

**'CAUTION – PRESUPPOSING A SUCCESSFUL OUTCOME MAY BE HAZARDOUS TO
ACHIEVING YOUR POLICY GOALS': EVALUATING WHETHER MANDATORY
WARNINGS FOR SOFT AND SEMI-SOFT CHEESES WOULD BE EFFECTIVE**

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ABSTRACT

This paper examines the labeling of soft and semi-soft cheeses in the United States, such as Brie and Camembert. These varieties of cheese can be viewed as posing higher risks to human health from a foodborne illness perspective, particularly if they are made from unpasteurized milk. Given existing labeling requirements for some higher-risk foods, the issue of whether federal law should require cheesemakers to include warning labels on product packaging could become a more significant part of the debate about how the United States Food and Drug Administration should regulate the manufacturing, distribution and sale of soft and semi-soft cheeses. Case law suggests that clear labeling of the risks associated with these cheeses could help manufacturers, retailers and intermediaries shield themselves from potential civil liability. The paper examines recent studies about recommended controls to manufacture cheese safely. It also describes mandatory labeling and related initiatives in the United States for other foods. Caution is recommended before a mandated warning proposal is pursued for soft and semi-soft cheeses. Maintaining the status quo for how cheese is made, aged, distributed and sold, while simply requiring mandatory label warnings about the potential food safety risks, is not likely to be an effective policy solution that will further society's interest in promoting safer food. Other, science-based precautions and controls should be applied in both milking dairy animals and in making, aging and distributing cheese. If mandated warnings are to be adopted, they should be part of a broader and sustained public awareness campaign that takes the unique characteristics of each target audience into account.

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I. Introduction

Many Americans enjoy specialty cheeses and support artisanal methods of cheese production. Because of the smaller scale of manufacturing and the local character of many of these cheeses, entrepreneurs can more readily gain a foothold in a competitive marketplace. This small, but growing,¹ segment of the market is of direct importance to the production and marketing of agricultural products in the United States. The future growth of this sector has implications for the local food movement and rural economic development. Fostering success through effective public policy is of interest to a broad range of stakeholders, including government regulators, consumers, family-run dairy operations, small cheese plants and large dairy processors.

Creativity has flourished in recent years. New approaches to cheesemaking in the United States have resulted in an expansion of the kinds of cheese available. When it comes to risk, however, not all cheeses are created equal. This paper examines the labeling of certain varieties of cheese that pose higher risks to human health from a foodborne illness perspective. In particular, the categories of cheese under consideration in this paper are soft and semi-soft cheeses, such as Brie and Camembert, including those soft and semi-soft cheeses that are made from unpasteurized milk² as opposed to pasteurized milk. Compared to the mainstream hard

¹ As an example of the growth of this sector, the number of artisan cheesemakers in Washington State grew from 18 to 34 from 2005 to 2010 and, in Vermont, from 27 to 48 during the same period. William Neuman, *Small Cheesemaker Defies F.D.A. Over Recall*, NEW YORK TIMES, Nov. 19, 2010, available at <http://www.nytimes.com/2010/11/20/business/20artisan.html?pagewanted=all> (last visited Apr. 10, 2013).

² Some original sources referenced and quoted from in this paper use the term “raw milk”. Where possible, the term “unpasteurized milk” will be used consistently in this paper. The term “unpasteurized milk” is meant to refer to milk from dairy animals that was not treated to achieve the prescribed time-temperature relationship mandated for pasteurization.

cheese varieties that are made from pasteurized milk in the United States, these cheeses pose a higher risk on a per-serving basis of transmitting foodborne illness to people. Soft and semi-soft cheeses are also the subject of the most recent initiative by the United States Food and Drug Administration (“FDA”) and Health Canada to assess risk in the context of developing policy options.³ As the FDA grapples with how the production and labeling of these cheeses should be regulated amid new developments in food safety science, more attention will likely be given to the issue of whether or not federal law should be altered to require clear statements about how cheeses are made (including mandated warning labels on the packaging of some cheeses).

There is a clear interest within the FDA to revisit the current rules around the manufacture and sale of soft and semi-soft cheeses, as well as all cheeses made from unpasteurized milk.⁴ Labeling requirements will likely be one consideration in that review. Precedents can be found in other higher-risk food products at both the state and federal levels. For example, in many states where unpasteurized milk can be purchased lawfully, there are

³ On February 11, 2013, the United States Food and Drug Administration (“FDA”) published a notice in the Federal Register about a draft quantitative risk assessment prepared jointly with Health Canada on the risk of listeriosis from soft-ripened cheese consumption in the United States and Canada. Although not exclusive to cheese made from unpasteurized milk, the notice referred to the possibility that the final risk assessment will be used by the FDA to complement other data and analyses in the re-evaluation of the existing 60-day aging requirement for cheeses made with unpasteurized milk found in 21 CFR § 133.182(a): *Draft Joint Food and Drug Administration/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada*, 78 Fed. Reg. 9701-01 (Feb. 11, 2013).

⁴ The FDA has been reviewing the 60-day aging requirement and other measures for cheeses made from unpasteurized milk since at least 1997: Bill Marler, *The Raw Milk Beat Goes On: A Look at the Literature and the 60-Day Raw Milk Cheese Aging Rule – Part 1*, MARLERBLOG, Dec. 12, 2010, <http://www.marlerblog.com/case-news/the-raw-milk-beat-goes-on-a-look-at-the-literature-and-the-60-day-raw-milk-cheese-aging-rule-part/> (last visited Feb. 21, 2013). See also Janet Fletcher, *Cheese Lovers Await the Fate of Fromage*, SAN FRANCISCO CHRONICLE, Aug. 11, 1999, available at <http://www.sfgate.com/health/article/Cheese-Lovers-Await-The-Fate-of-Fromage-2915549.php#ixzz2S0Qud6LO> (last visited Apr. 30, 2013). The FDA is reported to have developed a renewed interest in examining the 60-day aging rule since 2009. William Neuman, *Raw Milk Cheesemakers Fret Over Possible New Rules*, NEW YORK TIMES, Feb. 4, 2011, available at http://www.nytimes.com/2011/02/05/business/05cheese.html?_r=2&src=busln& (last visited Apr. 10, 2013).

already container labeling and point-of-sale signage requirements to address the inherent risks associated with consuming fluid milk that has not been pasteurized.⁵ For unpasteurized shell eggs, federal rules stipulate that safe handling instructions must appear on egg packages, whether the eggs are sold in intrastate or interstate commerce.⁶ For soft and semi-soft cheeses, the FDA will be examining how these cheeses can be made safer. If the inherent risks cannot be mitigated adequately, labeling is one possible policy proposal that could emerge from that review. For cheese, the mandatory labeling issue is, therefore, poised for a more thorough examination in the coming months and years.⁷

There is no statutory obligation at the federal level for manufacturers of any kind of cheese (whether made from pasteurized or unpasteurized milk) to warn consumers of the potential risks of contracting a foodborne illness.⁸ When it comes to the broader public policy question of whether the FDA should require some cheeses to carry written warnings, caution is advised. Pending further study, mandatory written warnings could be a helpful addition to –

⁵ In Massachusetts, all retail containers of raw cow or raw goat milk must be conspicuously labeled using prescribed font sizes with the following statement: “Raw milk is not pasteurized. Pasteurization destroys organisms that may be harmful to human health”. A sign must also be posted in the area where the unpasteurized milk is sold and placed in a location where it can be easily observed: 330 Mass. Code Regs. 27.08. In New York State, a farm that holds a permit to sell unpasteurized milk from the farm-gate must post visible signage stating “NOTICE: Raw milk sold here. Raw milk does not provide the protection of pasteurization.” N.Y. Comp. Codes R. & Regs. tit. 1, § 2.3(b). For other examples, see S.C. Code Ann. Regs. 61-34. IV and Utah Admin. Code R 70-330-7 A.

⁶ 21 CFR § 101.17(h).

⁷ In the case of cheese made from unpasteurized milk, the mandatory labeling issue has come up as a public policy issue in Canada as well: Ronald Doering, *Raw milk cheese – Another sterile debate*, FOOD IN CANADA, Oct. 2013 26.

⁸ Some states may have their own labeling requirements for the intrastate sale of cheese and other dairy products. In Arizona, cottage cheese and cheeses made from unpasteurized milk or cream must prominently state on the label’s principal display panel the term “raw milk product”: Ariz. Rev. Stat. Ann. § 3-606 C. Although unpasteurized milk in fluid form is required to carry an additional consumer warning on the label (“Raw milk: not pasteurized and may contain organisms injurious to your health”), cottage cheese and cheeses made from unpasteurized milk or cream are not specifically required to do so. In Alaska, cheese or cheese products made from unpasteurized milk must be labeled “RAW MILK PRODUCT,” “MADE FROM RAW MILK,” or “MADE FROM GRADE A RAW MILK” using prescribed text sizes: Alaska Admin. Code tit. 18, § 32.265(c).

but not a substitute for – other mandatory precautions and controls that should be applied. To make cheese safe, specific steps need to be taken consistently in both milking dairy animals and in making the cheese, including more stringent microbial standards for milk and greater attention to the hygienic and other controls used in making, storing, packaging and distributing cheese. In short, maintaining the status quo, while simply requiring mandatory label warnings about the potential food safety risks, is not likely to be an effective policy solution that will further society's interest in promoting safer food.

II. Human Health Risks with Soft and Semi-Soft Cheeses (Including Cheese Made from Unpasteurized Milk)

Cheese is a ready-to-eat food. Most cheeses are made to be consumed in the form in which they are purchased. Although they can be used as ingredients in other foods, it is reasonable to expect that soft and semi-soft cheeses will often be consumed without a further control step, such as cooking, that might be capable of destroying pathogens. If a product is contaminated with pathogenic bacteria when it leaves the cheesemaker's control, there are likely to be few, if any, opportunities to address the contamination before the cheese is consumed.

There are a number of foodborne illnesses that can result from consuming soft and semi-soft cheeses. Invasive listeriosis is a significant foodborne illness that can result from ingestion of the bacterium *Listeria monocytogenes*. Other foodborne pathogens, such as verocytotoxin-producing *Escherichia coli* (VTEC), are also of significance, primarily for those

cheeses made with unpasteurized milk (even if they are aged prior to sale).⁹ Other relevant pathogens for cheese include, among others, *Staphylococcus aureus* (staphylococcal enterotoxins) and *Salmonella spp.*

For soft and semi-soft cheeses (regardless of whether they are made using pasteurized or unpasteurized milk), the bacterium *Listeria monocytogenes* is of particular concern as a foodborne pathogen. The reason for the concern is due to the potential severity of human illness that can result from invasive listeriosis and the relatively high case fatality rate. The fact that contaminated cheese can affect vulnerable segments of the population disproportionately (including young children, the unborn, the elderly, the immunocompromised and pregnant women)¹⁰ suggests that there are strong societal interests in addressing, to the extent practicable, the known risks. Invasive listeriosis can be fatal for someone in a high-risk group and can lead to tragic outcomes for expectant families. As the population ages, the proportion of people who are most at risk of invasive listeriosis can be expected to increase. Although *Listeria monocytogenes* can be found in samples of milk taken from the dairy farm bulk tank,¹¹

⁹ C. Vernozy-Rozand, C. Mazuy-Cruchaudet, C. Bavai, M.P. Montet, V. Bonin, A. Dernburg and Y. Richard, *Growth and survival of Escherichia coli O157:H7 during the manufacture and ripening of raw goat milk lactic cheeses*, 105 International Journal of Food Microbiology (2005) 83 and J. E. Schlessner, R. Gerdes, S. Ravishankar, K. Madsen, J. Mowbray, and A. Y.-L. Teo, *Survival of a Five-Strain Cocktail of Escherichia coli O157:H7 during the 60-Day Aging Period of Cheddar Cheese Made from Unpasteurized Milk*, 69 Journal of Food Protection (2006) 990.

¹⁰ According to the Centers for Disease Control and Prevention (“CDC”), the milder form of listeriosis typically causes fever and muscle aches, as well as diarrhea or other gastrointestinal symptoms. With invasive listeriosis, where the bacteria spread beyond the gastrointestinal tract, the illness can lead to a series of more severe symptoms, depending on the susceptibility of the individual. Complications can include, for pregnant women, fever, fatigue, miscarriage, stillbirth, premature delivery, or, following birth, a serious infection of the baby, such as meningitis. For other people, in addition to fever and muscle aches, symptoms can include headache, stiff neck, confusion, loss of balance, and convulsions. Septicemia and meningitis are also possible life-threatening complications. CDC, *Listeria (Listeriosis)*, <http://www.cdc.gov/listeria/> (last visited Apr. 4, 2013).

¹¹ United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health, *Info Sheet: Salmonella and Listeria in Bulk Tank Milk on U.S. Dairies*, (Dec. 2003) at 2-3, available at

it is also found widely in the environment. It is spread to humans predominantly through contaminated food.¹² Unpasteurized milk can be a source of *Listeria monocytogenes*,¹³ but the bacteria is believed to be more commonly introduced to cheese and other ready-to-eat foods during human handling in processing and through contaminated food contact surfaces. *Listeria monocytogenes* can grow at refrigeration temperatures due to its psychrotrophic nature. On its own, keeping cheese cold prior to consumption is not a sufficient control step to prevent foodborne illness.

Listeria monocytogenes has been found in soft and semi-soft cheeses.¹⁴ The Centers for Disease Control and Prevention (“CDC”) notes that unpasteurized milk, plus cheese and other foods made from unpasteurized milk, are particularly likely to contain the bacterium.¹⁵ There have been several known outbreaks of foodborne illness in the United States, Canada and other countries that have been associated with cheese of all varieties, including cheeses made with

http://www.aphis.usda.gov/animal_health/nahms/dairy/downloads/dairy02/Dairy02_is_BulkTank.pdf (last visited Apr. 29, 2013).

¹² E.J. Cartwright, K.A. Jackson, S.D. Johnson, L.M. Graves, B.J. Silk, and B.E. Mahon, *Listeriosis outbreaks and associated food vehicles, United States, 1998–2008*, 19 Emerg. Infect. Dis. (Jan. 2013) 1 at 2, available at <http://dx.doi.org/10.3201/eid1901.120393> (last visited Feb. 20, 2013).

¹³ FDA, *The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk*, <http://www.fda.gov/Food/ResourcesForYou/consumers/ucm079516.htm> (last visited May 6, 2013).

¹⁴ “In the United States and Canada, sporadic cases and some outbreaks caused by the bacterium *Listeria monocytogenes* have been strongly associated with cheese, particularly soft and soft- ripened cheese.” FDA, Center for Food Safety and Applied Nutrition, and Health Canada, Food Directorate, *Joint FDA / Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Interpretative Summary* (2012) at 1, available at <http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM338618.pdf> (last visited Apr. 29, 2013).

¹⁵ CDC, *Listeria (Listeriosis)*, supra note 10. Although most soft and semi-soft cheeses are not made from unpasteurized milk in the United States, many of the highly-regarded European varieties are, in fact, required to be made from unpasteurized milk. For example, *camembert de Normandie* and *brie de Meaux* are both subject to controlled designations of origin (known by the initials “AOC” in France) and must be made from unpasteurized milk: Ministère de l’Agriculture, de l’Agroalimentaire et de la Forêt (France), *Produits et labels: Le camembert de Normandie AOC*, <http://alimentation.gouv.fr/camembert-de-normandie> (last visited Apr. 29, 2013) and L’Institut national de l’origine et de la qualité (France), *Fiche: Brie de Meaux*, <http://www.inao.gouv.fr/> (last visited Apr. 29, 2013).

pasteurized and unpasteurized milk. A recent report published in *Emerging Infectious Diseases* found six cheese-related outbreaks of foodborne listeriosis in the United States during the ten-year period 1998-2008. According to the authors, Mexican-style cheese¹⁶ was implicated in four outbreaks (three of which involved cheese made from unpasteurized milk) and two outbreaks involved other dairy products, including cheese made from pasteurized sheep's milk and flavoured, pasteurized milk.¹⁷ In 2012, 22 people were reported to be infected with the outbreak-associated strain of *Listeria monocytogenes* in 13 states and in the District of Columbia. Official investigations determined that the likely source of the illnesses was a brand of ricotta salata cheese that had been imported from Italy and distributed in the United States by Forever Cheese, Inc.¹⁸

Listeriosis is not the only foodborne illness of concern with cheese. In 2010, the CDC reported on 38 documented illnesses from *E. coli* O157:H7 in five states. Laboratory testing by the California Department of Food and Agriculture found *Listeria monocytogenes* and *E. coli* O157:H7 in associated cheese samples. The cheesemaker, Bravo Farms, had marketed a Dutch-

¹⁶ Mexican-style soft cheeses that have been implicated in some outbreaks in the United States, such as *queso blanco* and *queso fresco*, are often made in homes or other unlicensed and uninspected facilities. This fact should distinguish these outbreaks from the others cited in this paragraph and in the paragraphs that follow. See, for example, CDC, *Outbreak of Listeriosis Associated With Homemade Mexican-Style Cheese - North Carolina, October 2000-January 2001*, 50 MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR) (July 6, 2001), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5026a3.htm> (last visited Apr. 30, 2013).

¹⁷ E.J. Cartwright et al., *supra* note 12 at 3.

¹⁸ CDC, *Multistate Outbreak of Listeriosis Linked to Imported Frescolina Marte Brand Ricotta Salata Cheese (Final Update – 21 November 2012)*, available at <http://www.cdc.gov/listeria/outbreaks/cheese-09-12/index.html> (last visited Apr. 11, 2013). In Australia, Jindi Cheese Pty. Ltd. recalled a number of cheeses, including Brie and Camembert, that were sold in Victoria, New South Wales and Queensland due to contamination by *Listeria monocytogenes* in late 2012. See Food Standards Australia New Zealand (FSANZ), *Jindi Cheese – potential microbial contamination (Listeria spp)*, <http://www.foodstandards.gov.au/consumerinformation/foodrecalls/currentconsumerlevelrecalls/jindicheesemicrobial5762.cfm> (last visited May 2, 2013). The resulting outbreak has witnessed three deaths, one miscarriage and 23 illnesses: *Third listeria death linked to Jindi cheese*, ABC NEWS, Feb. 11, 2013, available at <http://www.abc.net.au/news/2013-02-10/third-death-linked-to-cheese/4510440> (last visited May 2, 2013).

Style Gouda cheese made from unpasteurized milk through retail channels, including Costco retailers throughout the Southwest.¹⁹ In 2013, cheeses made from unpasteurized milk by Gort's Gouda Cheese Farm in Salmon Arm, British Columbia, Canada, led to 27 known cases of illness (including one death) due to *E. coli* O157:H7 contamination.²⁰

Official reports of outbreaks of foodborne illness must be taken in context. The proportion of all human illnesses that are diagnosed by a physician, confirmed by laboratory analysis and reported to public health authorities where required by law is small.²¹ Sporadic cases of foodborne illness may not be reflected in CDC or other public health reports and the available outbreak data may be incomplete.

Although soft and semi-soft cheeses can be potential vehicles for foodborne illness, consumer perceptions of the risks associated with these cheeses vary. Some believe that health authorities in North America have been too concerned about mitigating risk given the small number of reported outbreaks and the high standards adopted by most food manufacturers.²² These perspectives are consistent with the general diversity of approaches

¹⁹ CDC, *Investigation Update: Multistate Outbreak of E. coli O157:H7 Infections Associated with Cheese (Final Update – 24 November 2010)*, available at <http://www.cdc.gov/ecoli/2010/cheese0157/> (last visited Apr. 11, 2013).

²⁰ Public Health Agency of Canada, *Public Health Notice - E. coli O157:H7 Illness Related to Cheese Produced by Gort's Gouda Cheese Farm*, <http://www.phac-aspc.gc.ca/fs-sa/phn-asp/2013/ecoli-0913-eng.php> (last visited Oct. 30, 2013).

²¹ "L. monocytogenes is rarely diagnosed as the cause of gastroenteritis and fever, partly because this organism is not detected by routine stool culture." E. Scallan, R.M. Hoekstra, F.J. Angulo, R.V. Tauxe, M-A Widdowson, S.L. Roy et al., *Foodborne Illness Acquired in the United States – Major Pathogens*, 17 *Emerg. Infect. Dis.* (Jan. 2011) 7 at 13, available at <http://dx.doi.org/10.3201/eid1701.P11101> (last visited Apr. 30, 2013). The CDC estimates that, for every case of listeriosis reported, there are two cases that are never diagnosed: CDC, *Food Safety Progress Report for 2012*, available at: <http://www.cdc.gov/Features/dsFoodNet2012/food-safety-progress-report-2012-508c.pdf> (last visited May 4, 2013).

²² As an example of this perspective, see David Gumpert, *FDA Hones in on Limited Raw Milk Cheese Despite Absence of a Single Documented Case in 23 Years*, *FOOD SAFETY NEWS*, Feb. 18, 2013, <http://www.foodsafetynews.com/2013/02/fda-hones-in-on-limited-raw-milk-cheese-despite-absence-of-a-single->

within the population when it comes to risk and decision-making: all consumers want to buy safe food, but, as individuals, we each have different competencies when it comes to understanding risk, different perceptions of what risks are material, and varying preferences about how to mitigate a material risk that has been identified.²³ This diversity would not be as relevant to public policy were it not for the fact that individual consumption decisions can have societal implications. Some individuals who consume these cheeses, whether or not they appreciate fully the risks of doing so, may incur costs as a result. In addition to their own vulnerability, their employers, their family members and society as a whole may also be affected. Costs can take the form of greater demands on health care funding (e.g., Medicare, Medicaid and private and employer-sponsored plans) and lost labor productivity. There are legitimate public policy issues to consider in terms of how the sale and consumption of these cheeses should be regulated.

III. Current Law

A. Legislative Requirements

Manufacturing dairy products (such as cheese) can fall under both federal and state legislation. Many states have comprehensive laws regarding the licensing and oversight of dairy manufacturing operations and provide for a regular series of inspections to ensure

[documented-case-in-23-years/](#) (last visited Feb. 21, 2013). For an unconventional perspective from health professionals, see also Carolyn Tam, Aida Erebara and Adrienne Einarson, *Food-borne illnesses during pregnancy : Prevention and treatment*, MOTHERISK (Apr. 2010),

http://www.motherisk.org/prof/updatesDetail.jsp?content_id=925 (last visited May 5, 2013).

²³ Elise Golan, Fred Kuchler, Lorraine Mitchell, Cathy Greene, and Amber Jessup, *Economics of Food Labeling*, United States Department of Agriculture, Economic Research Service, Agricultural Economic Report No. 793, Jan. 25, 2001, at 7, available at

<http://webarchives.cdlib.org/sw1m04028n/http://www.ers.usda.gov/publications/aer793/> (last visited Apr. 2, 2013).

compliance.²⁴ Cheese that enters interstate commerce is also subject to federal rules, including the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations (“CGMPs”).²⁵ For example, the CGMPs require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, must “be cleaned as frequently as necessary to protect against contamination of food.”²⁶ Other provisions in the CGMPs address such matters as employee hygiene, use of sanitizing agents, and process and product controls.

The FDA takes a very strict approach to both product and environmental contamination involving pathogens such as *Listeria monocytogenes* and *E. coli* 0157:H7 in dairy manufacturing facilities. Should cheese be found to have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby the cheese may have been rendered injurious to health, it could be deemed to be “adulterated” under the Federal Food, Drug, and Cosmetic Act.²⁷ Failure to meet the requirements can lead to enforcement action by the FDA.²⁸

Federal regulations provide further particulars for how cheese is to be made, identified, sold and distributed in interstate commerce. There is a general prohibition against the delivery into interstate commerce or the sale, distribution or holding for sale or other distribution after shipment in interstate commerce of any milk product, such as cheese, in final package form for

²⁴ See, for example, Manufacturing Milk Law of 2001, Mich. Comp. Laws Ann. Ch. 288 (West).

²⁵ 21 CFR Part 110.

²⁶ 21 CFR § 110.35.

²⁷ 21 USC § 342(a)(4).

²⁸ For example, FDA, Warning Letter to Mexicali Cheese Corp. (NYK-2011-04), (Oct. 27, 2010), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm232014.htm> (last visited May 6, 2013) and FDA, Warning Letter to Gioia Cheese Co., Inc. (WL# 17-13), (Jan. 23, 2013), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm337398.htm> (last visited May 6, 2013). See also Neuman, *supra* note 1 for an example of further enforcement action by the FDA against a Washington State cheesemaker.

direct human consumption, unless the product has been pasteurized or is made from dairy ingredients (that is, milk or milk products) that have been pasteurized according to the regulations. There is an exception where “alternative procedures to pasteurization are provided for” elsewhere in the regulations.²⁹ For some cheeses, if the cheese is labeled as “heat treated”, “unpasteurized,” “raw milk”, or “for manufacturing”, the milk used to make the cheese may be made from milk that was never thermally treated or from milk that was heated to a temperature below what is prescribed for pasteurization. However, cheese made from milk that was not pasteurized milk is required to be “cured for a period of 60 days at a temperature not less than 35 °F”.³⁰ There are separate 60-day aging requirements for specific varieties of cheese found elsewhere in the regulations that also apply. For example, under the definition and standard of identity for soft ripened cheeses, if the milk used is not pasteurized, the cheese must be cured at a temperature of not less than 35° F for not less than 60 days.³¹

The 60-day aging requirement became a part of federal regulations in 1949, when the foodborne illnesses of concern were different than what they are today. The primary concern in cheesemaking at the time was the risk of infecting individuals with brucellosis, typhoid fever or bovine tuberculosis.³² The aging requirements were also intended to apply to hard cheeses, such as Cheddar, in which the identified pathogens of concern would die-off as the moisture level and the pH of the cheese each decreased. (Many soft and semi-soft cheeses, in contrast, have higher moisture levels and become less acidic as they age.) As will be shown below, the

²⁹ 21 CFR § 1240.61(a).

³⁰ 7 CFR § 58.439. 35 degrees Fahrenheit is the equivalent of approximately 1.67 degrees Celsius.

³¹ 21 CFR § 133.182(a). Similar aging requirements are found in federal regulations for hard cheeses (21 CFR § 133.150) and for semi-soft cheeses (21 CFR § 133.187).

³² Marler, *supra* note 4.

applicable regulations have not kept pace with developments in food safety science and the understanding of what causes foodborne illness. A prudent cheesemaker today would be primarily concerned about preventing consumers from contracting listeriosis, salmonellosis, an *E. coli* O157:H7 infection or food poisoning due to staphylococcal enterotoxins.

There are also provisions in federal regulations governing the transfer of cheese to a facility for aging and the required labeling that must be used on bulk, unaged cheese during this process.³³ However, this labeling is intended for further processors rather than for consumers. At retail, a purchaser of Brie made from unpasteurized milk may notice on the label that the cheese was made from “raw milk” (or even “heat treated” milk), but may not appreciate that the milk was never pasteurized. At present, there is no requirement for consumer packages of soft and semi-soft cheeses, including those made from unpasteurized milk, to warn individuals of the potential food safety risks associated with consumption.

B. Common Law

Manufacturers and retailers of cheese may be held liable to injured consumers under a variety of legal theories, such as negligence and products liability (including failure to warn).³⁴ Courts have treated potentially hazardous foods with greater scrutiny due to the fact that these foods are not designed and made in the same way as other consumer products and because, unlike a more durable consumer good, they have the potential to spoil.³⁵

To be sure, a plaintiff in a products liability case would face a number of significant

³³ 21 CFR § 101.100(f)(2) & (3).

³⁴ Restatement (Third) of Torts: Prod. Liab. § 2(c) (1998) (comment – i).

³⁵ Damian C. Adams, Michael T. Olexa, Tracey L. Owens, and Joshua A. Cossey, *Déjà Moo: Is the Return to Public Sale of Raw Milk Udder Nonsense?* 13 Drake J. Agric. L. 305 (2008) at 320.

challenges before succeeding at court. In a negligence claim, for example, he or she would be required to prove, on a balance of probabilities, that the defendant owed a legal duty of care and that this duty was breached by the defendant in the circumstances. Showing causation – that the cheese was the cause of his or her injuries – could be particularly challenging in the absence of sufficient evidence. A plaintiff may also be barred from bringing the suit due to the passage of time and other factors.

In these unfortunate situations, cheesemakers and retailers would want to be in the best possible position as a defendant. A warning label is not a complete shield from liability. However, courts do appear to take the presence of a label and its wording into consideration.³⁶ There is support in case law for well-drafted warning statements aimed at the most vulnerable audiences. As one example, in *Woeste v. Wash. Platform Saloon & Rest.*,³⁷ a restaurant and an oyster supplier were sued in negligence and in strict liability when a patron died after becoming infected with the bacterium *Vibrio vulnificus* following the consumption of raw oysters at the restaurant. The Ohio Court of Appeals held, in a review of a prior summary judgment in favor of the defendants, that both the restaurant and the oyster supplier had a duty to warn of the possible risks of consuming raw oysters. The restaurant had provided warning language on its menu, directly underneath the list of oyster entrees. (The restaurant appeared to have done so voluntarily, as a state requirement to provide such a warning for eating raw animal foods did not come into effect until March 1, 2001).³⁸ Even though the patron made his order without ever opening the menu, the Court of Appeals determined that it could not subject the

³⁶ Id. at 324-325 and 335.

³⁷ 836 N.E.2d 52 (Ohio Ct. App. 2005).

³⁸ Ohio Admin. Code 3717-1-03 (“prior effective dates”) and citing 2000-2001 OMR 1273 (E), eff. Mar. 1, 2001.

defendants to liability for the deceased person's failure to read a prominent and adequately-drafted warning.

Although not related to foodborne illness, the Court of Common Pleas of Ohio held, in *Immormino v. J & M Powers, Inc.*³⁹, that a McDonald's restaurant franchisee was not liable to a customer who spilled hot tea on her body following a purchase made at a drive-thru window. Unlike similar cases, there had been warnings printed on two locations on the cup that advised caution due to the potential for the contents to be hot. In its decision, the court determined that the warnings were adequate as matter of law. The defendant was successful in its motion for summary judgment as the court found that there was no genuine issue of material fact for trial.

The presence of pathogenic bacteria is not an inherent aspect of soft, semi-soft and other higher-risk cheese varieties, such that the possibility of developing a serious illness would be obvious or widely known among consumers (thus potentially relieving manufacturers and retailers of the duty to warn of the risk).⁴⁰ Unlike the risk of the intoxicating effects of alcohol⁴¹ or the long-term, cumulative health consequences associated with consuming fast food⁴², the risk of developing a serious foodborne illness from consuming certain kinds of cheese – particularly for the most vulnerable members of the population – is not generally understood or appreciated.⁴³

³⁹ 698 N.E.2d 516 (Ohio 1998).

⁴⁰ As in the case of possible temporary gas and gastrointestinal discomfort for lactose intolerant individuals following the consumption of fluid milk products: *Mills v. Giant of Maryland LLC*, 508 F.3d 11 (2007).

⁴¹ *Maguire v. Pabst Brewing Co.*, 387 N.W.2d 565 (Iowa 1986).

⁴² *Pelman v. McDonald's Corp.*, 237 F.Supp.2d 512 (SDNY 2003).

⁴³ Sheryl C. Cates et al., *Pregnant Women and Listeriosis: Preferred Educational Messages and Delivery Mechanisms*, 36 J. Nutr. Educ. Behav. (2004) 121 at 123 and 126.

IV. Potential Policy Changes

Although a cheesemaker may have common law duties to consider when developing strategies to protect against legal liability in a private law context, the broader regulatory framework continues to operate based on risk mitigation measures that have not kept pace with developments in the scientific understanding of food safety. There is clear evidence that the FDA is in the process of reconsidering the current rules.⁴⁴ At the present time, it remains unknown whether this reconsideration will lead to a proposal for significant change.

A. Re-Consideration of the 60-day Aging Requirement for Cheese Made from Unpasteurized Milk

The scientific understanding of the risks that different cheese varieties and cheesemaking processes can present is beginning to outpace the generic regulatory requirements that are found in federal regulations. An article in the *New York Times* explained the course of history in the following way: “The primary pathogens that now cause illness associated with cheese, like toxic forms of *E. coli* and *listeria*, were either unknown in the 1940s [when the 60-day aging requirement was adopted] or not of great concern. And artisan cheesemakers today are making many cheeses whose chemistry varies greatly from the basic

⁴⁴ Supra note 3 and note 4. There has been creative speculation about what policy proposals may emerge from this review. Some cheese enthusiasts are concerned that the FDA may make a rule effectively banning the sale and distribution of cheese made from unpasteurized milk in interstate commerce, even if it has been aged. See 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 (2003) and Neuman, supra note 4. Others have speculated that the 60-day aging rule will be lengthened to 90 or 120 days: William Herkewitz, *On the cutting block – Raw-milk cheese: deadly, nutritious, or just delicious?* SCIENCELINE – a publication of the Science, Health and Environmental Reporting Program (SHERP) at the Arthur L. Carter Journalism Institute, New York University, Apr. 23, 2013, <http://scienceline.org/2013/04/on-the-cutting-block/> (last visited Apr. 29, 2013).

hard cheddar of six decades ago.”⁴⁵

The specific identity and composition of a particular cheese is critical to understanding the microbial risks. Not all cheeses are alike. Factors such as moisture content, processing method, amount of handling, and the use of unpasteurized or pasteurized milk⁴⁶ all play a role in determining the risk profile of the cheese. The focus of this paper is the risk posed by soft and semi-soft cheeses, whether made from pasteurized milk or unpasteurized milk. Public health authorities have directed much of their focus towards cheese made from unpasteurized milk, but caution is advised whenever members of higher-risk segments of the population consume soft and semi-soft cheeses.

When soft and semi-soft cheeses are made from unpasteurized milk as opposed to pasteurized milk, the key requirement in federal regulations is the 60-day aging requirement. However, this aging requirement may not be sufficient to ensure the safety of soft and semi-soft cheeses when *Listeria monocytogenes* is introduced as a contaminant during or following processing.⁴⁷ Handling during the final phases of processing, plus the aging, rind-washing and wrapping phases, all provide opportunities for contamination to occur. With many soft and semi-soft cheeses, such as Brie and Camembert, these cheeses become less acidic as they age. Any pathogens that may be present can survive and might multiply during the aging process on

⁴⁵ Neuman, supra note 4. Notations in square-bracketed text added by the author.

⁴⁶ It should be noted that the use of pasteurized milk in making surface-mold-ripened soft cheeses does not necessarily mean that the cheese will be free of *Listeria monocytogenes*. Even if pasteurization killed the bacteria that might be present in the milk, the bacteria can be re-introduced as a contaminant during and after cheese processing. D.J. D’Amico, M.J. Druart, and C.W. Donnelly, *60-Day Aging Requirement does not Ensure Safety of Surface-Mold-Ripened Soft Cheeses Manufactured from Raw or Pasteurized Milk when Listeria monocytogenes is Introduced as a Postprocessing Contaminant*, 71 J. Food Prot. (2008) 1563 at 1569. The use of unpasteurized milk to make soft and semi-soft cheeses is still a key factor in determining risk: the draft FDA-Health Canada risk assessment noted that consumers are up to 160 times more likely to contract listeriosis from soft-ripened cheese made from unpasteurized milk compared to similar cheeses made from pasteurized milk. Supra note 3 at 11.

⁴⁷ D’Amico et al. Id.

surface-mold-ripened cheeses. The 60-day aging rule in the federal regulations mandates the storage of these cheeses for an extended period of time. If present, *Listeria monocytogenes* can survive and grow to levels that could cause human illness by the end of this 60-day aging period. The result is an increased risk to consumers compared to allowing the cheese to be sold and consumed following a shorter aging process.⁴⁸

The safety of soft and semi-soft cheeses made from unpasteurized milk must be addressed through control steps other than aging for 60 days at a mandated temperature. Regardless of whether these cheeses are made from pasteurized or unpasteurized milk, the optimal solution for producing safe cheese is a multi-pronged approach that begins on the dairy farm and extends through to the point when the final product leaves the control of the cheesemaker:

Cheese safety can be better assured through a combination of stringent raw milk production and microbiological quality, improved process controls, the use of performance criteria, and aggressive environmental monitoring and finished product testing.⁴⁹

The challenge for the FDA is that an effective set of new food safety regulations for these cheeses requires a more complex regulatory framework than what the 60-day aging requirement currently provides in the case of cheeses made from unpasteurized milk.⁵⁰ With

⁴⁸ Id. at 1569.

⁴⁹ Id. Indeed, of the identifiable options, mandated product testing may be one of the most effective measures that could be implemented for soft and semi-soft cheeses made from unpasteurized milk. FDA, Center for Food Safety and Applied Nutrition, and Health Canada, Food Directorate, *supra* note 14 at 3. A heat treatment of the milk at sub-pasteurization temperatures may also assist in achieving a more appropriate level of public health protection than using milk that was never heat treated or thermalized in this manner: Schlessner et al., *supra* note 9 at 997.

⁵⁰ One possible model from North America might be found in the Province of Quebec, Canada. Cheeses made from unpasteurized milk and aged less than 60 days may be manufactured in licensed facilities and sold within the province and, if made in a federally-registered dairy establishment, in most other Canadian provinces. More

so many possible variations in source milk, cheese types, manufacturing processes and ripening techniques, the onus should be on the manufacturer to design and implement a written food safety program based as much as practicable on the principles of a hazard analysis and critical control points (HACCP) system. Although not fail-safe, such an approach may offer controls and verifications that would go a long way towards addressing the particular risks presented by each cheese variety that is made in the facility.

B. Warning Labels and Enhanced Labeling

Even if manufacturers and retailers of soft and semi-soft cheeses benefit from the liability protections that consumer warnings can offer, there seems to be little interest within the industry to use them. The existing label requirements for cheese made from unpasteurized milk are not, strictly speaking, warnings directed at consumers. Requiring the package to state that a cheese is “heat treated”, “unpasteurized,” “raw milk”, or “for manufacturing” may not communicate enough information to consumers to allow for informed decision-making about risk. For soft and semi-soft cheeses made from pasteurized milk, there is no indication provided at all that the food may present a greater food safety risk than other cheese varieties. Governments may decide to take legislative action to remedy this situation. For example, as one possible outcome of its review, the FDA may decide that cheesemakers should not be subject to additional process requirements but instead operate under a rule mandating that

stringent milk production and cheesemaking rules apply in the case of these cheeses. Regulation respecting food, R.R.Q., c. P-29, r. 1, Division 11.6, available at <http://canlii.org/en/qc/laws/regu/rrq-c-p-29-r-1/latest/rrq-c-p-29-r-1.html> (last visited May 4, 2013). See also American Cheese Society, *Notes from the “Cheese & Fromage: Common Cultures” Conference Held in Montreal, Quebec, Canada* (Aug. 2011), <http://www.cheesesociety.org/wp-content/uploads/2011/02/ACS-2011-Montreal-Raw-Milk-Cheese-Track-Summary.pdf> (last visited Apr. 4, 2013).

warning labels be used on particular cheese varieties.⁵¹ The labeling may also provide directions to consumers on proper storage and handling. In addition to potential FDA action, states and local authorities could also require that warning signs, menu warnings, table-top tent cards and other devices be used at retail stores and at food service premises.

The purpose of requiring a warning label to appear on a product is not to prevent or discourage manufacturers from making certain varieties of cheese, but rather to assist consumers in making informed decisions about purchase and consumption. A mandatory warning label could prove to be controversial, however, particularly for small cheesemakers looking to build markets and attract new customers. A warning label might send the message to potential purchasers that the product cannot be made safely under any circumstances. To justify any such regulatory burden, government would need to demonstrate that a mandated warning can be effective in furthering public protection.

V. Evaluation

A. Other Mandated Labeling Precedents

There are other food-related examples where governments require warning labels on food packages, on menus or in proximity to areas where food is ordered and served. Because of the dangers posed by the bacterium *Vibrio vulnificus*, several states require mandatory warning labels and statements to appear prominently on menus and on signage in food premises that sell raw oysters. The State of Louisiana requires establishments that sell or serve

⁵¹ For cheeses made from unpasteurized milk, the idea of enhanced labeling has been discussed within the industry. See Marlene Cimon, *Food Safety Concerns Drive FDA Review of Fine Cheeses*, 2 AMERICAN SOCIETY FOR MICROBIOLOGY (ASM) NEWS (2001) 85 at 89, available at <http://newsarchive.asm.org/feb01/images/f3.pdf> (last visited Apr. 30, 2013).

raw oysters to display signage, menu notices, table-top tent cards or other messages at point-of-sale that are clearly visible and that contain prescribed warning language about the risks posed by consuming raw shellfish (with particular advice for those suffering from chronic illness of the liver, stomach or blood, as well as those with other immune disorders, that they should eat such products fully cooked).⁵² California has a similar requirement for raw Gulf of Mexico oysters, requiring a warning statement to be printed in both English and Spanish using prescribed text sizes.⁵³

In a broader context than raw oysters, the FDA's *Food Code* (2009)⁵⁴ requires consumer advisories prior to the consumption of animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens. Under the *Food Code*, permit holders, such as restaurants, are required to advise consumers of the increased risks of consuming such foods as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish that are served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in a ready-to-eat form or as an ingredient in another ready-to-eat food. The advisory is to be made by way of both a disclosure and a reminder "using brochures, deli case or menu advisories, label statements,

⁵² All establishments in the State of Louisiana that sell or serve raw oysters must display signs, menu notices, table tents, or other clearly visible messages at the point of sale with one of two possible warnings: (a) "THERE MAY BE A RISK ASSOCIATED WITH CONSUMING RAW SHELLFISH AS IS THE CASE WITH OTHER RAW PROTEIN PRODUCTS. IF YOU SUFFER FROM CHRONIC ILLNESS OF THE LIVER, STOMACH OR BLOOD OR HAVE OTHER IMMUNE DISORDERS, YOU SHOULD EAT THESE PRODUCTS FULLY COOKED" ; or (b) "CONSUMING RAW OR UNDERCOOKED MEATS, POULTRY, SEAFOOD, SHELLFISH OR EGGS MAY INCREASE YOUR RISK OF FOODBORNE ILLNESS, ESPECIALLY IF YOU HAVE CERTAIN MEDICAL CONDITIONS." This message must also appear on the principal display panel and on the top of containers of pre-packaged raw oysters. La. Admin. Code tit. 51, pt. IX, § 319.

⁵³ Cal. Code Regs. tit. 17, § 13675.

⁵⁴ FDA, *FDA Food Code 2009*, § 3-603.11, available at

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm186451.htm#part3-6> (last visited Apr. 29, 2013). The Food Code is intended as a model to be adopted by federal, state, tribal and local authorities to govern operations in retail and food service businesses. See, for example, Ohio Admin. Code 3717-1-03.5 (E).

table tents, placards, or other effective written means.” For disclosure⁵⁵, the permit holder must include either a description of the animal-derived foods (e.g., “oysters on the half shell (raw oysters)”) or identification of the animal-derived foods by the use of an asterisk and a footnote stating that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. The reminder⁵⁶ must include an asterisk for the animal-derived foods, with disclosure to a footnote that states either that, regarding the safety of these items, “written information is available upon request”; “consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness”; or “consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.”

There are additional precedents. Since 1999, following several high-profile outbreaks, the FDA has required that cider and fruit and vegetable juices that were not specifically processed to prevent, reduce or eliminate the presence of pathogens must bear a warning on the container stating that the product was not pasteurized and that it could contain harmful bacteria that could lead to serious illness in children, the elderly and the immunocompromised.⁵⁷ Since only a small percentage of juice and cider in the United States is not pasteurized, the warning label helps alert consumers to the risks that these unique

⁵⁵ A disclosure is a written statement “that clearly identifies the animal-derived foods which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.” *Id.* A disclosure would generally be provided prior to or when the consumer orders food, such as on a menu.

⁵⁶ A reminder “means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.” *Id.* The reminder provides consumers with information about the health risks of eating the foods. It might be placed in combination with the disclosure – for example, “We make our own Caesar salad dressing in-house using raw eggs. Consuming raw or undercooked eggs may increase your risk of foodborne illness.”

⁵⁷ 21 CFR § 101.17(g).

products present. Since 2001, safe handling instructions have been required to be printed on packages of untreated shell eggs that are sold in both interstate and intrastate commerce.⁵⁸ The safe handling instructions make specific reference to the prevention of “illness from bacteria” and provide information about how to store and handle the eggs.

There are, therefore, precedents in the United States where warning labels have been mandated for other higher-risk foods. Whether or not these requirements are effective in furthering food safety policy goals, however, must still be assessed.

B. The Effectiveness (or Ineffectiveness) of Warning Labels

The relationship between consumers and the labels on food packages is complex. Food labels might be “...the most critical channel available for directly communicating information about food products to consumers.”⁵⁹ However, this channel is not always used effectively and, in spite of the importance of this medium for commerce and public policy, labels also appear to be a source of significant confusion for consumers.⁶⁰ The results of the general studies that have been conducted on food labeling show that, although the evidence is contradictory, consumers use food labels as a source of information. The frequency of use and the degree to which food safety information is understood and used, however, seems to vary from study to study. The length of time that an individual may look at a package label before purchase or consumption, and how he or she will understand and use the information, may vary depending

⁵⁸ *Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution*, 65 Fed. Reg. 76092-01 (Dec. 5, 2000).

⁵⁹ Clare Hall and Felipe Osses, *A Review to Inform Understanding of the Use of Food Safety Messages on Food Labels*, Int.J.Consum.Stud. (2013) at 1, doi: 10.1111/ijcs.12010.

⁶⁰ Mary Alton Mackey and Marilyn Metz, *Ease of Reading of Mandatory Information on Canadian Food Product Labels*, 33 International Journal of Consumer Studies (2009) 369.

on the label design and such individual factors as the person's age, gender, parental status, attitudes, food safety knowledge, degree of trust in the information providers and any past experience in handling the food product.⁶¹

Since the target audiences for any warnings that might accompany the higher-risk soft and semi-soft cheeses are so varied in their demographic make-up (namely, pregnant women, parents of young children, the elderly and the immunocompromised), a mandatory standardized warning may not be equally effective for all target audiences.⁶² A recent review of published work on consumer behaviour regarding food labels found that it is difficult to understand fully what drives consumer behaviour in this area because, among other factors, "...decision making is not driven by objective risk assessment...and is not consistent across consumer groups."⁶³ This lack of consistency in outcomes suggests that mandated labeling initiatives may have uneven effects.

The nature of cheese as an easily divisible, ready-to-eat food product may affect a consumer's opportunity to interact with any label that is used. Some soft and semi-soft cheeses may be cut and re-packaged by random weights or cut-to-order at cheesemongers from larger wheels, blocks or other formats. Although the cheese may have been labeled when it left the manufacturer, retailers may not necessarily relay any manufacturer's warnings to

⁶¹ Hall and Osses, *supra* note 59.

⁶² Mandatory labeling of the alleged health risks associated with the artificial sweetener saccharin in diet soft drinks in the United States was imposed in the late 1970s. One study conducted shortly after the warnings came into effect found a short-term reduction in sales growth in grocery stores. However, the results varied depending on the demographic make-up of the neighborhood, with a faster initial response shown in neighborhoods with higher rates of post-secondary education compared to neighborhoods with greater proportionate numbers of the elderly and heads of households with less than a high school education: Raymond E. Schucker, Raymond C. Stokes, Michael L. Stewart and Douglas P. Henderson, *The Impact of the Saccharin Warning Label on Sales of Diet Soft Drinks in Supermarkets*, 2 *Journal of Public Policy & Marketing* (1983) 46.

⁶³ Hall and Osses, *supra* note 59 at 10.

consumers at the point-of-sale or on any retail package labels applied at the counter. In addition, to capture cheese sold at restaurants and at other food premises, mandatory menu warnings and signage may be necessary. This could require state and local legislative action, plus revisions to the *Food Code*, in order to match any federal rulemaking.

Policymakers also need to be concerned about the potential risk of requiring too much information on package labels and the potential for consumers to become confused by the amount of printed information on the package. As a policy choice, a mandated warning label is an information-based response to the potential human health effects of individual consumption decisions. Mandatory food labeling requirements may be “best suited to alleviating problems of asymmetric information”, such as where consumers are at an informational disadvantage compared to the manufacturer.⁶⁴ Consumers of fine cheeses may know a great deal about many of the attributes of the products they purchase, given the prices being paid and the fact that they are often sought out for specific organoleptic qualities. The manufacturer will promote a cheese as being made from unpasteurized milk if that information results in obtaining a premium price in the marketplace. Neither the manufacturer nor the consumer, however, may appreciate fully the food safety risks associated with soft and semi-soft cheeses. Nonetheless, it could be questioned whether additional labeling requirements about those potential risks are the best response to address the negative consequences associated with the production and consumption of food.⁶⁵ Businesses would likely be concerned about the potential for increased costs to be imposed through a mandatory warning label requirement, in the form of lost sales and compliance costs. As such, any policy proposal for mandatory

⁶⁴ Golan et al. *supra* note 23 at 6.

⁶⁵ *Id.*

warning labels would also need to be accompanied by a cost-benefit analysis showing that the anticipated benefits would outweigh the costs, as well as demonstrating how these benefits and costs might be distributed throughout society.⁶⁶

To be effective, any mandatory warning label requirement should be part of a broader and sustained public awareness campaign that takes into account the specific information needs and behaviors of the most vulnerable population groups. This might require the use of targeted communication strategies tailored to the characteristics of each audience and their different perceptions of risk.⁶⁷ For some audiences, the use of social media might be effective. To change behavior, messages must be relevant, contain information that is reliable, be distributed rapidly and at the right times, and be repeated often enough to be effective.⁶⁸ The information about risk must also be easily received and understood.⁶⁹ This will be a significant challenge for regulatory agencies and human health officials, given the subject matter and the differing demographic characteristics of the target audiences.

If mandatory warnings are going to be a part of the forthcoming policy discussions for regulating soft and semi-soft cheeses, the FDA should also be realistic about the likely outcome and cautious about the unintended consequences that could result. Oysters provide an illustration. In spite of the number of states that have required menu and other warnings for raw oysters since the early 1990s, the United States did not witness a significant decline in

⁶⁶ Id. at 1, 6 and 16. Schucker et al., *supra* note 62.

⁶⁷ Hall and Osses *supra* note 59 at 8. Casey Jacob, Lisa Mathiasen and Douglas Powell, *Designing Effective Messages for Microbial Food Safety Hazards*, 21 Food Control (2010) 1 at 2.

⁶⁸ Jacob et al., Id.

⁶⁹ Jacob et al., Id. Golan et al. *supra*, note 23 at 14 and at 17-18 also make the point that labels must be clear and concise and not cluttered by other warnings or product information that would lead the consumer to disregard the label completely.

Vibrio vulnificus cases between 2001 and 2008.⁷⁰ Another study found that warning labels, such as the earlier 1991 consumer warning requirement for raw oysters in California (which was subsequently adopted in other states), reduced the demand for Gulf Coast and Chesapeake oysters and increased the demand for Pacific and imported products (even though the Chesapeake oysters are not harvested from the warmer Gulf of Mexico waters).⁷¹ A warning label mandated for one product can “have negative or positive impacts on related products that compete for the consumer’s limited budget.”⁷² If a similar substitution effect could occur in the cheese market, this consideration is worthy of further investigation before a policy proposal involving mandatory warnings is finalized.

VI. Conclusion

As a dairy product category, soft and semi-soft cheeses present greater risks for consumers than other dairy products. Those cheeses made from unpasteurized milk represent the most significant sub-set of this category from a foodborne illness perspective. However,

⁷⁰ The one exception would appear to be California. Beginning in 2003, the State of California banned the sale of all oysters from the coastal waters of the Gulf of Mexico that were harvested during the warm summer months (when *Vibrio vulnificus* can flourish and pose the most significant threat) and that had not undergone a suitable post-harvest processing method. This post-harvest processing requirement “has largely eliminated *Vibrio vulnificus*-related deaths and illness from consuming raw oysters” in California. Michael Taylor, Senior Advisor to the Commissioner, FDA, *Address at the Interstate Shellfish Sanitation Conference (ISSC) Biennial Meeting*, Manchester, NH (Oct. 17, 2009), available at <http://www.fda.gov/NewsEvents/Speeches/ucm187012.htm> (last visited May 2, 2013). A 2011 report from the United States Government Accountability Office (GAO) found that the FDA and the joint industry-government Interstate Shellfish Sanitation Conference (ISSC) did not agree on a common *Vibrio vulnificus* illness reduction goal and had taken few steps to assess how well the existing consumer education efforts were working: GAO, *Food Safety: FDA Needs to Reassess its Approach to Reducing an Illness Caused by Eating Raw Oysters*, Report No. GAO-11-607 (Sept. 2011), available at <http://www.gao.gov/new.items/d11607.pdf> (last visited Oct. 29, 2013).

⁷¹ Cheikhna Dedah, Walter R. Keithly, Jr., Hamady Diop and Richard F. Kazmierczak, Jr., *An Inverse Almost Ideal Demand System for Oysters in the United States: An Empirical Investigation of the Impacts of Mandatory Labels*, Southern Agricultural Economics Association Annual Meetings, Mobile, Alabama, Feb. 3-6, 2007, available at <http://ageconsearch.umn.edu/bitstream/34957/1/sp07de05.pdf> (last visited: May 2, 2013).

⁷² Id. at 2.

even those cheeses made with pasteurized milk may pose significant risks for certain segments of the population. It is unclear at this stage where the FDA is headed in terms of future policy-making for cheese safety. The research suggests that the health of the dairy herd, milking practices, sanitation, hygiene, microbial criteria, testing, verification procedures and record-keeping are all required steps to manufacture cheese safely in the United States, especially for those cheeses made from unpasteurized milk. Where product labeling and warning statements will be situated in the mix of policy tools to be employed by the FDA and state authorities remains to be seen.

The case law suggests that clear labeling of the risks associated with these cheeses may help manufacturers, retailers and intermediaries address some of their potential legal liability. However, mandatory requirements for clear labeling of the risks should not be viewed as the only policy option for addressing the safe manufacture and sale of these cheeses.

Cheesemaking in America is becoming more diverse and complex, especially within the growing artisanal sector. Any mandated labeling proposal that is part of the public policy discussion should be accompanied by further analysis on the costs and benefits (and their distribution across society), the likelihood of success and the potential substitution effects. If used, any mandatory warnings must be part of a broader suite of rules that require manufacturers to take into account the different compositions and risk profiles of the specific kinds of cheese that they are introducing into the marketplace. A broader and sustained public awareness campaign that takes the unique characteristics of each target audience into account would also be worthy of serious consideration as a companion initiative.