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Division of Dockets Management (HFA- 305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted online at <https://www.federalregister.gov/articles/2015/08/03/2015-18972/understanding-potential-intervention-measures-to-reduce-the-risk-of-foodborne-illness-from#open-comment>

Re: Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk

Dear Food and Drug Administration:

The Weston A. Price Foundation (WAPF) is a nonprofit organization with members in every state and internationally. WAPF was founded in 1999 to disseminate the research of Dr. Weston Price, whose studies of isolated nonindustrialized peoples established the parameters of human health and determined the optimum characteristics of human diets. WAPF is dedicated to restoring nutrient-dense foods to the human diet through education, research and activism.

I. Summary

- Cheese, including cheese produced from unpasteurized milk, is a low-risk product. The CDC data for the 16-year period from 1998 to 2013 show that, given the amount of cheese produced and consumed in the United States, there are relatively few outbreaks.
- Outbreaks of foodborne illness that resulted from **fresh** (unaged) raw milk cheeses should not be included in the FDA's analysis of this issue because sale of fresh raw milk cheeses are already illegal in this country; thus, new regulations would make no difference whatsoever to the risks posed by such cheeses.
- Looking only at **aged** raw milk cheeses, there have been at most 7 outbreaks of foodborne illness reported in the 16-year period; based on the information online, it is not possible to confirm whether all 7 outbreaks were in fact from aged cheeses. With less than one outbreak every other year, and an average of less than 10 illnesses per year, the track record of aged raw milk cheese safety in this country is excellent.
- The FDA's analyses to date have ignored the extensive scientific literature on the safety of aged hard raw milk cheeses, which are the majority of raw milk cheeses produced in this country.
- The CDC database lists over 280 outbreaks with over 6,000 associated illnesses that include pasteurized cheese as at least one of the food vehicles in the same 16-year period.

- The majority of cheese-related outbreaks are caused by postprocess recontamination of cheese. With postprocess recontamination, the risks may actually be higher for pasteurized cheeses, which lack the protective raw milk microbiota, as compared to unpasteurized cheeses.
- The diverse and dense populations of non-pathogens in raw milk cheese microbiota provide colonization resistance, outcompeting low densities of contaminating bacteria under conditions of modern cheesemaking.
- Specific pathogen testing of raw milk and raw milk cheeses is not a necessary, practical or effective approach to process control in cheesemaking.
- An aging period longer than sixty days is not warranted by the evidence.
- All cheesemakers, whether using pasteurized or unpasteurized milk, need to use appropriate sanitation measures, as are required already. More stringent regulations for raw milk cheeses are not supported by the data on foodborne illnesses nor the relevant scientific literature on the microbiology of cheese.

II. Background¹

Humans have been making and eating raw milk cheese for between 8,000 and 9,000 years. The production of cheese in America began in the mid 17th century.²

In modern U.S. cheesemaking operations, the occurrence of pathogens in cheese that cause disease in humans is very rare.³ This is due to multiple factors, including physical and chemical conditions (such as water content, pH levels, and salt content) and biological conditions (microbial ecology) that limit or prevent pathogen growth.⁴

Cheese produced in the U.S. is subject to strict sanitation and quality standards. The American Academy of Microbiology has stated that “From the initial step of milking animals to the shipment of cheese to consumers, the product is subjected to rigorous monitoring, quality assurance standards, and specific tests.”⁵ The requirements include process controls for microbiological indicators of proper sanitation (such total bacterial counts or standard plate counts); they also include physical indicators of conditions that limit pathogen growth (time, temperature, pH, and salt or a_w or % moisture).

The combination of the naturally protective factors in cheesemaking and the strict existing regulations have resulted in extremely rare outbreaks, despite the large quantities of cheese manufactured and consumed in the United States.

¹ The footnotes will use the short form for references; full citations are listed at the end of these comments in the Reference section.

² Cogan and Beresford 2002; AAM 2015.

³ AAM 2015.

⁴ AAM 2015.

⁵ AAM 2015, page 28.

III. Cheese is a low-risk product in general

The FDA's notice appears to be premised on the belief that cheese manufactured from unpasteurized milk under the current regulatory requirements poses an unacceptable risk. The data, however, show that this is not the case.

The CDC's Foodborne Outbreak Online Database (FOOD) currently includes outbreaks for the 16-year period from 1998 to 2013. The database lists 33 outbreaks for which the food vehicle included raw or unpasteurized cheese, an average of two outbreaks per year.

A closer review shows that the majority of these outbreaks were **not** due to cheeses that were legally made and sold. Many are clearly listed as being due to fresh cheeses, such as queso fresco, which are illegal to sell in the United States. These cheeses must have either been made at home – “bathtub” cheese produced under notoriously unsanitary conditions⁶ -- or sold illegally. In four more of the outbreaks, although the FOOD does not provide specifics, the more detailed report from the CDC reveals that the outbreaks stemmed from either homemade cheese or cheese that had been illegally manufactured.

In total, over 80% of the illnesses and hospitalizations attributed to raw milk cheeses came from these fresh or illegally manufactured cheeses. **Adding more regulations to raw cheese manufacturers would do absolutely nothing to address these outbreaks.**

Of the remaining seven outbreaks, one was from Bravo Farms Cheeses, and a second was from Sally Jackson Cheeses. Sally Jackson Cheeses closed shortly thereafter.⁷ The FDA's report claims that there were serious violations of existing good manufacturing processes at both facilities.⁸ In fact, the Sally Jackson Cheeses facility had already been cited by the Washington State Department of Agriculture.⁹

For the remaining five outbreaks, there is insufficient information available online to determine whether each one was connected to properly aged and legally manufactured cheese. Even including all seven outbreaks, this data reflects a very low-risk product: an average of less than one outbreak every other year, and fewer than 10 illnesses per year on average.

Unfortunately, the FDA has repeatedly looked at the numbers of outbreaks and illnesses attributed to “raw cheese” and failed to accurately identify the outbreaks that are due to cheeses that have been produced and sold legally. **It would be futile to impose more regulations on legal raw milk cheesemakers, when the data shows that the vast majority of the illnesses -- both in terms of numbers of outbreaks and the largest outbreaks -- occur with homemade or illegally produced cheeses or pasteurized cheeses.**

⁶ Burkett 2010.

⁷ Flynn 2011.

⁸ FDA Jackson Report 2010; FDA Bravo Report 2010.

⁹ Food Safety News 2010.

Moreover, even among raw milk cheeses that were aged in accordance with the regulations, two of the outbreaks came from facilities that were not complying with the existing regulations for sanitation (Bravo Farms Cheeses and Sally Jackson Cheese). Adding more stringent restrictions or regulatory burdens on the legal manufacture of raw milk cheese does not reduce the risk of illness from homemade cheeses, illegally sold cheeses, or those that are not complying with the existing regulations.

The Federal Register notice heavily emphasized one epidemiologic study in the background section, Langer et al., 2012. Not only does the Langer study ignore the millennia of human experience in making and consuming raw cheese, but it fails to distinguish fresh cheeses, which could not be legally sold, from properly manufactured and aged raw milk cheese. In other words, it completely ignores the facts – as reported by the CDC – that are set out in Tables 1 and 2 below. **The Langer study, which conflates illegal “bathtub” cheese with legally produced aged raw cheeses, is a wholly inappropriate basis for policy making.** It would be counterproductive to use data from outbreaks from cheese that was made at home, of types that would be **illegal** to manufacture and sell, as the basis for developing new regulations.

Table 1: Outbreaks attributed to raw milk cheeses, either legally manufactured or unspecified, 1998 – 2013. Drawn from data on CDC FOOD.

Year	State	Genus & species	Illnesses	Hospitalizations	Deaths	Food Vehicle	Notes
2011	Multi state	<i>Listeria monocytogenes</i>	15	1	1	Blue-veined cheese, unpasteurized	
2010	AZ	<i>Campylobacter</i>	15	1	0	Cheese, unspecified, unpasteurized; whole milk, unpasteurized	
2007	PA	<i>Salmonella enterica</i>	13	1	0	Cheese, Raw Milk	
2010	Multi state	<i>E. coli</i> , Shiga toxin-producing	38	15	0	Gouda cheese (unpasteurized milk)	Bravo Farms Cheese Factory
2010	Multi state	<i>E. coli</i> , Shiga toxin-producing	8	0	0	Multiple cheeses, unpasteurized	Sally Jackson Cheeses
2001	Multi state	<i>Salmonella enterica</i>	27	12	0	Multiple cheeses, unpasteurized	
2003	VT	<i>Campylobacter jejuni</i>	18	0	0	Other cheese, unpasteurized; other milk, unpasteurized	
Total			134	30	1		

Table 2: Outbreaks attributed to unpasteurized cheeses made at home or sold illegally, 1998-2013. Drawn from data on CDC FOOD.

Year	State	Genus and species	Illnesses	Hospitalizations	Deaths	Food Vehicle	Notes
2007	UT	<i>Campylobacter jejuni</i>	62	4	0	butter; goat cheese/chevre, unpasteurized; goat milk, unpasteurized; whole milk, unpasteurized	The milk itself was identified as the vehicle; the butter and cheese appears to have been homemade. (CDC 2007)
2006	IL	<i>Salmonella enterica</i>	96	36	0	other cheese, unpasteurized	Cheese had been made from raw milk that had been illegally sold to an unidentified manufacturer (the label did not specify the manufacturer or the distributor). (CDC 2008)
1998	WI	<i>E. coli</i> , Shiga toxin-producing	63	24	0	cheddar cheese, unpasteurized; cheddar cheese, unspecified	Outbreak was from fresh cheese curds that had “inadvertently” been made from raw milk and then sold with a label indicating pasteurized cheese. (CDC 2000)
2007	KS	<i>Campylobacter jejuni</i>	16	0	0	Cheddar cheese, unpasteurized; raw milk	The outbreak stemmed from fresh cheese made and consumed the same day at a community fair (CDC 2009)
2012	UT	<i>Campylobacter jejuni</i>	2	0	0	Cheese curds	
2006	KS	<i>Brucella</i> unknown	5	3	0	Goat cheese/ chevre unpasteurized	
2000	Multi state	<i>Campylobacter jejuni</i>	18	0	0	Homemade cheese, unpasteurized milk	
2001	CA	<i>Brucella</i> unknown	4	0	0	Homemade cheese, unpasteurized milk	
2003	WA	<i>Campylobacter jejuni</i>	9	1	0	Homemade cheese, unpasteurized	
2006	WI	<i>Campylobacter jejuni</i>	58	2	0	Homemade cheese, unpasteurized	
2007	KS	<i>Campylobacter jejuni</i>	68	2	0	Homemade cheese, unpasteurized	
2009	UT	<i>Campylobacter jejuni</i>	10	0	0	Queso fresco, unpasteurized	

2011	CA	<i>Salmonella enterica</i>	37	7	0	Queso fresco, unpasteurized	
2013	MN	<i>Salmonella enterica</i>	26	15	0	Queso fresco, unpasteurized	
2003	CA	<i>Campylobacter</i> unknown	11	0	0	Queso fresco, unpasteurized	
2003	TX	<i>Listeria monocytogenes</i>	12	2	1	Queso fresco, unpasteurized	
2004	WA	<i>E. coli</i> , Shiga toxin-producing	3	2	0	Queso fresco, unpasteurized	
2003	CA	<i>Salmonella enterica</i>	50	7	0	Queso fresco, unpasteurized	
2004	CA	<i>Salmonella enterica</i>	12	1	1	Queso fresco, unpasteurized	
2005	CA	<i>Salmonella enterica</i>	12	2	0	Queso fresco, unpasteurized	
2005	CA	<i>Salmonella enterica</i>	3	0	0	Queso fresco, unpasteurized	
2005	CA	<i>Shigella</i> unknown	2	0	0	Queso fresco, unpasteurized	
2005	TX	<i>Listeria monocytogenes</i>	12	12	0	Queso fresco, unpasteurized	
2005	TX	<i>Brucella</i> unknown	2	2	0	Queso fresco, unpasteurized	
2007	CA	<i>Brucella</i> unknown	3	1	0	Queso fresco, unpasteurized	
2005	CA	<i>Salmonella</i> unknown	2	0	0	Queso fresco, unpasteurized	
2006	PA	<i>Salmonella enterica</i>	20	2	0	Queso fresco, unpasteurized; Raw milk	
Totals			618	125	2		

IV. Hard cheeses in particular are low-risk products

WAPF conducted a literature search to evaluate the safety of processes for the manufacture of hard cheeses produced from raw milk. These comments focus primarily on hard and very hard cheeses because this extensive literature was not considered in the recent risk assessment of listeriosis in soft cheeses by FDA and Health Canada. The information contained in the literature on hard cheeses is the most relevant to the question of whether any new regulatory restrictions should be adopted for raw milk cheeses, since the existing regulations already require a 60-day aging process, which excludes the production of most soft raw milk cheeses.

Hard cheeses were among four food commodities determined to pose “very low risk” of listeriosis to U.S. consumers.¹⁰ Donnelly cited an FDA letter from 1999 (Retail Food and Interstate Travel Team Letter: Aged Hard Cheeses) stating that growth of pathogens in hard cheese aged for 60 days is unlikely to occur.¹¹ Internationally, Food Standards Australia New Zealand¹² determined that the scientific evidence supports the premise that manufacturers of very hard cheeses (e.g., parmesan style cheeses) using unpasteurized milk can achieve an equivalent level of safety as cheeses using heat-treated milk and do not pose any significant public health and safety risk. **Further, Donnelly cited no growth of *L. monocytogenes* (and other pathogens) at specific pH ranges (4.3-5.6) in the following cheeses: Cotija, Cream, Blue, Monterey Jack, Swiss, Cheddar, Colby, String, Provolone, Munster, Feta, Kasseri, Parmesan, and Grana.**¹³

V. Raw milk cheese may be safer than pasteurized because of the competing microbiota

The agency’s targeting of raw milk cheeses is misguided. All cheesemakers, whether using pasteurized or unpasteurized milk, need to use appropriate sanitation measures.

While the exact number of outbreaks attributed to pasteurized cheese is unclear because cheese is often included as one of multiple ingredients in an outbreak, the CDC database lists over 280 outbreaks with over 6,000 associated illnesses that include cheese as at least one of the food vehicles in the same 16-year period.¹⁴ Even this number of illnesses still reflects a relatively low level of risk, given that over 900 million pounds of cheese are manufactured every month in the U.S.¹⁵ But consider the contrast: at most seven outbreaks, with a total of 134 illnesses, attributed to presumably legally manufactured raw milk cheeses (aged 60 days), compared to 280 outbreaks with more than 40 times as many illnesses attributed to products containing pasteurized cheese.

The majority of cheese-related outbreaks are caused by postprocess recontamination of cheese.¹⁶ With postprocess recontamination, the risks may actually be higher for pasteurized cheeses, which lack the protective raw milk microbiota, as compared to unpasteurized cheeses. For example, although nonpathogenic psychrotrophic bacteria, such as the pseudomonads, have been known for decades to dominate the microbial ecosystem in unheated raw milk at refrigeration temperatures,¹⁷ recent research on microbial interactions of the diverse bacterial populations in raw milk indicates that this dominance changes with duration and intensity of heat treatments. The initial populations density and growth rates of the group of psychrotrophic bacteria in raw

¹⁰ FDA 2003.

¹¹ Donnelly 2004.

¹² Food Standards Australia New Zealand 2002.

¹³ Donnelly 2004.

¹⁴ Table 5, Appendix A, drawn from CDC FOOD.

¹⁵ USDA NASS 2015.

¹⁶ Donnelly 2014.

¹⁷ Zall, 1990.

milk were found to be progressively lower following heat treatments of increasing intensity (140°F, 150°F, and 165°F for 10 seconds).¹⁸ However, after heat treatment at temperatures approaching pasteurization or ultrapasteurization levels, an **increased rate of growth** of the psychrotrophic pathogen *L. monocytogenes* was observed in multiple studies.¹⁹ **Higher growth and longer persistence of the pathogen *E. coli* O157:H7** was observed in pasteurized whey than unpasteurized whey.²⁰ The complex microbial interactions in cheese ecosystems²¹ are essential to consider in assessing risk and developing policies that effectively promote cheese quality and safety.

Since cheese requires extended periods of time for production, and is then often stored for significant periods of time during ripening, this potential for increased **growth** rates of *Listeria* in heat-treated dairy products needs to be fully considered in assessing relative risks to consumers of pasteurized and unpasteurized milk and cheese products. **Higher** risk of listeriosis deaths may be associated with pasteurized milk and cheese contaminated after heat treatments, and **lower** risk may be associated with raw milk and raw milk cheeses. No outbreaks of listeriosis in cheese aged for 60 days had been reported prior to 1990²² or between 1973 and 1992.²³ Epidemiologic data compiled from CDC (Table 1) also support a low-risk scenario for cheeses manufactured from raw milk, though duration of aging is not specified.

The increased growth rate for *L. monocytogenes* in heated milk can be attributed to disruption of colonization resistance, a well-characterized principle in population ecology.²⁴ Based on the evolving understanding of the microbiota of raw and pasteurized milks, the increased rate of growth of the pathogen in pasteurized milk could be explained by the reduction of the natural bacterial competition from the raw milk microbiota, predominately pseudomonads at refrigeration temperatures, that would otherwise outgrow *Listeria* spp., as well as *Campylobacter* spp., *E. coli* O157:H7, and *Salmonella* spp.,²⁵ and other enteropathogens that grow poorly, if at all, at refrigeration temperatures.²⁶ Other evidence of the indigenous microbiota of cheeses is consistent with this finding. **No growth of high levels of *L. monocytogenes* inoculated into raw milk was observed, while pasteurized milk inoculated at the same high level did support growth.**²⁷ Non-pathogens typical of the raw milk cheese microbiota (non-starter lactic acid bacteria, propionic acid bacteria, enterococci, and yeasts) grew to higher densities in hard cheeses (Comte and Cheddar) produced from raw milk than in the same cheeses made from pasteurized milk.²⁸

¹⁸ Zall, 1990.

¹⁹ Northolt et al., 1988; Brouillaud-Delattre et al., 1997; Donnelly, 2001; Stasiewicz et al., 2014.

²⁰ Marek et al., 2004.

²¹ Beuvier and Duboz, 2014.

²² Genigorgis et al., 1991; Ryser and Marth, 1991.

²³ Donnelly, 2004.

²⁴ van der Waaij et al., 1971.

²⁵ Coleman et al., 2003.

²⁶ FDA, 2001.

²⁷ Schwartzman et al. 2011.

²⁸ Cogan and Beresford, 2002.

Thus, raw milk is more likely than pasteurized milk to support a competing microbiota that limits the growth of pathogens contaminating cheese during manufacturing and ripening, contributing to the safety of hard cheeses produced from raw milk.

VI. The possible occurrence of natural contamination does not necessarily result in a significant risk of foodborne illness

The existing regulations for raw milk cheesemakers include strict standards for the quality of the milk used and the sanitation measures taken during cheese production. These requirements minimize the chances that pathogens will be present in the raw milk or the cheese during production.

Nonetheless, contamination does occur infrequently. Even when contamination occurs, however, it does not mean that the final product will cause any human illnesses. An unbiased assessment of risk must consider: the levels or counts of pathogens per gram (or per mL for liquids) observed in **naturally** contaminated foods; the conditions of **growth** of pathogens in the presence of the established microbiota naturally present in raw milk and raw milk cheeses that compete with pathogens and limit their growth; and dose-response models for predicting human health risks,²⁹ rather than opinions on “infective dose” that are not supported by definitive scientific evidence. Unbiased risk assessments would need to consider the effects of varying percentages of commercial starter cultures added during cheesemaking that also compete with pathogens and limit their growth, in addition to limitation of pathogen growth by the raw milk microbiota and the human gut microbiota.³⁰

Data from challenge studies of raw milk and raw milk cheeses artificially inoculated with thousands, millions, or billions of pathogens are not representative of the levels of pathogens observed for modern production using proper sanitation and animal husbandry practices. These comments focus on studies in the published literature of realistic experimental designs that document growth/no growth of observed levels of pathogens in raw milk and cheeses produced from raw milk in the presence of raw milk microbiota and starter cultures.

A. Microbial Ecology of Cheese

“Cheese is alive,” containing up to 10 billion microbes per serving, including lactic acid bacteria, non-lactic acid bacteria, yeasts, and molds. Microbial ecology -- the competition and cooperation of microbes -- plays a significant role in cheesemaking, converting milk to cheese.³¹

Recent advances in the field of microbial ecology are linked to innovations in culture-independent methods of analysis for many ecosystems dominated by bacteria, including the

²⁹ E.g. Marks et al., 1998; Cassin et. al, 1998; USDA/FDA 2005; Pouillot et al., 2015.

³⁰ Avendaño-Pérez & Pin, 2013; Kamada et al., 2013; Gahan and Hill, 2014.

³¹ Cogan and Beresford, 2002; D’Amico, 2014; AAM, 2015.

human body.³² These advances have greatly expanded our knowledge in the last decade. For example, prior to this, scientists assumed that human breast tissue and aseptically collected human milk would have very low bacterial counts and diversity. Yet recent studies found both a high diversity of bacteria in human breast tissue and in aseptically collected human milk, including up to 700 bacterial species in breast milk of healthy mothers.³³

Similarly, knowledge of the density, diversity, and functions of microbiomes in milk of dairy animals and cheese has also advanced³⁴ since the 60-day aging period for raw milk cheeses was established in 1949³⁵ based on proven elimination of *Brucella abortus* during this time period.

Traditional cheeses are complex ecosystems that depend on the density and diversity of the raw milk microbiota, as well as starter cultures, for transforming milk into safe and flavorful cheese.³⁶ The bacterial ecosystems of cheese undergo predictable successions of different bacteria that dominate as cheese is produced and ripened.³⁷ For example, *Lactobacillus* spp. are usually present in fresh cheese at <50 cfu/g immediately after manufacture, but outcompete other microbes during ripening to dominate the microbiota after 10-60 days of ripened cheese at very high densities (~10⁷/g), while the non-lactic acid bacterial group is also present at this high density after a year of ripening and storage.³⁸ Data on the microbial ecology of Pasta Filata Caciocavallo Pugliese cheese produced from raw cow milk reported by De Pasquale and colleagues (2014) are summarized in Tables 3 and 4 below.

Table 3. Microbial ecology of raw cow milk and Pasta Filata Caciocavallo Pugliese cheese (derived from De Pasquale et al., 2014)

Microbial Group	Mean log colony forming unit/gram					
	Raw milk	Cheese curd	Cheese on days of ripening			
			1	30	60	90
Mesophilic lactobacilli	4.2	5.2	5.0	7.2	8.4	8.5
Mesophilic lactococci	5.2	5.3	4.2	4.5	4.6	4.0
Thermophilic streptococci*	4.7	8.6*	8.8	8.2	8.0	7.3
Enterococci	2.6	3.9	4.1	3.0	2.0	1.5
Yeasts	3.4	4.5	3.7	1.8	<1	<1
Molds	2.3	2.2	<1	<1	<1	<1
Total coliforms	3.4	4.4	2.7	2.4	<1	<1

*Primary starter culture for cheesemaking, supplementing indigenous populations in raw milk

³² Human Microbiome Project; <https://commonfund.nih.gov/hmp/>.

³³ Hunt et al., 2011; Cabrera-Rubio et al. 2012; Jost et al., 2013; Urbaniak et al., 2014.

³⁴ Quigley et al., 2011, 2012, 2013; De Pasquale et al., 2014.

³⁵ Ryser and Marth, 1991.

³⁶ Donnelly, 2014; Dalmasso and Jordan, 2014; Beuvier and Duboz, 2014.

³⁷ De Pasquale et al., 2014; Wolfe and Dutton, 2014.

³⁸ Donnelly, 2004.

Table 4. Core microbiota of raw milk and Pasta Filata Caciocavallo Pugliese cheese (derived from De Pasquale et al., 2014)

Food product	Dominant genera (% abundance)	Dominant phyla (% abundance)
Raw milk	<i>Lactococcus</i> (32%)	<i>Firmicutes</i> (53%)
	<i>Acinetobacter</i> (31%)	<i>Proteobacteria</i> (39%)
	<i>Streptococcus</i> (16%)	<i>Bacteroidetes</i> (8%)
	<i>Chryseobacterium</i> (8%)	<i>Fusobacteria</i> (<1%)
	<i>Lactobacillus</i> (5%)	<i>Actinobacteria</i> (<1%)
	<i>Yersinia</i> (4%)	
	<i>Pseudomonas</i> (3%)	
	<i>Hafnia</i> (1%)	
Cheese curd	<i>Streptococcus</i> (>99%)	<i>Firmicutes</i> (>99%)
Ripened cheese	<i>Streptococcus</i> (79%)	<i>Firmicutes</i> (>99%)
	<i>Lactobacillus</i> (20%)	

Such diverse and dense populations of non-pathogens provide colonization resistance, outcompeting low densities of contaminating bacteria under conditions of modern cheesemaking.³⁹

This natural colonization resistance can be overcome in challenge studies that inoculate cheese or cheesemilk with unrealistically high levels of pathogens which have never been observed in naturally contaminated cheese. Such flawed experimental designs are invalid for determining the appropriate aging period for cheese.

For example, two studies cited in the Federal Register notice -- Reitsma and Henning, 1996, and Schlessler et al., 2006 -- do not support the contention that pathogens would survive the aging process in cheeses made from raw milk at natural levels of contamination. The Reitsma study used pasteurized rather than raw milk, which makes it an invalid basis for decisions about raw milk cheese, since raw milk has competing microbiota as discussed more below. Even then, the Reitsma study indicates that naturally low levels of contamination (such as 1 cfu/ml) do *not* survive the aging process, although unrealistically high levels (such as 1,000 cfu/ml) do. Similarly, in the Schlessler study, pathogens inoculated at 10 cfu/ml did not survive the aging process even though unrealistic inoculations of 1,000 and 100,000 cfu/ml did. Moreover, the Schlessler study used raw milk already contaminated by *E. coli* O157:H7, and many cheesemaking parameters were outside normal ranges for good manufacturing processes, including: moisture non-fat substance (MNFS); fat in dry matter (FDM); salt in moisture (SM); and pH. Therefore, these study designs and results are not representative of high quality raw milk

³⁹ Van der Waaij et al., 1971.

cheese production, and the data generated from these studies are invalid for determination of appropriate aging periods for raw milk cheeses.

The dense and diverse indigenous microbiota of raw milk and proper levels of commercial starter cultures limit the growth of pathogens in realistic challenge studies with raw milk cheese⁴⁰ or naturally contaminated cheeses.⁴¹ Without accounting for colonization resistance in the raw milk ecosystem and adjusting for pathogen growth limitations by the microbiota of cheeses during manufacture, ripening, and storage, any analysis of the available body of evidence will be biased and incomplete.

Consider the following:

- Tests of pre-pasteurized milk from silos represent multiple commingled bulk tanks stored for extended periods showed on average less than 1 cfu/ml of pathogens, with a maximum of 60 cfu/ml.⁴² This was in milk intended for pasteurization, **not** fresh raw milk from licensed or certified dairies intended to be consumed or used unpasteurized, and positive tests for pathogens were expectedly more frequent than would be found in licensed raw milk dairies.⁴³
- Some researchers studying survival of pathogens in raw milk cheesemaking have selected inoculation levels for pathogens many orders of magnitude greater than ever observed naturally.⁴⁴
- Even in studies that used extremely high levels of *Listeria* as inoculants, the results show that the pathogen does not grow well at the typical pH and other conditions used for cheesemaking; although some survived, there was consistent die-off during ripening.⁴⁵
- In a study that used high levels of *E. coli* O157:H7 as inoculants, the results show that the pathogen does not grow well at the typical pH and other conditions used for cheesemaking; although some survived, there was consistent die-off during ripening.⁴⁶
- When tested under normal conditions, *L. monocytogenes* at the level actually found in raw milk did not survive the cheesemaking process.⁴⁷
- Recent work by Schwartzman et al. (2011) cautions that presence and magnitude of pathogen growth in challenge studies may be misinterpreted without use of consistent units (counts per gram dry weight for both milk and cheese) rather than counts/mL milk and counts/gram cheese.

Milk quality tests (standard plate count or total aerobic plate count; coliform count; fecal coliform count; non pathogenic *E. coli*; somatic cell counts) are useful indicators of sanitation, but few studies document any predictive value of milk quality tests for the presence of pathogens, the level of pathogens if present, or the likelihood or severity of human illness to

⁴⁰ Cogan and Beresford, 2002; Donnelly, 2004; D'Amico, 2014.

⁴¹ Dalmaso and Jordan, 2014.

⁴² Jackson et al., 2012.

⁴³ Jackson et al. 2012.

⁴⁴ Samelis et. al 2009, Schwartzman et al. 2011.

⁴⁵ Giannou et al. 2009, Samelis et al. 2009.

⁴⁶ D'Amico et al., 2010.

⁴⁷ D'Amico et al. 2008, Dalmaso and Jordan 2014.

consumers.⁴⁸ However, standard plate count is useful as an indicator of the level of aerobic and facultative aerobic microbiota dominated in milk at refrigeration temperatures by bacteria including *Pseudomonas* spp.⁴⁹ and of the presence of *E. coli* O157:H7 in one study of pre-pasteurized commingled silo milk.⁵⁰

B. Additional protective factors in cheese

The occurrence of pathogens in hard and very hard raw milk cheeses produced and stored under proper sanitation and good manufacturing practices is rare.⁵¹

Various factors used by cheesemakers combine synergistically to limit the growth of pathogens beyond the effectiveness of each single factor in the production of safe cheeses,⁵² including:

- the types and initial levels of added starter cultures;
- the types and initial levels of the indigenous microbiota of raw milk;
- the time and temperature conditions during manufacture and storage of cheese during ripening;
- microbiological changes influenced by starter cultures (e.g., *Lactobacillus*, *Pediococcus*, *Lactococcus*, *Streptococcus*) and the indigenous raw milk microbiota before, during, and after fermentation;
- physiological changes and byproducts of fermentation, primarily production of antibacterial compounds (bacteriosins, antimicrobial peptides and proteins including defensins and lactoferrins, enzymes including lactoperoxidase, oils, etc.) and pH reductions; and
- changes in salt or water activity (a_w) or % moisture during manufacture and storage.

VII. Pathogens of Concern in Current Cheese Production

The literature review in these comments focuses on the three pathogens specified in the FDA's Federal Register notice: *Listeria monocytogenes*, *Salmonella* spp., and *E. coli* O157. Additional evidence for other pathogens will be briefly addressed.

Many of the pathogens associated with milk-borne and cheese-borne illness in the past century are considered low risks to current US cheeses consumers.⁵³ Some of the low risk pathogens identified by D'Amico (2014) for properly produced and refrigerated cheese will not be discussed herein: *Bacillus cereus* (gastroenteritis, emetic intoxication); *Brucella melitenis/abortus* (brucellosis); *Campylobacter jejuni* (campylobacteriosis); *Coxiella burnetii* (Q

⁴⁸ Van Kessel et al., 2004; D'Amico et al., 2010; Jackson et al., 2012.

⁴⁹ Dogan and Boor, 2003; De Jonghe et al., 2011; Machado et al., 2015.

⁵⁰ Jackson et al., 2012.

⁵¹ Giannou et al., 2009; Samelis et al., 2009; AAM, 2015.

⁵² Donnelly, 2004; Giannou et al., 2009; Samelis et al., 2009; Wolfe and Dutton, 2014; Arqués et al., 2015.

⁵³ Hahn, 1996; D'Amico, 2014.

fever); *Mycobacterium bovis/tuberculosis* (tuberculosis); *Salmonella enterica* serovar Typhi (typhoid fever); *Shigella dysenteriae/sonnei* (shigellosis); and *Yersinia enterocolitica* (yersiniosis).

Campylobacteriosis is considered by several to be a low risk pathogen for consumers of hard cheeses.⁵⁴ Some outbreaks of campylobacter in raw cheese have been reported, almost all involving fresh, unaged cheeses.⁵⁵ A 2003 outbreak in Vermont and a 2010 outbreak in Arizona involve unspecified raw cheeses; it is unclear if these were in fact aged cheeses or fresh ones (particularly since the outbreaks involved both unpasteurized milk and unpasteurized cheese, which often means that people were consuming raw milk and making cheese themselves from the same milk).⁵⁶

Recent human clinical data on dose-response relationships for campylobacteriosis establish that healthy humans have innate resistance to a high dose, 10^8 cfu (100,000,000 cfu), and those who developed illness at this high dose developed short and long term immunity to future challenges.⁵⁷ Further, a more recent study reports that the human gut microbiota of frequently exposed poultry abattoir workers provide colonization resistance, resulting in reduced susceptibility to campylobacteriosis (asymptomatic infection or no infection).⁵⁸ Thus, campylobacteriosis is considered a low risk for aged cheese consumers due to the nature of the organism as a poor competitor amidst the dense and diverse microbiota of raw milk cheese, as well as the low infectivity and virulence in healthy humans.

Two of four major bacteria of concern noted by D'Amico (2014), nonpathogenic *Escherichia coli* and *Staphylococcus aureus*, are considered indicators of proper sanitation and animal husbandry, not human health risks at the levels typically detected in milk and cheese. While these bacteria can cause mastitis in dairy animals and quality issues in milk and cheese production, both organisms are present in the healthy human microbiota.⁵⁹ These organisms rarely cause disease, as noted in the CDC FOOD database: only 19 outbreaks in 16 years related to *Staphylococcus* spp. or non-O157 *E. coli* in foods that included cheese as an ingredient, and none occurred in unpasteurized cheeses.⁶⁰ At densities below 10^6 /g in raw milk cheese, *S. aureus* does not form enterotoxin.⁶¹ Enterotoxin formed at very high densities of *S. aureus* is linked to human disease.⁶² The low risk of foodborne illness from *S. aureus* is recognized internationally, as the EU determined that raw milk cheeses containing <10,000 *S. aureus* per gram are satisfactory.⁶³

⁵⁴ D'Amico 2014; Hahn, 1996; Cogan and Beresford, 2002.

⁵⁵ Table 2, drawn from CDC FOOD.

⁵⁶ Table 1, drawn from CDC FOOD.

⁵⁷ Tribble et al., 2010.

⁵⁸ Dicksved et al., 2014.

⁵⁹ Feazel et al., 2012; Popov et al., 2014.

⁶⁰ Table 5, Appendix A, drawn from CDC FOOD.

⁶¹ Hahn, 1996.

⁶² D'Amico, 2014.

⁶³ Little et al., 2008.

Recent studies on hard and very hard cheeses produced from raw milk identified in the WAPF literature searches relevant to the three pathogens mentioned in the Federal Register notice, *L. monocytogenes*, *Salmonella* spp., and *E. coli* O157, are listed below.

A. *Recent Data on Presence, Level, Growth, and Interactions of L. monocytogenes*

The following studies are relevant to FDA considerations of the likelihood and severity of listeriosis in consumers of aged raw milk cheeses.

- **Poillot et al., 2015:** FDA risk assessment predicts most US listeriosis cases result from consumption of foods containing 10,000 or more *L. monocytogenes*; updated food survey and dose-response data permit modeling listeriosis with adjustments for strain virulence and host susceptibility.
- **Dalmasso and Jordan, 2014:**
 - No *L. monocytogenes* was quantifiable in raw milk used in cheesemaking or in Cheddar cheese by direct plating or enrichment plating immediately after cheese production.
 - No growth was observed in Cheddar cheeses naturally contaminated with *L. monocytogenes* during the cheesemaking process.
 - Density of *L. monocytogenes* in Cheddar cheese naturally contaminated during ripening did not exceed 20 cfu/g by enrichment methods (unquantifiable by direct plating methods).
 - During ripening, post-production contamination of cheese by *L. monocytogenes* was detected at 1, 2, and 3 months by both direct plating and enrichment methods (below detection by both methods at months 4 and 5).
 - In cheese contaminated during ripening, *L. monocytogenes* was present below the limit of quantification by direct plating and detected by enrichment plating at 10 cfu/g at 1 month, 20 cfu/g at 2 months, and <10 cfu/g (non-quantifiable) at 3 months.
 - Environmental samples from the farmhouse cheesemaking facility were occasionally positive for *L. monocytogenes* during the study (7% positive on average), presumably the source of the post-production contamination.
 - The authors concluded: “These results demonstrate that this farmhouse Cheddar cheese does not support *L. monocytogenes* growth.”
- **Stasiewicz et al., 2014:**
 - Milk samples that were pasteurized at 82°C for 25 seconds and inoculated with *L. monocytogenes* at 3×10^3 cfu/ml supported **higher pathogen growth** than samples pasteurized at 72°C for 25 seconds (statistically significant decrease in lag and increase in maximal population density for 82°C pasteurization temperature, nonsignificant trend toward increased maximal growth rate)
 - Exposure to *L. monocytogenes* was higher in milk pasteurized at 82°C than 72°C from outgrowth of pathogen following contaminated post-pasteurization

- **Higher** milk pasteurization temperature **increased** predicted number of listeriosis deaths
- The authors conclude that lower milk processing temperatures and improved consumer storage behavior could reduce listeriosis deaths
- **Pricope-Ciolacu et al., 2013:** interactions of human intestinal epithelial cells (Caco-2) with milks inoculated with of *L. monocytogenes* strains at high dose (10^8 cfu/mL) include lower adhesion, invasion, and proliferation for raw milk than pasteurized milk and buffer, indicating a protective effect of the raw milk microbiota on resistance of human cells to listeriosis.
- **Jackson et al., 2012:**
 - For pre-pasteurized commingled (from multiple bulk tanks) silo milk at dairy plant, 23 of 184 samples were positive for *L. monocytogenes*, enumerated at <1 cfu/mL (mean, median; max 29 cfu/mL)
 - Also reported: total aerobic bacteria, total coliforms, *Enterobacteriaceae*, *Escherichia coli*, and *Staphylococcus aureus*
 - These data reflect a relatively **low level** of contamination that occurs naturally, but the frequency of contamination is unrealistic for raw milk cheeses because pre-pasteurized milk from silos storing multiple commingled bulk tanks for extended periods is not representative of the fresh raw milk from licensed or certified dairies used for making raw milk cheeses under current regulations.
- **Schwartzman et al., 2011:**
 - No growth was observed in raw milk inoculated with *L. monocytogenes* at 3.5 log cfu/gram dry weight (gdw; 430 cfu/mL) incubated at 30°C; initial total bacterial count for raw milk was 6×10^3
 - Growth was observed in pasteurized milk inoculated with *L. monocytogenes* at 3.4 log cfu/gdw (330 cfu/mL) with incubation at 30°C; initial total bacterial count for pasteurized milk was 35 cfu/mL
 - After 30 days of ripening at 13°C, then 8°C, growth was observed in raw milk cheese at pH 5 during the first 150 hours of ripening, not in pasteurized milk cheese at pH 4.7;
 - This study used high density pathogen inoculations that do not reflect natural levels of contamination that may occur in raw milk from licensed dairies, making this data inappropriate for basing regulation of raw milk cheeses.
- **Giannou et al., 2009:**
 - No growth of a cocktail of five *L. monocytogenes* strains inoculated on surface of fully ripened Greek Graviera cheese at 3 log cfu/cm² and stored at 4, 12, or 25°C under air or vacuum conditions
 - Survival of extremely high *L. monocytogenes* inoculum also reported up to 90 days
 - These data are unrealistic for determining the appropriate aging period for hard cheeses contaminated naturally because the high inoculation level is not representative of naturally contaminated cheese.

- **Samelis et al., 2009:**
 - Thermized Graviera cheese milk (heated at 63°C for 30 seconds) was inoculated with a high density (4 log cfu/mL) of a cocktail of three *L. monocytogenes* strains, with or without mixed LAB starter culture, and incubated for 6 hours at 37°C and then for 66 hours at 18°C to simulate commercial processes of milk curdling and cheese ripening
 - Initial counts of pseudomonads, *Enterobacteria* spp., and coagulase-positive staphylococci were <2 log cfu/mL , and *L. monocytogenes* was not detected
 - Groups of lactic acid bacteria (LAB; mesophilic, thermophilic, and *Enterococcus* spp.) were monitored
 - The high inoculum of *L. monocytogenes* increased 1-2 log units with and without starter culture and were detectable at the last sampling (72 hours)
 - Growth of *L. monocytogenes* was inhibited by growth of LAB with and without starter culture from 12-72 hours
 - Starter culture had significant growth retarding effect on *L. monocytogenes*
 - Graviera cheese commercially manufactured with mixed LAB starter culture were inoculated with a high density (3 log cfu/g) of a cocktail of 3 nonpathogenic strains of *L. monocytogenes* and *L. innocua* in the pilot area of the plant to simulate contamination before pressing and storage; inoculated cheese was immersed in 20% brine at 12°C for 24 hours, ripened at 18°C for 20 days, and stored at 4°C for up to 60 days.
 - Groups of lactic acid bacteria (LAB; mesophilic, thermophilic, and *Enterococcus* spp.) were monitored.
 - Complete growth inhibition of the high inoculum of *L. spp.* was observed in the core of Graviera cheese during processing and storage, and surviving contaminants were unable to grow after brining and during ripening and storage.
 - Significant decreases in the high inoculum of *L. spp.* were observed in fresh brined cheese at the onset of ripening (from day 0 to days 3-5) when LAB populations increased significantly; the high inoculums of *L. spp.* resulted in detection at the time of last sampling (60 days).
 - Addition of commercially defined, concentrated mixed LAB starters of high cell density and activity to thermized raw milk rapidly accelerates organic acid production, and thus pH reduction and acidification of cheese curds, and effectively prevents growth of *L. monocytogenes* contaminants up to 1,000 cfu/g in manufacture of traditional Graviera cheeses.
 - Traditional Graviera cheeses will not support growth of *L. monocytogenes* surviving at 100 cfu/g or 100 cfu/cm² at time of sale.
- **D'Amico et al., 2008:**
 - For all raw milk samples (cow, goat, and sheep), 3 of 133 samples were positive for *L. monocytogenes* from VT farmstead dairies at <1 count per mL; 3 of 62 cow milk samples were positive.

- For pathogen positive milks, cheeses after manufacture and after 60-day aging were not positive for any pathogen using BAX PCR system.
- Also reported: standard plate counts, coliforms, somatic cell counts, and *Staphylococcus aureus*.
- **Millet et al., 2006:**
 - No growth was observed for a cocktail of two *L. monocytogenes* strains in cheeses prepared from inoculated raw milk samples from 3 farms (F4, F5, and F6) at 5 to 10 cfu/25 mL (~1-3 cfu/mL) that rapidly acidified (pH <5 at day 8 of ripening)
 - Growth was observed for a cocktail of two *L. monocytogenes* strains in cheeses prepared from inoculated raw milk samples from 3 farms (F1, F2, F3) at 5 to 10 cfu/25 mL (~1-3 cfu/mL) that acidified slowly (pH 5.2-5.5 after 8 days of ripening)
 - This study indicates production (acidification rate), farm, and other effects contribute to variability in growth/no growth of low levels of *L. monocytogenes*.
- **Donnelly, 2004:** Review cited no growth of *L. monocytogenes* (and other pathogens) in the following cheeses: Cotija, Cream, Blue, Monterey Jack, Swiss, Cheddar, Colby, String, Provolone, Munster, Feta, Kasserli, Parmesan, and Grana (pH ranges 4.3-5.6).
- **Van Kessel et al., 2004:** For bulk tank milk, 56 of 861 samples were positive for *L. monocytogenes* (serotypes 1/2a, 1/2b, 3b, 4b, and 4c) at 1 to 37 colony forming units per mL by direct plating or 10-40 cfu/10 mL (1-4 cfu/ml) after enrichment.
- **Chen et al., 2003:** Risk assessment based on US data for foodborne exposures and epidemiologic surveillance predicts negligible listeriosis risk at low doses of *L. monocytogenes*.
- **WHO/FAO, 2004:** Risk assessment predicts negligible listeriosis risk at low doses of *L. monocytogenes*.
- **Bovill et al., 2000:**
 - Growth of 10³ cfu/mL inoculations of *L. monocytogenes* at 30°C for 20 hours was highest for culture broth (maximal density 10⁹ cfu/mL), lower in ultrapasteurized milk (maximal density 10⁷ cfu/mL), and lowest in pasteurized milk (maximal density 10⁵ cfu/mL).
 - Growth of *L. monocytogenes* at 7°C and 30°C was slower in milk than broth due to longer lag attributed to natural microbiota remaining in pasteurized milk.

B. Recent Data on Presence, Level, Growth, and Interactions of Non-Typhoidal *Salmonella* spp.

The following studies are relevant to FDA considerations of the likelihood and severity of non-typhoidal salmonellosis in consumers of aged raw milk cheeses.

- **Avendaño-Pérez and Pin, 2013:** Anaerobic cultures of human gut microbiota inhibited and inactivated high doses of *Salmonella enterica* serovar Typhimurium (6 to 8 log₁₀ cfu/ml), consistent with colonization resistance of the gut microbiota to non-typhoidal *Salmonella* spp.

- **Jackson et al., 2012:**
 - Up to 33 of 184 pre-pasteurized commingled silo milk samples were positive for *Salmonella* spp. by direct plating, enumerated at <1 cfu/mL (mean by 4 of 5 methods and median by all 5 methods; maximum 4.7 by three methods, 17 and 60 by other methods).
 - Also reported: total aerobic bacteria, total coliforms, *Enterobacteriaceae*, *Escherichia coli*, and *Staphylococcus aureus*.
 - These data reflect a **low level** of contamination that occurs naturally, but the frequency of contamination is unrealistic for raw milk cheeses because pre-pasteurized milk from silos storing multiple commingled bulk tanks for extended periods is not representative of the fresh raw milk from licensed or certified dairies used for making raw milk cheeses under current regulations.
- **D'Amico et al., 2008:**
 - None of 133 samples from all raw milk (cow, goat, sheep) from Vermont farmstead dairies were positive for *Salmonella* spp.
 - Also reported: standard plate counts, coliforms, somatic cell counts, and *Staphylococcus aureus*.
- **Van Kessel et al., 2004:** For bulk tank milk, 22 of 861 samples were positive for *Salmonella* spp. (serotypes Montevideo, Newport, Muenster, Meleagridis, Cerro, Dublin, Anatum) at ~4 cfu per mL by direct plating or 10-40 cfu/10 mL (1-4 cfu/ml) after enrichment.
- **Hahn, 1996:** Author concluded that salmonellosis in cheese is no longer a relevant food safety problem.

C. *Recent Data on Presence, Level, and Growth of E. coli O157:H7*

The following studies are relevant to FDA considerations of the likelihood and severity of enterica illness from pathogenic *E. coli* in consumers of aged raw milk cheeses.

- **Jackson et al., 2012:**
 - Up to 30 of 184 pre-pasteurized commingled silo milk samples were positive for *E. coli* O157:H7 by direct plating, enumerated by MPN at <1 cfu/mL (mean, median, and max by two of three methods, third method max 1.1 cfu/mL).
 - Also reported: total aerobic bacteria, total coliforms, *Enterobacteriaceae*, *Escherichia coli*, and *Staphylococcus aureus*.
 - These data reflect a **low level** of contamination that occurs naturally, but the frequency of contamination is unrealistic for raw milk cheeses because pre-pasteurized milk from silos storing multiple commingled bulk tanks for extended periods is not representative of the fresh raw milk from licensed or certified dairies used for making raw milk cheeses under current regulations.
- **Madic et al., 2011:** None of 400 raw milk cheeses was positive for *E. coli* O157:H7.
- **D'Amico et al., 2010:**
 - Raw milk used in this study contained non-detectable *E. coli* O157:H7.

- Raw milk samples were inoculated with approximately 20 cfu/mL *E. coli* O157:H7 strains and refrigerated overnight before use in cheesemaking for stirred-curd Cheddar cheese and Gouda cheese.
- Freeze dried direct set lactic acid starter cultures were added:
 - RA 021 or RA 022 to Cheddar at 6 Danisco culture units (DCU) per 100
 - RA 021 and LH 100 to Gouda at 6.25 and 0.75 DCU/100L
- The relationships between microbial quality indicators, pathogens, and physical parameters are complex. Statistically significant negative correlations were noted between microbial quality indicators and physical parameters: between log₁₀ standard plate count and pH of Cheddar cheese (higher standard plate count results in lower pH); and between log₁₀ coliform count and moisture content of Gouda cheese (lower moisture content, higher coliform counts).
- A positive correlation was detected between pH and growth of the pathogen during manufacturing, indicating that lowering the pH (related to higher standard plate counts) lowers pathogen growth.
- The pathogen concentrated (entrapped in curd) or grew in the initial phase of manufacture of both cheddar and Gouda cheese, and declined thereafter.
- Out of the 19 Cheddar cheese trials, no detection of *E. coli* O157:H7 was observed by direct plating of 7 whey samples and 9 curd samples, presumably due to overgrowth of the cheese microbiota.
 - These samples were excluded from the analysis, but indicate that pathogens were completely outcompeted by the cheese microbiota.
- The inoculated pathogen strain at the two lowest densities in Cheddar cheese after curd formation (~60 and 150 cfu/g) declined to <20 cfu/g by 60 days (Figure 2A, B) and from approximately 225 cfu/g after curd formation to <50 cfu/g by 60 days for the third strain
- The inoculated pathogen strain in Gouda cheese declined from 150 cfu/g after curd formation to <10 cfu/g by 60 days (Figure 3).
- At these high densities not observed in naturally contaminated cheeses, presence of the inoculated pathogen strains was nondetectable by direct plating by 80-300 days, but sporadically detectable by enrichment plating.
- The authors note that the presence and survival of such low levels of the inoculated *E. coli* O157:H7 strains may be too low to cause human disease concerns.
 - Natural levels of contamination would most likely be completely eliminated during manufacturing and ripening.
 - This is supported by the very low incidence of *E. coli* O157:H7 in cheese; only 3 samples of 3,360 tested positive for *E. coli* O157:H7 in FDA sampling from January 2004 to December 2006.
- These data are unrealistic for determining the appropriate aging period for hard cheeses contaminated naturally because the high inoculation level is not representative of naturally contaminated cheese.
- **D'Amico et al., 2008:**
 - None of 62 raw cow milk samples from VT farmstead dairies were positive for *E. coli* O157:H7; 1 sample of goat milk was positive.

- No cheeses were positive for any pathogen using BAX PCR system after manufacture from positive milk and after 60-day aging.
- Also reported: standard plate counts, coliforms, somatic cell counts, and *Staphylococcus aureus*.
- **Perelle et al., 2007:** Six of 205 raw milk samples were positive for *E. coli* O157 at 1 or 2 MPN/kg.
- **Schlesser et al., 2006:**
 - Raw milk used in this study was contaminated by *E. coli* O157:H7, and moisture non-fat substance (MNFS), fat in dry matter (FDM), salt in moisture (SM), and pH varied considerably and were periodically far outside normal ranges; the raw milk and production processes used in this study are therefore of questionable quality.
 - Raw milk was inoculated with 1% bulk starter culture and a cocktail of 5 *E. coli* O157:H7 acid-resistant strains at 10^1 cfu/mL during manufacture concentrated or grew in cheese and declined during ripening until non-detectable at 150 days.
 - Raw milk was inoculated with 1% bulk starter culture and a cocktail of 5 *E. coli* O157:H7 acid-resistant strains at 10^3 or 10^5 cfu/mL during manufacture concentrated or grew in cheese and declined during ripening but were detectable at 360 days of aging.
 - The quality of the study (using contaminated milk, presumably low quality) and process controls (cheesemaking parameters MNFS, FDM, SM, and pH outside normal ranges) are questionable and thus inappropriate for basing new regulatory requirements.
- **Coia et al., 2001:** None of 743 raw milk cheeses were positive for *E. coli* O157:H7.
- **Heuvelink et al., 1998:** None of 1011 raw milk samples were positive for *E. coli* O157:H7.
- **Reitsma and Henning, 1996:**
 - No growth or survival of *E. coli* O157:H7 inoculated at 1 cfu/mL into **pasteurized** milk containing 1% commercial bulk starter culture (REDI-SET #253) was detected in Cheddar cheese during ripening.
 - Concentration or growth (approximately an order of magnitude) of the inoculated pathogen was detected at both 1 cfu/mL and 1,000 cfu/mL challenge levels during manufacturing of Cheddar cheese.
 - No growth of *E. coli* O157:H7 inoculated at 1,000 cfu/mL into **pasteurized** milk containing 1% commercial bulk starter culture (REDI-SET #253) was detected in Cheddar cheese during ripening. The pathogen survived at very low levels after 158 days of ripening to <1 cfu/g (three samples), 20-21 cfu/g (2 samples), and 40 cfu/g (1 sample).
 - Salt in moisture phase (SM) was inadequate by current standards.
 - This study used pasteurized milk, which lacks the protective microbiota of fresh raw milk, and high density pathogen inoculations, which do not reflect natural levels of contamination that may occur in raw milk from licensed dairies, making this data inappropriate for basing regulation of raw milk cheeses.

VI. Conclusion

Current requirements already address both microbiological indicators of proper sanitation (total bacterial counts or standard plate counts) and physical indicators of conditions that limit pathogen growth (time, temperature, pH, salt or a_w or % moisture), and have been effective for many decades in preventing outbreaks of human illness in consumers of raw milk cheeses from legal producers.

Specific pathogen testing of raw milk and raw milk cheeses is not a necessary, practical or effective approach to process control in cheesemaking. The cost of such testing would be prohibitive, especially to small businesses, and the approach of testing for rare contamination events is not merited by the exemplary record of safety of raw milk cheeses. Similarly, an aging period longer than sixty days is not warranted by the evidence.

All cheese, whether pasteurized or unpasteurized, should be made under appropriate sanitation measures. The data and scientific literature do not support singling out unpasteurized cheese for more onerous requirements. Again, it is vital to distinguish between outbreaks from legally produced raw milk cheeses and homemade cheeses or illegally produced cheeses; adding additional burdens on legal cheese producers will do absolutely nothing to address the risk of illness from illegal or homemade cheeses.

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Appendix A

Table 5: Outbreaks in which the food vehicle included pasteurized cheese, 1998-2013
Drawn from data on CDC FOOD.

Year	State	Genus_Species	ill	Hospital Deaths	FoodVehicle	Contaminated_Ingr
Outbreaks that list cheese as a vehicle, excluding raw milk cheeses, 1998-2013						
2011	Michigan	Listeria monocytogenes	2	2	1	ackawi cheese, pasteurized; chives cheese, pasteurized
2001	Maryland	Norovirus Genogroup II	4	0	0	american cheese, pasteurized; ground beef, hamburger
2007	Colorado	producing; E.coli, Shiga toxin-	135	10	0	american cheese, pasteurized; margarine cheese
2004	New Hampshire	Norovirus Genogroup I	25	0	0	american cheese, unspecified; deli meat, sliced ham & sliced turkey
2011	Florida	Norovirus Genogroup II	9	0	0	apple potato salad; spinach cheese dip
2011	Oregon	Norovirus Genogroup II	16	0	0	asparagus citrus salad; Goat cheese profiterole
2010	Florida	Norovirus	6	0	0	bacon, egg, and cheese biscuit
2004	California	Norovirus Genogroup I	27		0	bagels; cream cheese bread; cheese
2008	Colorado	Norovirus Genogroup I	16	0	0	bagels; cream cheese
1999	Florida		3	0	0	beans, unspecified; other cheese, unspecified; tortilla, unspecified
2011	Ohio		3	0	0	beer; blue cheese dressing; celery, unspecified; chicken, buffalo wings
2006	New York	Norovirus Genogroup I	25	0	0	beverage with ice, unspecified; cheese spread; green salad cheese; leafy green
2006	Ohio	Norovirus Genogroup I	20	0	0	beverage with ice, unspecified; multiple cheeses, pasteurized; vegetable tray
2002	Alabama		3	0	0	biscuit, unspecified; chicken, fried; macaroni and cheese
1999	New York	Salmonella enterica	9	0	0	Blintz, Cheese; eggs, other
2011	Florida	Norovirus Genogroup II	3	0	0	blue cheese dressing
1998	Florida		3	0	0	blue cheese dressing
1999	Florida		3	0	0	blue cheese dressing cheese
2000	Florida	Staphylococcus aureus	2			blue cheese dressing cheese; milk; Sauces/ Dressings
2000	Florida	Bacillus cereus	2	0	0	blue cheese dressing Spices
1998	Minnesota		16	0	0	blue cheese dressing
2002	Florida		4	0	0	blue cheese dressing Sauces/ Dressings

2007	Rhode Island	Salmonella enterica	2	1	0	blue cheese dressing	
1999	Florida		2	0	0	blue cheese dressing; chicken, buffalo wings	
1999	Florida		11	0	0	blue cheese dressing; chicken, buffalo wings	chicken
1999	Michigan		2			blue cheese dressing; cottage cheese, unspecified	
1999	Ohio		3	0	0	blue cheese dressing; ranch dressing	
2000	California		2	0	0	blue cheese dressing; roast beef, unspecified; salad bar	beef; cheese; Sauces/Dressings
1998	Minnesota	Norovirus Genogroup I	25	0	0	bread, unspecified; butter; cheese and crackers	
2005	California		4	0	0	bread, unspecified; cake, cheese	
2013	Minnesota	Norovirus Genogroup II	7	0	0	bread, wheat; swiss cheese, pasteurized	bread, wheat; swiss cheese
2007	New York	Norovirus unknown	21	0	0	bread, white; other cheese	bread; cheese
2008	Minnesota	Norovirus Genogroup I	3	0	0	brie, unspecified; cantaloupe; pineapple, unspecified; sauces, unspecified	
1999	Oregon	Norovirus Genogroup I	8	0	0	brie, unspecified; cocktail sauce, unspecified	
2012	Texas		3	0	0	broccoli and cheese sauce	
2008	Florida	Norovirus Genogroup I	3	0	0	bun; cheese, unspecified; ground beef, hamburger; pizza; potato chips	
2012	California		2	0	0	burrito (bean & cheese)	
2007	California	perfringens; Bacillus cereus	8	0	0	burrito, beef; burrito, cheese	beef; chicken
1999	New Mexico	Salmonella enterica	73	16	0	burrito, beef; nachos and cheese	
2000	California	Clostridium perfringens	73			burrito, cheese	
2001	Ohio		2			burrito, cheese	
2005	California	Norovirus Genogroup I	22	0	0	burrito, cheese	
1999	Colorado	Staphylococcus aureus	8	0	0	burrito, unspecified	cheese
2011	Florida		3	0	0	cake, cheese	
1999	Oregon	Norovirus Genogroup I	12	0	0	cake, cheese	

1998	California		24	0	0	cake, cheese	
2001	Georgia	Norovirus Genogroup I	329	2	0	cake, cheese	
2006	California	Norovirus unknown	4	0	0	cake, cheese	
2006	California	Norovirus Genogroup II	11	0	0	cake, cheese	
1998	Michigan		2			cake, cheese; chicken, unspecified	
1998	Florida		2	0	0	cake, cheese; fried onions/onion rings, unspecified	
2007	Pennsylvania	Norovirus Genogroup I	95	2	0	cake, cheese; garden salad	
1998	California		39	0	0	cake, cheese; pasta, unspecified	
2013	Minnesota	Norovirus Genogroup II	23	0	0	cake, cheese; potato, baked	
2005	North Carolina	Salmonella enterica	14	1	0	cake, cream cheese; cheese bread	
2008	New Jersey	Salmonella enterica	70	0	0	cheddar cheese	
2003	California	Norovirus Genogroup I	13	0	0	cheddar cheese, unspecified	cheese
2006	Georgia	Norovirus Genogroup II	17	0	0	cheddar cheese, unspecified; chips, tortilla; sour cream	
2002	Alaska		9	0	0	cheddar cheese, unspecified; red salsa	
2009	Wyoming	Norovirus Genogroup II	22	0	0	pasteurized; leaf lettuce; lettuce based salads; milk, 1% milk pasteurized; salad	pasteurized; leaf lettuce
2001	Massachusetts		45	0	0	cheese and crackers; grapes, unspecified	unspecified; Other baked goods
2002	South Dakota	Norovirus Genogroup I	19	0	0	cheese and crackers; rice crispy treat; venison, jerky	
2004	California	Norovirus Genogroup I	7	0	0	cheese ball	
2004	Ohio		3	0	0	cheese bread	
2010	Colorado	Campylobacter jejuni	3	0	0	cheese curds	milk, whole milk pasteurized
2009	Tennessee	Norovirus Genogroup II	11	0	0	cheese dip	
2004	North Carolina	Shigella sonnei	77	2	0	cheese dip	
1998	Florida		7	0	0	cheese dip; cheese sauce; taco dip	

2004	Alabama		4			cheese dip; fajita, chicken	
2010	Ohio	Norovirus Genogroup I	8	0	0	cheese dip; vegetable dip, unspecified	
2013	Connecticut	E.coli, Enteroaggregative	34	0	0	cheese dish, other; dips; fruit; salad, unspecified; vegetable tray	
2003	Tennessee	Salmonella enterica	5	2	0	cheese dish, other; ham, other; omelette	
2001	Massachusetts		19	0	0	cheese dish, other; rice dishes, unspecified	
2005	Florida	Bacillus cereus	3			cheese fondue	
2013	Illinois		16	0	0	Cheese platter	
2007	Minnesota	Norovirus Genogroup II	8	0	0	cheese products	
2002	Delaware	Salmonella enterica	21	4	0	cheese sauce; chicken, buffalo wings	
1998	Illinois	Salmonella enterica	8	4	0	cheese sauce; potato, baked	
2004	Florida	Bacillus cereus	3	0	0	cheese sauce; potato, mashed	
2004	Ohio	Clostridium perfringens	269		0	cheese sauce; tortellini, cheese	
2004	Texas		18	1	0	cheese spread	
2003	California	Norovirus Genogroup I	15	0	0	cheese sticks	cheese
2000	Illinois		3	0	0	cheese sticks; ground beef, cheeseburger	
1999	Florida		2	0	0	cheese sticks; ground beef, hamburger	
2013	New York	Norovirus Genogroup II	6	0	0	Cheese Toast	
2001	Connecticut	Salmonella enterica	4	1	0	cheese, pasteurized	
2001	New York		13	0	0	cheese, pasteurized	
2001	Ohio		3	0	0	cheese, pasteurized	
2004	Washington	Norovirus unknown	14	0	0	cheese, pasteurized	
2006	Maryland		5	0	0	cheese, pasteurized	cheese
2006	Ohio		2	0	0	cheese, pasteurized	

2009	New York	Norovirus	40	0	0	cheese, pre-sliced; deli meat, unspecified	
2012	Minnesota	Norovirus	13	0	0	cheese, unspecified	cheese, unspecified
1999	Minnesota	Norovirus Genogroup I	7	0	0	cheese, unspecified	
2001	Florida	Staphylococcus aureus	3			cheese, unspecified	
2008	Arizona	Salmonella enterica	101	21	0	cheese, unspecified; chicken, raw; cilantro, unspecified	
2007	Maryland	Salmonella enterica	5	3	0	cheese, unspecified; chicken, unspecified; tomato & fruit, unspecified	
2000	New York		16			cheese, unspecified; dips, unspecified; unspecified vegetables	
2003	Michigan		2			cheese, unspecified; eggs, unspecified; ham, unspecified	
1998	Maryland		4	0	0	cheese, unspecified; eggs, unspecified; ham, unspecified; potato, unspecified	
2000	Florida		2			cheese, unspecified; eggs, unspecified; pork, bacon	
2000	California	Norovirus Genogroup I	19			cheese, unspecified; ground beef, unspecified; lettuce, unspecified; tortilla, unspecified	
2006	New York	Salmonella enterica	12	3	0	cheese, unspecified; honeydew melon; pizza, unspecified; plum, unspecified	cheese; fruit, unspecified
2006	Colorado	Norovirus Genogroup I	18	0	0	cheese, unspecified; iceberg lettuce, unspecified; tortilla, unspecified	
2011	Minnesota	Norovirus	6	0	0	cheese, unspecified; lettuce	cheese, unspecified; lettuce
2002	Tennessee	Norovirus unknown	11	0	0	cheese, unspecified; lettuce, unspecified; tomato, unspecified	
2007	Virginia	Salmonella enterica	33	4	0	cheese, unspecified; Shami Kabob	
2009	Oregon	Norovirus Genogroup II	18	0	0	Cheese/roll; rolls; watermelon	bread; cheese, unspecified
2010	California	Norovirus unknown	8	0	0	cheese; cheese and crackers	
2013	Tennessee		15	0	0	cheese; Chicken Based Food; salsa	
2013	Nebraska	Salmonella enterica	64	2	0	cheese; chicken; cilantro, unspecified; quesadillas; tortilla, unspecified	
2013	Michigan	Norovirus Genogroup II	15	0	0	cheese; crackers; fruit	
2009	Ohio		3	0	0	cheese; deli meat, sliced turkey	deli meat, sliced turkey

2011	Michigan	Norovirus Genogroup II	25	0	0	cheese; focaccia	
2008	Illinois	Norovirus Genogroup I	35	0	0	cheese; ham	
2005	Iowa	Norovirus Genogroup I	27	0	0	cheese; relish tray	cheese; leafy green; Root (eg. potato)
2012	California		10	0	0	cheese; yogurt, unspecified	
2006	Washington	Norovirus Genogroup I	18	0	0	Cheesecake	
2009	Florida	Norovirus Genogroup II	3	0	0	cheesecake shooters	
2010	Ohio	Norovirus Genogroup II	55	0	0	Cheesecake with Strawberry; Warm Rolls & Butter	
2010	Georgia	Salmonella enterica	11	2	0	Cheesecake; Chile Con Queso	
2013	Multistate	Listeria monocytogenes	6	6	1	Cheese-Le Frere	cheese
2005	New Jersey		50	0	0	cheesy bread	
2009	Ohio		4	2	0	Cheesy Bread Stick; pizza, meat	
2010	Multistate	Salmonella enterica	44	7	0	Cheesy Chicken and Rice Frozen Meal	
2000	South Carolina	Staphylococcus aureus	8	4		chef salad; potato, baked	cheese; pork; turkey
2000	Florida	Norovirus Genogroup I	35			chicken salad; multiple cheeses, unspecified; punch, unspecified	
1998	Michigan		6			chicken, unspecified; macaroni and cheese	
2009	Michigan		13	0	0	chicken, unspecified; macaroni and cheese; turkey dishes	cheese, unspecified; cream sauce
2003	Alabama		3	0	0	chicken, unspecified; other cheese, unspecified	
2001	Maryland		9	0	0	chicken, unspecified; parmesan cheese, unspecified	cheese; Sauces/ Dressings
2007	Colorado	Campylobacter jejuni	26	4	0	chili; ground beef, cheeseburger	leafy green
1999	Florida	Norovirus Genogroup I	28	0	0	chips and salsa; multiple cheeses, unspecified	cheese
2008	Arizona		18	0	0	pasteurized; olive, unspecified; onion, unspecified; other vegetable; parmesan cottage cheese, unspecified; fruit-based	
2004	Arizona	Norovirus Genogroup I	49	0	0	salads unspecified; vegetable-based salads unspecified	
2005	Michigan		4	0	0	cottage cheese, unspecified; lettuce based salads	

2009	Virginia	Brucella unknown	4	1	0	Cow Cheese; Goat Cheese	
1998	Colorado	Other - Virus	6		0	cream cheese	
2003	New York	Clostridium perfringens	32			cream sauce, unspecified; tortellini, cheese	
2002	Minnesota	Norovirus Genogroup I	6	0	0	cucumber, unspecified; feta cheese, unspecified; oil, unspecified	
1998	Oregon		36	0	0	deli meat, sliced ham; deli meat, sliced turkey; other cheese, unspecified	
1998	New York	Staphylococcus aureus	19			deli meat, sliced turkey ham; macaroni and cheese	
1998	Colorado	Norovirus Genogroup I	34			deli meat, unspecified; other cheese, unspecified	
2002	California	Norovirus Genogroup I	23	0	0	flauta, cheese	Sauces/ Dressings; Wraps/tortillas
2002	Alabama		2	0	0	french fries; ground beef, cheeseburger	
2003	Alabama		2	0	0	french fries; ground beef, cheeseburger	
2003	Michigan		2			french fries; ground beef, cheeseburger	
1998	Florida		5	0	0	french fries; ground beef, cheeseburger; ground beef, hamburger	
2000	Massachusetts		3			french fries; ground beef, cheeseburger; lettuce, unspecified	leafy green
1999	Florida		3	0	0	french fries; ground beef, cheeseburger; soda, unspecified	
2000	Florida		3			french fries; ground beef, cheeseburger; soda, unspecified	
1999	Maryland		2	0	0	french fries; ground beef, cheeseburger; unknown beverage	
1998	Maryland		3	0	0	french fries; other cheese, unspecified	
2000	Wisconsin	Norovirus Genogroup I	23	0	0	fruit salad; multiple cheeses, unspecified	
2001	Massachusetts	Norovirus Genogroup I	20	0	0	goat cheese/chevre, unspecified; pastry, unspecified; tomato, unspecified	
2003	Michigan		2			goat cheese/chevre, unspecified; peppers, red	
2008	Georgia	Norovirus Genogroup II	27	0	0	grapes, unspecified; other cheese, pasteurized; watermelon	
2006	New York	Clostridium perfringens	4	0	0	gravy, chicken; macaroni and cheese; rice, yellow	Pasta; rice; Sauces/ Dressings
2013	Alabama	Salmonella enterica	38	30	0	green beans, unspecified; macaroni and cheese	

2001	Florida		2			ground beef, cheeseburger; mozzarella, unspecified	
2001	Louisiana	Salmonella enterica	93	18	1	ground beef, other; macaroni and cheese; peppers, green	
1998	Florida		2	0	0	ground beef, unspecified; other cheese, unspecified	
2002	Minnesota	Norovirus Genogroup I	55	0	0	ham, unspecified; other cheese, unspecified	
2013	Pennsylvania	Staphylococcus aureus; Bacillus cereus	27	1	0	ham; ice cream, homemade; pie, coconut cream; pie, peach; stuffing/dressing	ham
1998	Oregon	Salmonella enterica	8	0	0	homemade cheese, unspecified	
2002	Michigan	Salmonella enterica	7	2	0	homemade cheese, unspecified	
2002	Washington DC	Staphylococcus aureus	8	0	0	honeydew melon; other cheese, pasteurized; potato, fried	cheese; melon; Root (eg. potato)
2005	New York	Norovirus Genogroup I	18	0	0	ice cream, commercial; pizza, cheese; potato chips	bread; Ice Cream; Root (eg. potato)
1998	Florida		3	0	0	lasagna, unspecified; macaroni and cheese	
2013	Multistate	Listeria monocytogenes	8	7	1	latin style soft cheese	
2009	Connecticut	Bacillus cereus	47	0	0	macaroni and cheese	
2009	Connecticut	Bacillus cereus	100	0	0	macaroni and cheese	
2011	Michigan		100	1	0	macaroni and cheese	
2012	South Carolina	Salmonella enterica	23	4	0	macaroni and cheese	
2012	New Mexico	Salmonella enterica	17	2	0	macaroni and cheese	
1998	Maryland		2			macaroni and cheese	
2000	Virginia	Salmonella enterica	106	14	0	macaroni and cheese	egg
2000	Alabama	Norovirus Genogroup II	29			macaroni and cheese	
1998	Ohio	Staphylococcus aureus	51	0	0	macaroni and cheese	
2002	Missouri	Salmonella enterica	104	22		macaroni and cheese	egg
2004	Georgia	Other - Chemical/Toxin	68	0	0	macaroni and cheese	
2004	New York	Staphylococcus aureus	7	0	0	macaroni and cheese	

2005	South Carolina	Salmonella enterica	35	15	0	macaroni and cheese	
2006	Mississippi	Salmonella enterica	25	12	0	macaroni and cheese	
2008	South Carolina	Salmonella enterica	12	6	0	macaroni and cheese	egg
2008	California	Salmonella enterica	4	0	0	macaroni and cheese	
2008	California	Salmonella enterica	16	2	0	macaroni and cheese	egg
2000	South Carolina	Salmonella enterica	31			macaroni and cheese; multiple foods; unspecified fish	
2012	Tennessee		48	0	0	macaroni and cheese; pork, BBQ; sandwich, ham/cheese	
1998	Michigan		2			macaroni and cheese; salad, unspecified	
2000	Michigan		2			macaroni and cheese; shrimp, unspecified; unspecified fish	
2007	California	Salmonella enterica	14	3	0	macaroni and cheese; turkey	
1998	Michigan		27			macaroni and cheese; turkey, unspecified	
2008	Colorado	Norovirus Genogroup I	31	0	0	mayonnaise, commercial; sandwich, ham/cheese	
2000	Pennsylvania	Salmonella enterica	27	5	0	meat, unspecified; other cheese, unspecified	
2006	California	Salmonella enterica	4	4	0	Mexican Cheese (queso fresco and/or other)	
2009	Multistate	Listeria monocytogenes	8	3	0	mexican style cheese, pasteurized	mexican style cheese
2010	Multistate	Listeria monocytogenes	6	4	1	mexican style cheese, pasteurized	
2011	New Jersey	Listeria monocytogenes	2	2	0	mexican style cheese, pasteurized	
2013	Multistate	Listeria monocytogenes	9	8	1	mexican style cheese, pasteurized	
2008	Multistate	Listeria monocytogenes	8	4	0	mexican style cheese, pasteurized	cheese
2009	Multistate	Listeria monocytogenes	18	6	0	Mexican-Style Cheese	
2006	California	Norovirus unknown	108		0	mixed fruit; sandwich, beef	fruit, unspecified; leafy green; melon;
2004	Maryland	Salmonella enterica	4	0	0	mozarella sticks, fried	
2010	Ohio		3	0	0	mozarella, pasteurized	

2002	Florida		10	0	0	mozzarella, pasteurized	
2003	Wisconsin	Norovirus Genogroup I	9	0	0	mozzarella, pasteurized	
2000	Florida	Norovirus Genogroup I	6			mozzarella, unspecified	
2008	Connecticut	Norovirus Genogroup II	21	0	0	mozzarella prosciuto	
2001	Florida	Norovirus unknown	34			multiple cheeses, pasteurized	
2007	Colorado	Salmonella enterica	6	2	0	multiple cheeses, pasteurized	cheese
1998	Maryland	Norovirus Genogroup II	258	4	0	multiple cheeses, unspecified	cheese
1998	Wisconsin		13	0	0	multiple cheeses, unspecified; other cheese, pasteurized	
1999	Maryland	Norovirus Genogroup I	37	2		multiple cheeses, unspecified; vegetable tray	
2003	Wyoming	Salmonella enterica	65	14	0	mushrooms, canned; swiss cheese, pasteurized	
2009	Georgia	Norovirus Genogroup II	3	0	0	nachos and cheese	
2010	Wisconsin	Norovirus Genogroup II	44	0	0	nachos and cheese	lettuce; tomato
1999	Florida		2	0	0	nachos and cheese	
1998	Michigan		2	0	0	nachos and cheese	
2003	Florida		3			nachos and cheese	
2005	Florida	Staphylococcus aureus	2			nachos and cheese	
2005	Illinois		2	0	0	nachos and cheese	
2000	Florida	Staphylococcus aureus	2			omelette	cheese
2008	Virginia	Salmonella enterica	17	2	0	omelette	cheese; leafy green
1999	Maryland		2			omelette; other cheese, unspecified; tomato, unspecified	
2002	Indiana	Norovirus Genogroup I	25	0	0	other cheese, pasteurized	
2006	Oregon	Listeria monocytogenes	3	2	1	other cheese, pasteurized	
1999	Maryland	Salmonella enterica	49	6	0	other cheese, unspecified	

1998	Florida	Salmonella enterica	2	1	0	other cheese, unspecified	
2000	Florida		3	0	0	other cheese, unspecified	cheese
1998	Michigan		6	0	0	other cheese, unspecified	
2007	Colorado	Campylobacter jejuni	4	1	0	other cheese, unspecified	
2009	Florida		10	0	0	pizza, cheese	
2012	Kentucky		12	0	0	pizza, cheese	
1998	Maryland		5			pizza, cheese	
1999	Florida		2			pizza, cheese	
1999	Florida		4			pizza, cheese	
1998	Florida		2	0	0	pizza, cheese	
1998	Florida		3	0	0	pizza, cheese	
2000	Maryland		4	0	0	pizza, cheese	
2000	Illinois	Norovirus Genogroup I	13	0	0	pizza, cheese	
2000	Florida	Staphylococcus aureus	7	0	0	pizza, cheese	
2001	Florida	Staphylococcus aureus	4			pizza, cheese	
2001	Florida		4			pizza, cheese	
2002	Florida	Staphylococcus aureus	2			pizza, cheese	
2002	Florida	Staphylococcus aureus	4			pizza, cheese	
2002	Florida		3			pizza, cheese	
2003	Florida		6			pizza, cheese	
2003	Florida		2			pizza, cheese	
2003	Florida		3			pizza, cheese	
2003	Florida	Salmonella enterica	4			pizza, cheese	

2003	Florida	Clostridium perfringens	2			pizza, cheese	
2006	Florida	Norovirus Genogroup I	3			pizza, cheese	
2006	Florida		10			pizza, cheese	
2004	Florida		10			pizza, cheese; pizza, meat	
2003	Florida	Norovirus Genogroup I	5	0	0	pizza, cheese; pizza, meat and vegetable	
2004	Pennsylvania	Bacillus cereus	4	0	0	pizza, cheese; pizza, meat and vegetable	
2000	Florida	Clostridium perfringens	12	0	0	pizza, unspecified; steak, unspecified	beef; cheese
2011	Pennsylvania	Norovirus unknown	57	1	0	pizza, vegetable	broccoli; cheese, unspecified; cream
2003	Maryland	Norovirus Genogroup II	9	0	0	quesadilla, cheese	
2008	Illinois		11	0	0	quesadilla, cheese	
2000	North Carolina	Listeria monocytogenes	12			queso fresco, unspecified	
2001	California	Salmonella enterica	38	14	0	queso fresco, unspecified	milk
2008	Oregon	Campylobacter unknown	10	0	0	queso fresco, unspecified	
2013	Minnesota		9	0	0	relish tray	cheese; fruit, unspecified; olives;
2006	Ohio	Salmonella enterica	9	1	0	rice, broccoli and cheese	
2012	Multistate	Listeria monocytogenes	23	21	5	ricotta salata cheese	
2010	Florida	Norovirus	11	0	0	salad, unspecified	cucumber; egg; leaf lettuce; onion; tomato
2013	Florida	Norovirus Genogroup II	55	0	0	salad, unspecified	lettuce; tomatoes, red round
2000	Florida	Staphylococcus aureus	3			sandwich, beef	beef; bread; cheese
1998	Ohio		4	0	0	sandwich, cheese	
2011	Pennsylvania	Norovirus	50	0	0	sandwich, deli	pasteurized; lettuce; tomatoes, red round
2010	Minnesota	Norovirus Genogroup II	16	0	0	sandwich, ham/cheese	
1998	Florida		2	0	0	sandwich, ham/cheese	

2002	Arkansas	Staphylococcus aureus	8	4	0 sandwich, ham/cheese	pork
2003	Florida		3		sandwich, ham/cheese	
2002	Florida		3		sandwich, ham/cheese; sandwich, roast beef	
2007	Iowa	Norovirus Genogroup I	71	0	0 sandwich, turkey	bread; cheese; turkey
2006	New York	Clostridium perfringens	55	0	0 seafood dish, unspecified; shrimp, fried; tortellini, cheese	crustacean
2007	Multistate	Salmonella enterica	20	9	0 Shredded Cheese, pasteurized	cheese
2012	California	Clostridium botulinum	2	2	0 soup, broccoli and cheese	
2004	Minnesota	Norovirus Genogroup I	10	0	0 soup, broccoli and cheese	
2013	Hawaii	Staphylococcus aureus	139	23	0 Spaghetti w/meat sauce and Spaghetti w/cheese	
2012	Ohio	Norovirus Genogroup II	42	0	0 Spanish Piquillo Peppers with Goat Cheese	
2001	Ohio	Norovirus Genogroup II	73	0	0 swiss cheese, pasteurized	
2006	Connecticut	Norovirus Genogroup II	11	0	0 swiss cheese, pasteurized	
1998	New York		7	0	0 swiss cheese, unspecified	
2004	California	Shigella boydii	7	1	0 tamale, unspecified	cheese
TOTAL			6034			