials of allowing impermissibly high levels of the bacterium, although no illness had been reported.¹⁴⁶ Months prior to Errington’s exoneration in court, 61% of retailers reported an increase in the sale of Lanark Blue Cheese – a veritable “protest against institutional generalization and standardization of products.”¹⁴⁷

If “health” does not matter to purchasers of artisanal cheese, and government opprobrium may even be viewed as additional proof of quality and difference, then raw milk cheese produced in violation of current U.S. regulations epitomizes postmodern cheese-consumer identity. The use of raw milk is associated with many of the distinctive features that separate artisanal cheese from mere specialty cheese: limited number of suppliers of raw ingredients, producer often directly associated with farmer, smaller production facilities resulting in greater control over production and less mechanization, and, mostly importantly, “superior” (and more varied) tastes and smells. As discussed at supra, Part I, European scientists have demonstrated that raw milk cheeses actually do exhibit differences in organoleptic properties when compared to their pasteurized counterparts.

¹⁴⁵Id. at 240.

¹⁴⁶Arthur Cunynghame, *British Cheese-Makers Under Threat*, THE ECOLOGIST, June 2001.

¹⁴⁷KUPIEC & REVELL, supra note 140, at 241.

Furthermore, it is not clear that postmodern consumer theory should be concerned over whether these differences are scientifically determined or if consumers can even perceive any actual differences. As long as consumers believe there is a difference, they will value their ability to purchase raw milk cheese over its pasteurized counterparts. Irrespective of utterly subjective notions of “superiority,” there can be no question that the presence of different varieties of raw milk and pasteurized artisanal cheeses on the market would contribute to the experience of the postmodern consumer, who, above all else, seeks diversity and plurality of choice. If artisanal cheese epitomizes the specialty cheese increasingly sought after by the postmodern consumer, and then purchasing raw milk artisanal cheese represents the ultimate postmodern consumer decision.

Artisanal cheese producers should feel confident about an expanding U.S. market for their products. Trade groups which represent artisanal cheese producers should be considering additional ways in which they can encourage the growth of this market and differentiate their products from European competitors.

Lessons from France

When people think of raw milk cheese, they think of France. French consumption of cheese is the largest in the world, with an average of 54.0 lbs per capita per year.¹⁴⁸ In addition to a thriving domestic consumer economy, French exports of cheese were valued at 2 billion euros in 2002.¹⁴⁹ When compared to French imports of 0.7 billion euros, the trade balance surplus was 1.3 billion euros in that year.¹⁵⁰ The largest export markets for French cheese, by value, were Germany (25.2%), Belgium (13.6%), the United Kingdom

¹⁴⁸ *The French Market for Cheese*, supra note 133, at 1.

¹⁴⁹ *Id.* at 4.

¹⁵⁰ *Id.*

(10.4%), Italy (8.7%), and Spain (7.7%).¹⁵¹ The United States received only 4.6% of French cheese exports – a figure only slightly higher than the Netherlands, Luxembourg, or Switzerland.¹⁵² The main suppliers of cheese to France in 2002 were the Netherlands (25.6%), Germany (23.9%), Italy (21.1%), Switzerland (6.0%), Belgium (5.8%%), the United Kingdom (3.4%), and Denmark (3.2%). The United States is not a noticeable supplier to cheese to France.¹⁵³

What accounts for the economic success of the French cheese industry, both domestically and abroad? The clear answer to the domestic success is a cultural explanation: the French consume much more cheese per capita per year than do Americans (54.0 lbs compared to 30.58 lbs, or a ratio of 1.7 : 1). This gap has narrowed since 1958, when the ratio of French to American consumption was 2.17 : 1.¹⁵⁴ There is a certain circularity, however, in pointing to greater consumption of cheese as the cause of the French cheese industry's success. The real question, therefore, is why do the French consume so much cheese, and, correlatively how can the American cheese industry achieve similar prominence within its own country?

There are two main aspects of French cheese production which the American industry lacks: (1) sheer variety of cheeses available, and (2) historic and geographic traditions which dictate production methods. The French produce over 400 varieties of cheese.¹⁵⁵ These cheeses are not, as in the United States, recently developed imitations of cheeses which originated abroad. Rather, the vast majority of these varieties are more than a century old, and their production is subject to standards based on historical and geographic tradition. For

¹⁵¹Id.

¹⁵²Id.

¹⁵³Id. at 8.

¹⁵⁴See supra note 133.

¹⁵⁵*The French Market for Cheese*, supra note 133, at 1.

example, Neufchâtel, made in the pays de Bray in Normandy, dates back to 1035 A.D., while Camembert, made in the pays d'Auge in Normandy, was created in 1791 in the midst of the French Revolution.¹⁵⁶ While these cheeses are now made in large factories in both the United States and in France, the French can also purchase Neufchâtel and Camembert manufactured according to strict, traditional methods, and sold as foods of Appellation d'Origine Contrôlé (AOC).

The AOC system does not translate easily into American culture, but it is important to understand because its presence has created enormous value for the French cheese industry. As early as the 17th century, the French have protected the appellation of origin of products such as wine and cheese.¹⁵⁷ Appellation of origin is not as simple as an indication of source (indication de provenance) – AOC indicates the quality of the product sold and not merely its geographic source. AOC status certifies that a product is derived from certain natural and human factors which are essential to its identity:

For the French, cheese production is more than the actual process of cheese making. French cheese is a product of geographic location, history and tradition. The geographic location of cheese production partially determines the taste and quality of the cheese. Geographic factors include the climate, soil, grass, milk produced in that location and the presence of certain animals and vegetation. Camembert is said to taste better in the spring because of the difference in the quality of the milk, which results from what the cows eat and the surrounding climate. It is possible to imagine being able to replicate certain geographical conditions when producing cheese; however, some argue that human factors, such as culture and tradition, are lacking. Cheese making traditions vary from one locale to another. Accordingly, you could never produce the exact cheese of one appellation of origin in a different place.¹⁵⁸

The official dual purpose of the AOC system is to protect consumers from being deceived by an inferior

¹⁵⁶Danielle B. Shalov, *Will The European Union Prove to be Lactose Intolerant?* 11 CARDOZO J. INT'L & COMP. L. 1099, 1103-04 (Spring 2004).

¹⁵⁷Id. at 1106.

product and to protect producers from unfair competition.¹⁵⁹ Most importantly, however, the AOC system enables the production of high quality products and legitimizes the price premium that such products command over roughly comparable foods. As such, the AOC system is fundamentally anticompetitive – the ability to designate one’s product as Camembert de Normandie (AOC) instead of simply as camembert, creates value for smaller, local producers whose success depends on recognition of superiority and not volume production.

The anticompetitive value of the AOC system is easily seen in its 20th century evolution. Although it first was designed to set standards for small-scale producers, the system now sets standards for four categories of cheese production:

1. *Fermier*, or farmhouse, where an independent owner-operator uses traditional methods and milk from a herd raised on the property.
2. *Artisanal*, a term we’re appropriating in English-American usage, which means the cheeses are handmade by an independent farm or small dairy owner but the milk can come from outside sources.
3. *Fruitière*, *cremier*, or *cooperative*, where the milk is bought from local farms and made in the small local dairy.
4. *Industriel*, or factory, cheeses, where the cheese is made by factory-style methods and milk can come from afar.¹⁶⁰

The post-World War II introduction of *industriel* AOC cheeses represents a clear departure from the official purposes of appellation of origin. *Industriel* AOC’s are little more than certification that a cheese is produced according to certain factory methods in a certain location, allowing practices such as collection of milk from multiple sources, pasteurization, use of synthesized starters and rennets, centralization of production, loss

¹⁵⁹Id. at 1107.

of traditional animal breeds, and artificially induced rinds.¹⁶¹ An AOC for any given cheese, therefore, may include four sets of standards, of which three will at least partially serve the official purpose of the AOC system, and of which the *industriel* appellation, if applicable, will serve as little more than commercial branding.

There is economic value, however, in commercial branding. The success of *industriel* AOC's is that they are regulated alongside, and associated with, the truly traditional standards. Indeed, the value of the *industriel* AOC depends on the existence of more stringent methods, so that cheese connoisseurs can claim that the AOC is a reliable indicator of good – even very good – cheeses.¹⁶² The *industriel* AOC can also be seen as evidence of how many French cheeses have become victims of their own stellar reputations and success.¹⁶³ The foreign demand for soft French cheeses in countries which did not allow import of raw milk cheese has created financial incentives for the French to manufacture pasteurized versions of their traditional products. In order to compete against French homogenized and pasteurized-milk cheeses created for export, some AOC's decided to create their own standards for factory cheeses. For example, Vacherin du Haut-Doubs (AOC), a raw cow's milk cheese from the mountainous Franche-Comté, is sold in the United States as L'Edel de Cleron, a factory-made cheese which uses pasteurized milk. In this manner, the AOC protects itself against market-share erosion by French or foreign competitors who may use the same factory methods as L'Edel de Cleron.

The current AOC system therefore simultaneously generates value for small-scale producers and large fac-

¹⁶¹Id. at 181.

¹⁶²Id.

¹⁶³Id.

tories. It provides protection against foreign and domestic imitators. It acts as an indication of value which justifies a price premium over unreliable competitor brands. Its use has not gone unchallenged in the European Union, as a barrier to the free movement of goods.

The past decade has witnessed a series of cases in the European Court of Justice which address the conflict between protection of designation of origin and free movement of goods.¹⁶⁴ Many Member States entered the EU with systems highly similar to the French AOC. For a while, it was unclear whether these systems would be respected. In 1992, Article 17 of the Council Regulation EEC No. 2081/92 recognized the importance to Member States of maintaining stringent standards of production and permitted registration with the EU of Protected Designation of Origin (POD).¹⁶⁵ The POD system affords somewhat less protection within the EU than the AOC system guarantees within France (for example, Member States can petition for removal or denial of POD status, which happened to Feta cheese, because it had been made and marketed outside the proposed origin for a substantial period of time).¹⁶⁶ Nonetheless, the POD system affords additional protection within the European Union, as seen when producers of Gorgonzola (PDO) successfully petitioned the European Court of Justice for cancellation of the trademark Cambozola in the marketing of an Austrian blue cheese.¹⁶⁷ Currently, all 38 cheese varieties which have attained AOC status within France have been granted POD status within the European Union.¹⁶⁸

The value of the AOC label as a marketing tool, however, was plainly visible prior to the formation of the

¹⁶⁴Shalov, *supra* note 156, at 1120-24.

¹⁶⁵*Id.* at 1120.

¹⁶⁶*Id.*

¹⁶⁷*Id.* at 1119.

¹⁶⁸*Id.*

EU. Its value lies not in the ability to enjoin production of imitators under similar names, but in the ability to signal high quality to domestic and foreign consumers. Nowhere has the success of the AOC system abroad been more visible than in the sale and marketing of wine. Restaurant *sommeliers* and even moderately seasoned consumers of French wine have learned to distinguish between AOC wine and wine that is merely designated as Vin de Pays or as Appellation d'Origine Vin D elimit e de Qualit e Sup erieure. Among the confusion of French wines, none of which are labeled according to the grape varietal contained therein, the AOC designation serves as a baseline indicator of quality. Although American consumers have not proved to be as attuned to the AOC designation in their purchases of cheese, this reflects the relatively recent expansion of the U.S. market for expensive and imported cheese. The value of the AOC label is shown by the positive recognition of cheese experts such as Max McCalman.¹⁶⁹ Although any factory in America or France can produce camembert and sell it under the generic name, only Camembert de Normandie (AOC) will be identified as such.

The lesson which American artisanal cheese-makers should take from the success of the AOC system in France is that consumers can learn to associate quality and product desirability with traditional methods of production and geographic designations of origin. The several hundreds of producers of artisanal cheese in the United States are located across all fifty states, with virtually no pattern of regional specialties. This contrasts with France, where, for example, Normandy is associated with soft, unaged cow's milk cheeses. The French model does not need to be copied directly into American practices, but trade groups consisting of artisanal cheese producers, organized by geographic area, by method of cheese production, and/or by variety of cheese produced, could develop similar signaling devices which would help their products develop

¹⁶⁹McCALMAN, *supra* note 11, at 180.

interstate markets.

Already, California and Vermont enjoyed a strong reputation for producing quality American artisanal cheeses, largely because many of the first artisanal cheeses were created there in the 1980s.¹⁷⁰ As a result, although there is little homogeneity among the varieties of artisanal cheeses sold from these two regions, and no actual oversight of the quality of their methods of production, new artisanal cheeses from California and Vermont can free-ride on established regional reputations. One can imagine American derivatives of the French AOC system that would unite producers of one state, or many states. For example, there could be a trade group of artisanal Louisiana cheese producers, or a national trade group for organic producers, or one for blue cheese. There can be little question, however, that a regional trade group (such as a northern California goat cheese association) would be a stronger signal of quality than a mere national trade group for producers using organic methods or making a specific variety of cheese.

One major benefit of adoption of an AOC-type system by U.S. artisanal producers is that it would legitimize American cheeses in comparison to their European counterparts and domestic factory-made competitors. When the present consumer buys a Roquefort (AOC), he can feel assured that it is produced according to traditional methods and that the product comes from the region which traditionally produces this cheese. In contrast, when a consumer purchases an American blue cheese (such as Great Hill Dairy, which produces Great Hill Blue in Marion, Massachusetts), in order for him to recognize the product as being made according to true artisanal methods or belonging to a particular region of the country, he must recognize the name of the individual producer or trust information contained on the packaging. An identifying qualification or membership more clearly justifies the price premium demanded by artisanal cheese, and would allow

¹⁷⁰ *Our 50 Favorite American Cheeses*, SAVEUR (Apr. 2005), at 68-73.

American cheese to compete more effectively with imported European varieties and domestic factory specialty cheeses. Although there is no measurable evidence of this phenomenon, it may be that even the best American artisanal cheeses are sold at a discount relative to the expense and care that went into their production, when compared to the price of comparable European cheeses.

A challenge to the effectiveness of geographically based AOC's in the United States is the present-day prohibition on cheeses made from unaged raw milk, and the looming threat of a complete ban on the use of unpasteurized milk. While in France, the AOC system operates successfully as a designation of *terroir* for wines and cheeses, there would be less force behind an American assertion that an artisanal cheese made from pasteurized milk retains the individual characteristics of milk from its geographic region. This is because pasteurization implies pure reliance on starter cultures and denaturing of certain proteins, and the technique encourages the combination of milk from far-flung sources that is produced at different times. Currently most artisanal hard cheeses are made from raw milk and are aged, and therefore these cheeses could fully benefit from trade organizations' establishment of AOC-type signals of quality. Unfortunately, federal and state regulations have made it difficult for American artisanal soft cheeses to credibly enjoy similar promotion and protection, and the danger of an analogous fate looms over hard cheeses produced in this country. Both levels of governments should consider the value that could be created by an American AOC-system that is credibly based on regional quality. And, the value of raw milk as an industry indicator of authenticity should be weighed as part of any cost-benefit analysis affecting regulation of cheese production.

The European Union's response to safety concerns over raw milk cheese

During 1990-1992, the EU Member States debated whether the use of raw milk was safe for fresh and

aged cheeses.¹⁷¹ While raw milk cheese played a major role in several European economies (France, Italy, and Spain, in particular), other countries, such as Denmark, had long required pasteurization of all milk products.¹⁷² A more complicated situation was that of Great Britain, which in the 1980s had experienced a *Listeria* scare that was unjustly blamed on unpasteurized cheeses (the culprit, as it turned out, was a contaminated cheese made from pasteurized milk). Although Great Britain considered and rejected a ban on raw milk cheeses in the late 1980s, all supermarkets agreed to stop stocking them, and artisanal producers therefore began using pasteurized milk.¹⁷³

Ultimately, the European Union reached a compromise: its Member States either use pasteurized milk in the manufacture of cheese or comply with self-controls based on the American principles of Hazard Analysis and Control Points (HACCP).¹⁷⁴ In the United States, HACCP is employed by the U.S. Department of Agriculture to promote the safety of meat and poultry, and by the FDA for seafood, juice, and other food industries which have voluntarily adopted HACCP principles.¹⁷⁵ The milk and dairy products industries are among those which have voluntarily instituted HACCP procedures.¹⁷⁶ Unlike the European Union, the United States does not view HACCP as a substitute for requiring pasteurization of milk in unaged cheeses.

In France and other EU Member States, safety is deemed to be adequately protected by strict regulation and inspection of facilities, equipment, and operations of dairies, rigorous hygiene standards for the production and collection of milk, and microbiological criteria for products that reach the consumer market. Thanks to the EU's faith in the ability of its Member States to administer HACCP programs, sales of raw milk cheeses

¹⁷¹Vermont Cheese Council, The Raw Milk Debate in the European Union, available at http://www.vtcheese.com/vtcheese/rawmilk_files/rawmilk3.html (last visited Apr. 20, 2005).

¹⁷²*Id.*

¹⁷³MCCALMAN, *supra* note 11, at 15.

¹⁷⁴Vermont Cheese Council, *supra* note 171.

¹⁷⁵FDA Backgrounder, HAACP: A State-of-the-art Approach to Food Safety, available at <http://www.cfsan.fda.gov/~lrd/bghaccp.html> (last visited Apr. 20, 2005).

¹⁷⁶*Id.*

in Europe are valued at 7 billion dollars annually.¹⁷⁷ Some European producers have claimed that Americans do not have the technology or knowledge necessary to make raw milk cheeses safe.¹⁷⁸ This assertion is belied by the outstanding record of U.S. aged raw milk cheeses (there is no way to assess the safety record of fresh cheeses in this country because they are illegal). According to Catherine Donnelly, professor of food microbiology at UVM, [I]f you did a survey of hard cheeses in the U.S., you might find a higher incidence of *Listeria* in pasteurized cheeses.¹⁷⁹

The purpose of this paper is not to assert that HACCP would be an adequate substitute for existing U.S. regulations which imply pasteurization. Given that the FDA is currently preoccupied with reexamining the safety of aged raw milk cheeses, it would be extreme to propose that the agency consider legalizing the production of fresh raw milk cheeses. Indeed, the Cheese of Choice Coalition has avoided expressing an opinion on this topic, and has contented itself with advocating the continuation of existing standards. As the history of U.S. regulations has demonstrated, however, state and federal governments have never really addressed this issue. The current government enthusiasm over extending HACCP to as many food industries as possible – and in particular the factory-cheese industry’s voluntary adoption of HACCP – demonstrates the continued assumption that pasteurization is a necessary safety device.

¹⁷⁷Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 533 fn. 34 (1998).

¹⁷⁸Id. at 533 fn. 35.

¹⁷⁹Ingram, *supra* note 64, at 466 fn. 26.

CONCLUSION

It may be that the use of raw milk in cheese production is a relatively insignificant topic in American society. To claim that raw milk cheese is unimportant, however, is to marginalize the economic and cultural importance of the small dairy farmer by denying him the full opportunity to participate in a relatively new value-added industry. The government has failed to explore ways through which the small scale production of raw milk cheeses (fresh, aged, or both) can be made safe. Instead, the ongoing federal study assumes that raw milk will necessarily be contaminated with pathogens, and then proceeds to demonstrate that the current aging requirements are insufficient to destroy them.

In many ways, the raw milk cheese movement is unfortunate in that it is often confused with the fluid raw milk movement. There are a significant number of individuals who believe that fluid raw milk affords health benefits which are destroyed by pasteurization. These individuals often simultaneously advocate the use of raw milk in cheese, butter, and yogurt as well. The real dangers of fluid raw milk, however, cannot be equated with the asserted dangers of raw milk cheese. For example, fluid raw milk is obviously never allowed to curdle, meaning that it never undergoes lactic acid fermentation during which the acid environment kills off many pathogens. Furthermore, small-scale cheese producers insist that many varieties of contamination become visible during the cheese-making process because the milk will not curdle properly. This signaling device is also absent for fluid milk producers. Finally, many of the contamination dangers in fluid raw milk are the result of the difficulty in safe transportation, storage, and distribution – problems that are not similarly applicable to raw milk cheeses. To some extent, the federal government's lack of receptiveness to raw milk cheese advocates is probably related to its general disdain for the fluid raw milk movement.¹⁸⁰

¹⁸⁰The FDA's Got Milk? Make Sure It's Pasteurized? release states:

Many states which have acceded to the demands of fluid raw milk consumer advocates, however, have not extended similar state Department of Agriculture resources necessary to monitor safe production of milk for use in raw milk cheese. Instead, the country is peppered with states which allow production and sale of fluid raw milk, but will not permit the same milk to be sold as fresh cheese. This anomaly has little scientific basis and is probably the result of insufficient lobbying by artisanal cheese producers.

Artisanal cheese producers should look to their state governments to relax regulations prohibiting the intrastate manufacture of raw milk artisanal cheeses. The 1987 federal regulations refused to ban intrastate sales of raw milk products because it was deemed unnecessary to effect the interstate prohibition. This means that the state of New York, if it chose to, could establish HACCP procedures over small dairies in its many, relatively poor rural areas. These dairies could then sell raw milk artisanal cheeses to the finest restaurants in New York City. States such as Kansas, which do not have as many large cities and gourmet restaurants as New York, would also benefit from agritourism. Although changes in state regulations affecting intrastate sales would create unequal markets among states, the inequality would only apply to raw milk cheese which could not be legally shipped interstate.

It may be that states are justifiably afraid that such relaxation of intrastate sales would prompt the federal government to extend its interstate ban to intrastate sales. If the issue of the adequacy of HACCP is going

Raw milk advocates claim that unprocessed milk is healthier because pasteurization destroys nutrients and the enzymes necessary to absorb calcium. It also kills beneficial bacteria and is associated with allergies, arthritis, and other diseases, they say.

This is simply not the case, says Sheehan. Research has shown that there is no significant difference in the nutritional value of pasteurized and unpasteurized, he says. The caseins, the major family of milk proteins, are largely unaffected, and any modification in whey protein that might occur is barely perceptible.

Milk is a good source of the vitamins thiamine, folate, B-12, and riboflavin, adds Sheehan, and pasteurization results in losses of anywhere from zero to 10 percent for each of these, which most would consider only a marginal reduction. While the major nutrients are left unchanged by pasteurization, vitamin D, which enhances the body's absorption of calcium, is added to processed milk. Vitamin D is not found in significant levels in raw milk.

Pasteurization will destroy some enzymes, says Barbara Ingham, Ph.D., associate professor and extension food scientist at the University of Wisconsin-Madison. But the enzymes that are naturally present in milk are bovine enzymes. Our bodies don't use animal enzymes to help metabolize calcium and other nutrients.

See supra note 122, at 2.

to arise any time soon, however, it seems most likely that it will occur at the state level. Part III of this paper discussed the AOC system which benefits French cheese producers and proposed that U.S. artisanal cheese-makers could establish analogous trade groups. Another purpose of these trade groups would be organize the advocacy of sustainable small-scale dairy farming interests, among which would be legalization of fresh raw milk cheeses or at least the preservation of existing regulations allowing raw milk cheeses aged over 60 days. Although this topic might be viewed by some as insignificant, it deserves more attention than it has been given to-date by U.S. federal and state authorities.