Maryland's Dairy Industry: 2016

A Report
To
Governor Larry Hogan

From

The Maryland Dairy Industry Oversight and Advisory Council

October 2016

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Executive Summary

The Governor's Maryland Dairy Industry Oversight and Advisory Council is charged with improving and sustaining the economic viability of Maryland's dairy industry and reporting annually to the Governor. This report to Governor Larry Hogan represents the recommendations of a committee that includes milk processors, dairy farmers, dairy cooperative leaders, Maryland Farm Bureau members, Maryland Grange members, consumers, as well as representatives with Maryland Department of Health and Mental Hygiene, County health departments, State Legislators, the Maryland Department of Agriculture, and University of Maryland officials.

During 2016, Maryland dairy farmers are not making enough money to cover the cost of production. This suggests that producers are tapping into financial reserves to survive. The price of milk paid to dairy farmers is the lowest since 2009. Total expenses to produce a hundred pounds of milk among Maryland dairy farmers were, on average, $23.21, from 2012-2014. In July 2016, the average price paid to dairy farmers in Maryland was $15.87 per hundredweight. Despite declining prices in 2016, forty-nine (49) counties in New York and parts of New England have increased production of milk, while production in Maryland counties has decreased. National predictions for future milk prices suggest payments to dairy farmers to increase in 2017. Attachment 1 of this report provides an economic analysis of Maryland's dairy sector by University of Maryland economist Dr. Howard Leathers. This report discusses the three most important factors influencing the financial health of Maryland dairy farmers.

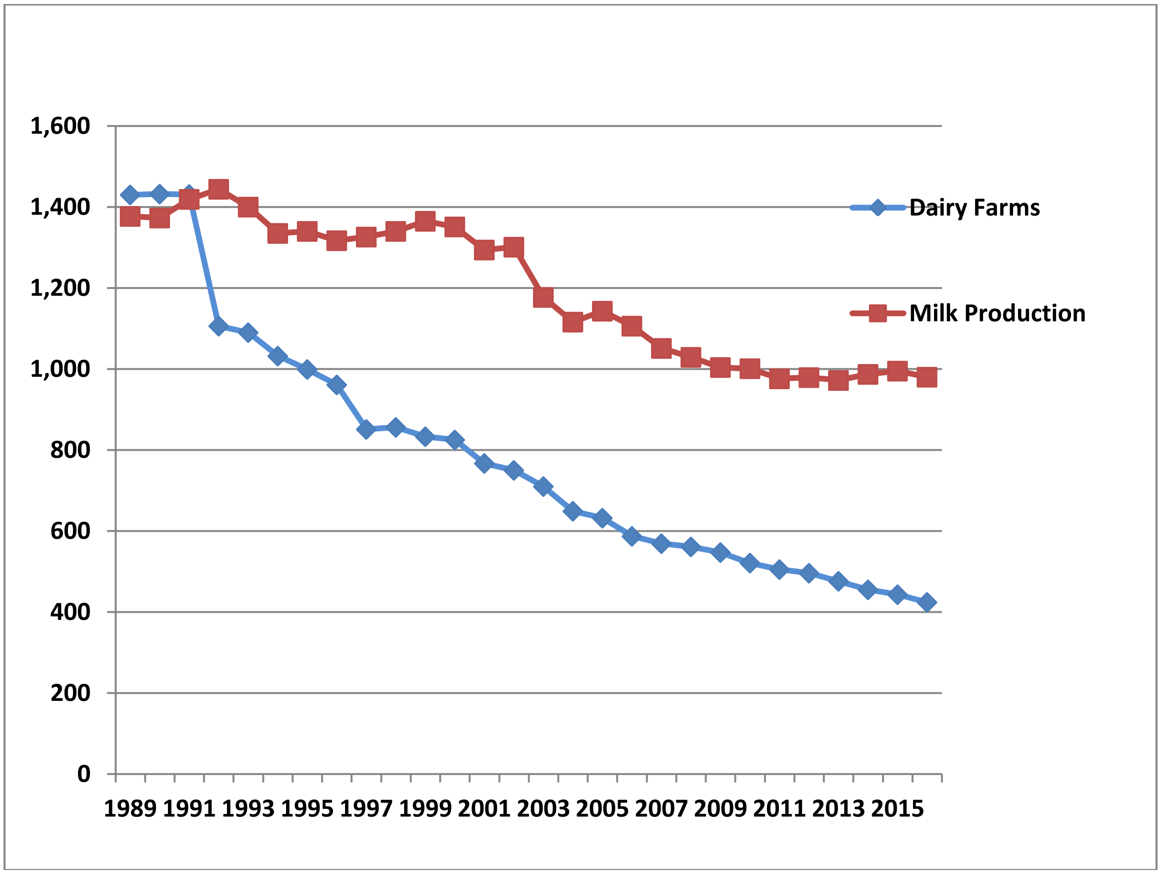
The number of dairy farmers in Maryland has declined from 455 in 2014 to 424 as of August 2016. Broken down by county, dairy farms are located in: Baltimore, 8; Caroline, 5; Carroll, 41; Cecil 28; Frederick, 88; Garrett, 61; Harford, 23; Howard, 4; Kent, 13; Montgomery, 7; Prince George's, 2; Queen Anne's, 7; St. Mary's, 14; Talbot, 4; Washington, 118; and, Worcester, 1.

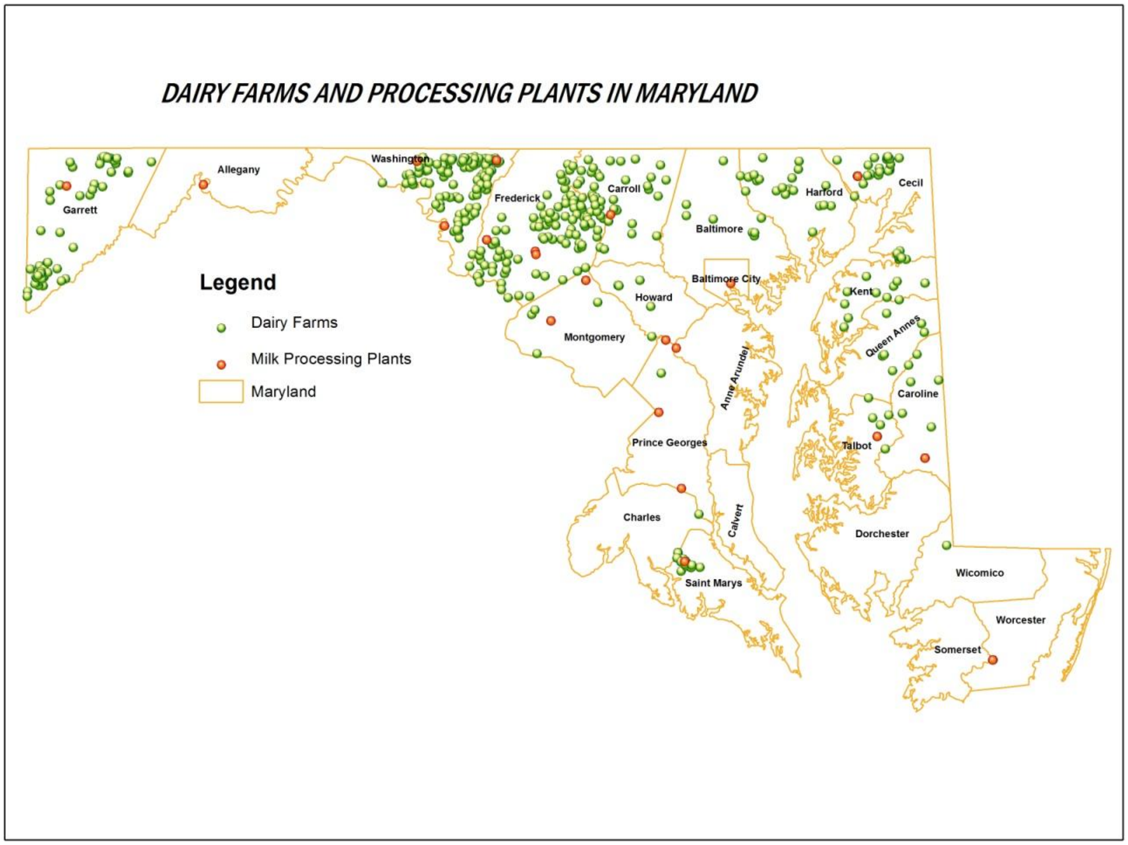
According to the U.S. Department of Agriculture, Maryland had about 48,000 dairy cows in 2016. The amount has been declining about 1,000 head a year since 2007. Maryland's current milk processing capacity includes 21 operations (Attachment 2). There are seven (7) large, commercial dairy processors. The rest are small or on-farm processors. Since June 2016, Lanco Dairy Farms Coop, LLC., www.lancopennland.com based in Hagerstown, Maryland, has been operating a dairy processing plant in Hancock, which is producing cheese, pasteurized condensed milk and cream. Processors in the state annually process more than 3 billion pounds of milk, according to the Maryland Department of Health and Mental Hygiene and the Federal Milk Market Order. More than 40,000 loads of milk are hauled from farms throughout the Mid-Atlantic to Maryland processors each year. Final products of all types are shipped throughout the nation and the world from Maryland. One plant, Nestle Dreyers Ice Cream in Laurel, is among one of the largest ice cream facilities in the world. www.nestle.com

The Advisory Council makes the following recommendations to Governor Larry Hogan, the General Assembly, and relevant state agencies:

1. Continue to prohibit the sale of raw milk for human consumption in Maryland.
2. Amend the MDA nutrient management regulations to change the start of the wintertime prohibition on manure spreading from November 1 to December 16.
3. Pursue federal ad hoc disaster payments for dairy farmers.
4. Reinstitute the state road seasonal permit to allow bulk milk trucks to haul up to 88,000 pounds with 1,000 pound tolerance on 5 axles.
5. Support sales of 1 percent flavored milk in Maryland public schools.
6. Support full funding of the Maryland Agricultural Water Quality Cost Share program at Maryland Department of Agriculture.
7. Fund the Maryland Dairy Farmer Emergency Trust Fund.

Number of Maryland Dairy Farms, Production of Milk in State




DAIRY FARMS AND PROCESSING PLANTS IN MARYLAND
Legend
Dairy Farms
Milk Processing Plants
Maryland
Garrett
Allegany
Washington
Frederick
Carroll
Baltimore
Harford
Cecil
Baltimore City
Howard
Kent
Montgomery
Queen Annes
Anne Arundel
Caroline
Prince Georges
Talbot
Charles
Calvert
Dorchester
Saint Marys
Wicomico
Worcester
Somerset

2016 Recommendations

Recommendation 1:

The Governor and the General Assembly should continue to prohibit the sale of raw milk directly to Maryland consumers for human consumption.

The Council strongly believes that the health risks associated with raw milk consumption are based on well documented, sound science, and repeats its recommendation against allowing the sale of raw milk directly to consumers for human consumption. Pathogens in milk can cause very serious, sometimes life altering conditions, and sometimes even death.

The only method proven to be reliable in reducing the level of pathogens in milk and milk products is proper pasteurization. Should raw milk be allowed for sale directly to the consumer, the Department of Health and Mental Hygiene (DHMH) would incur significantly more costs to staff and implement a raw milk program. Additional staff would be necessary to manage possible food recalls and foodborne outbreaks.

See Attachment 3 – Maryland Department of Health and Mental Hygiene Raw Milk Position and Rationale

See Attachment 4 – Johns Hopkins Bloomberg School of Health and Johns Hopkins - A Literature Review of the Risks and Benefits of Consuming Raw and Pasteurized Cow's Milk

See Attachment 5 – FDA Raw Milk Testimony

Recommendation 2:

Amend MDA nutrient management regulations to change the start of the wintertime prohibition on manure spreading from November 1 to December 16.

In light of the current economic situation facing Maryland dairy farmers, the Council recommends that MDA allow dairy farmers to spread manure during the November to March prohibition. The Annotated Code of Maryland, 8-801.1 provides in Section 2, No. 2, "Each nutrient management plan shall provide flexibility for management decisions that may be required by conditions beyond the control of the farmer." The Council also recommends that all dairy farmers be required to communicate with MDA and develop a strategy for manure storage over the next several years, with the use of temporary storage being a viable option. Working with dairy farmers to ultimately achieve compliance would benefit the environment and the economy rather than fining or suing them out of existence.

The MDA Nutrient Management Manual Application Timing Section provides for the application of manure in emergency situations, such as imminent overflow of a storage facility. While this provision appears to refer to weather issues, the Council believes that the current economic situation fits the test of 'conditions beyond the control of the farmer.' Maryland dairy farmers currently face such dire economic conditions that it is highly unlikely they can afford to install manure storage facilities to fully handle manure during the coming winters. Currently, Maryland farmers are losing about $17 for each hundredweight of milk they produce, according to the USDA Economic Research Service. That compares to a loss of $6.82 per hundredweight nationally. According to Farm Credit in the Northeast, dairy farmers did not make enough income to cover their costs at all in 2015.

The argument could be made that dairy farmers have had four years to meet the manure storage requirements. However, the past two years have seen remarkably low milk prices and many could simply not afford to put in manure storage. Another factor impacting the delay in compliance is that there are not enough state and federal resources (i.e. staffing, guidance) to review plans that have been submitted for approval. The Council is unsure if there is the capacity to do the necessary construction and provide the necessary assistance at soil conservation districts for those that could afford to install storage facilities.

Recommendation 3: Governor Hogan and MDA should pursue federal ad hoc disaster assistance for Maryland dairy farmers.

As this report is being written, regional dairy organizations are asking Congress and the USDA to help dairy farmers struggling with declining income from low milk prices. MDA has joined with other state departments of agriculture in asking the USDA to provide disaster assistance to dairy farmers. As of yet, that assistance has not come in a substantive way, although USDA has purchased 11 million pounds of commodity cheese to help reduce the glut of cheese in the United States. The Dairy Advisory Council encourages MDA to continue looking for and supporting federal policy options which will address the current low prices and market volatility.

Recommendation 4:

Reinstitute the state road seasonal permit to allow bulk milk trucks to haul up to 88,000 pounds with 1,000 pound tolerance on 5 axles.

Maryland adopted higher weight limits for milk trucks on interstate highways in 2016, following passage of federal legislation allowing this standard. Currently, Maryland allows 95,000 pounds of gross vehicle weight for milk haulers on interstates. This decision, by the Hogan Administration, provided milk haulers the ability to carry heavier, safer weights while providing them with the flexibility to move a fresh, fluid product to milk processing plants in a timely manner. However, an earlier seasonal permit allowing 88,000 pounds with 1,000 pound tolerance on 5-axle trucks on state roads ended in 2016. It is important that this 88,000 pounds (with 1,000 pound tolerance on 5 axles) limit on state roads be put back into place to allow the industry to be competitive with surrounding states. Pennsylvania has a 95,000 pound GVW limit on state roads and Virginia is creating a 94,000 pound permit for milk haulers on state roads.

Maryland's dairy farmers, milk processors and consumers rely on milk haulers to transport milk from farms to processing plants. This lack of uniformity among states affects the profitability of the state's dairy farmers and the milk processing plants, which employ more than 2,000 people, has an annual payroll of about $104 million and produce 1.3 billion pounds of dairy products.

Recommendation 5:

Support sales of 1 percent fat flavored milk in Maryland public schools by asking for change in the U.S. Department of Agriculture guidelines that currently limits the fat content to skim in flavored milk.

According to the National Institute of Child Health and Human Development, calcium deficiency is a dietary concern for American children. The USDA reports that 86 percent of teenage girls and 64 percent of teenage boys are calcium deficient. Milk competes with soft drinks and juices unsuccessfully among children. By maintaining the availability of flavored milk and increasing the fat content to 1 percent from the current USDA non-fat requirement in schools, dietitians would have the opportunity to increase milk consumption among children.

USDA Food and Nutrition Service created nutritional guidelines for agencies participating in the Child Nutrition Program. All 24 school systems in Maryland participate in these programs. Guidelines require milk to be served in schools during breakfast, snack, lunch, and supper. In addition, new nutritional guidelines have been created for USDA's Child and Adult Care Food Program which includes a serving of 8 ounces of milk.

It is vital that schools keep milk properly chilled to make it refreshing and appealing for students used to sugar-laden soda and other drinks. According to the Federal Trade Commission, in 2006, soda manufacturers and fast food companies spent $1.6 billion targeting children, while milk processors spent only $67 million on all advertising nationwide.

According to the USDA, between surveys in 1977-78 and 2007-08, the share of pre-adolescent children who did not drink fluid milk on a given day rose from 12 percent to 24 percent, while the share that drank milk three or more times per day dropped from 31 percent to 18 percent. Between 1977-78 and 2007-08, the share of adolescents and adults who did not drink fluid milk on a given day rose from 41 percent to 54 percent, while the share that drank milk three or more times per day dropped from 13 percent to 4 percent.

Differences across the generations in fluid milk intake may help account for the observed decreases in per capita fluid milk consumption in recent decades despite public and private sector efforts to stem the decline. Furthermore, these differences will likely make it difficult to reverse current consumption trends. In fact, as newer generations replace older ones, the population’s average level of fluid milk consumption may continue to decline.

Recommendation 6:

Support full funding of the Maryland Agricultural Water Quality Cost Share program at Maryland Department of Agriculture.

Maryland's Soil Conservation Districts are the local delivery system for the state's agricultural conservation programs to install agricultural best management practices as well as review and approve erosion and sediment control plans for the urban community. The districts' workload increased significantly with the Watershed Implementation Plan requirements as well as the state's increased nutrient management requirements. For dairy farmers, the districts provide conservation planning, design and implementation of best management practices. They also help secure cost share funding. Staffing in the districts is supported by the district, county, state and federal governments.

In FY 2016, funding for the districts was reduced which previously supported 14 district managers and 11 administrative positions in 15 counties. The Maryland Association of Soil Conservation Districts (MASCD) made a successful request to the legislature to approve using the Chesapeake Bay Trust Fund (CBTF) to replace these funds. Currently, 43 planner and technician positions are also funded using CBTF funding. Many of these positions are without benefits, and because funding is approved on an annual basis, employee retention is difficult. In 2016, the legislature adopted budget language requiring the Maryland Department of Agriculture to conduct a district staffing study. Adequate and knowledgeable conservation district staffing is essential for agricultural communities, especially for the dairy sector who install complex and costly systems.

The Council requests that the administration consider the staffing report from MDA and work with partners to find solutions.

Maryland Agricultural Cost Share Program

The Maryland Agricultural Cost Share Program (MACS) provides financial support to Maryland farmers who want to install best management practices and enhance environmental quality. MACS does not cover the full cost of these conservation practices and farmers contribute a minimum of 12.5 percent of their own capital for these projects. This is often higher for manure management systems as they may exceed the per farm funding limits. The program helps farmers afford new or upgraded manure storage, heavy use areas and other practices essential to preventing nutrient loss. MACS is especially important to help dairy farmers comply with the nutrient management requirements for manure storage and no winter nutrient application. Advanced manure storage and handling systems can cost upwards of $300,000, putting a significant financial strain on dairy farmers, especially when milk prices are down. This funding is essential for Maryland's agricultural community

Recommendation 7: The Council recommends funding the Maryland Dairy Farmer Emergency Trust Fund.

Created as a result of recommendations from this advisory body in 2007, the Dairy Emergency Trust Fund is needed to shore up the Maryland dairy economy. The state has never invested in this fund. As documented in this report, federal programs are not functioning well enough to stabilize the wildly swinging dairy farmer incomes in Maryland, making a state investment in maintaining the dairy industry critical at this point. Based upon original recommendations, the Council recommends a $5 million state investment this year.

Attachment 1

Dairy Situation and Outlook, October 2016

Howard Leathers
University of Maryland, College Park, MD.

This report discusses the three most important factors influencing the financial health of dairy farmers in Maryland. Those factors are: (1) milk prices; (2) feed prices; and (3) the regulatory and policy environment.

Milk Prices

The dairy economy has been on a roller-coaster in recent years. Milk prices for Maryland farmers reached an all time high, pushing past $26 in spring of 2014 (averaging $24.80 in calendar year 2014), but then fell sharply in 2015 (averaging $17.70 for the year), and continued to fall into 2016, reaching a bottom of $15.30 in May of 2016. Since May, milk prices have rebounded and are expected to rise to the $19 range by the end of 2016.

The outlook for Maryland's dairy farmers is for prices (and operating margins) to stabilize in the upcoming year, above the "bad times" seen in late spring of 2016, but slightly below the levels experienced in fall of 2016. There is little prospect for returning to the high milk prices of 2014, but prices over the next year and throughout 2017 should stay well above the low levels seen in spring 2016.

Feed Prices

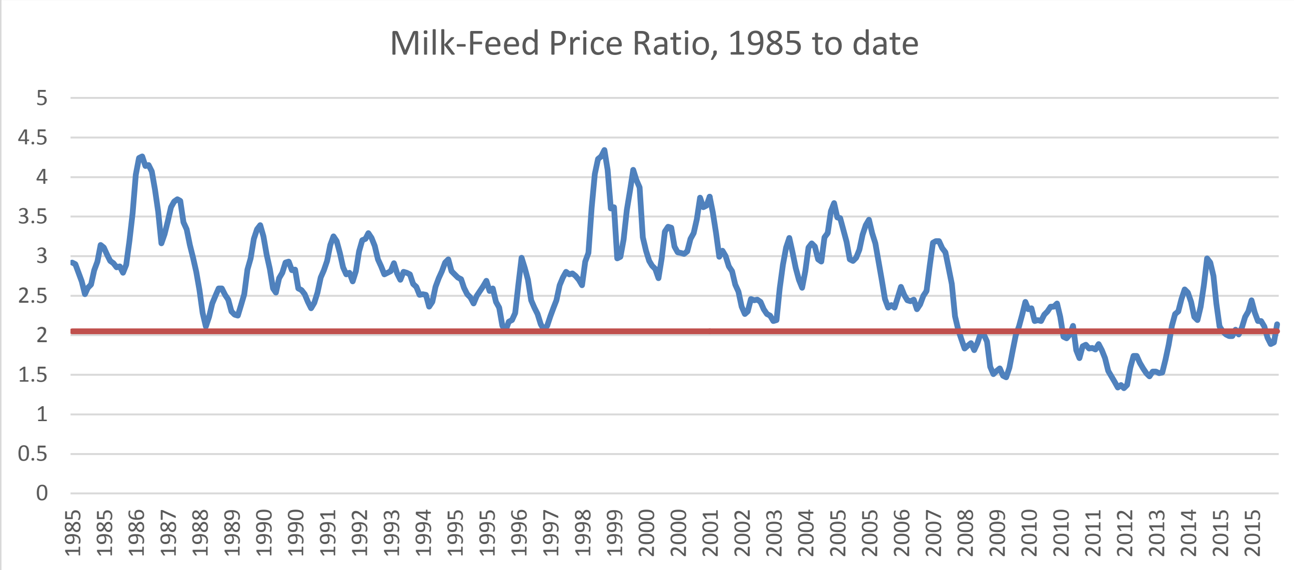
In the 2008-2014 period, analysts of the dairy farm sector began to put more and more attention on the threat of high feed costs. In the years 2011-13, corn prices averaged $6.28/bushel; soybean prices averaged $13.52; alfalfa hay prices averaged about $200 per ton.

However, since 2014, feed costs have been relatively low and stable. National corn prices have been below $3.82/bushel every month since August 2014. National soybean prices have been below $10 in all but a few months since late 2014. The alfalfa hay price in 2016 is below $150. Experts and futures markets expect corn prices to stay below $4 and soybean prices to stay below $10 through the 2017 harvest.

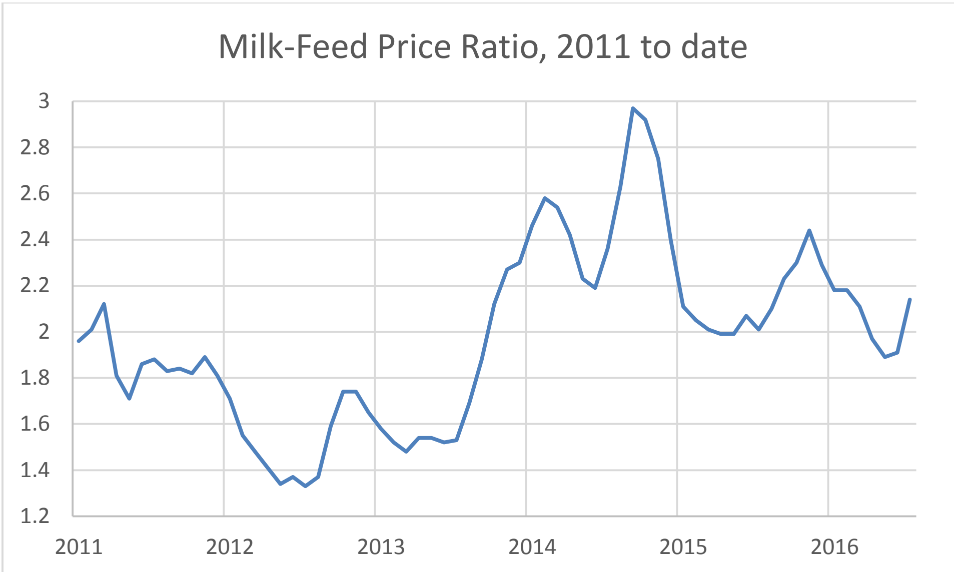
Milk-Feed Price Ratio

One commonly used measure of economic health of the dairy industry is the milk-feed price ratio which shows the ratio of milk price to the price of a feed cost ration. A high ratio means that milk prices are high relative to feed prices, and therefore times are good for dairy farmers. A low ratio means times are bad. In the <u>22 years</u> from January 1985 to March 2008, the milk-feed price ratio had <u>never fallen below 2.06</u>. But in the <u>4+ years</u> from April 2008 to October 2013 it had been <u>below 2.06</u> in 39 of 54 months.

However, from October 2013 until the late summer of 2015, the milk feed price ratio has been consistently above the 2.06 level.



The "roller coaster" described above is illustrated in a view of the above chart that focuses on the years since 2011. The high feed prices of 2011-2013 caused a low milk-feed price ratio in those years. The large increase in milk price through mid-2014 is reflected in the more than doubling of the ratio between 2013 and 2014. Then, as milk prices dropped precipitously through 2016, that decline was partially offset by declining feed prices.



Recently, dairy policy has focused more attention on the "gross margin" or the difference between milk price and feed price (rather than ratio of milk price to feed price, shown above). Of course, the two measures are built upon the same fundamental price measures, so they will show the same general pattern. During the "hard times" of May-July 2012, one measure of the gross margin (all milk prices minus 16 percent feed ration price per cwt of milk produced) was in the low $4 range. During the "strong price" period of 2014, the gross margin reached a high of $17. In 2015, the gross margin averaged about $9. And for 2016, it appears that the gross margin will average about $8.75. Since the gross margin measures how much money the farmer has "left over" after paying the feed costs – to cover all other costs plus returns to entrepreneurship (or "profits"), one can see that $10 per cwt more in gross margin is a big difference ($200,000-$300,000 dollars a year for a "typical" – 100 cow -- dairy farm). So the current levels reflect a moderate case, not as strong as the 2014 months, nor as dire as the 2012 months.

As described above, looking forward to the upcoming year, we anticipate that relative prices facing farmers will improve in a moderate way. Futures markets predict that the 2017 milk price will go up at least a dollar over the 2016 average. USDA's outlook calls for milk prices to increase by 30 cents in 2017 over 2016. Feed prices are expected to remain at current levels.

Regulatory and Policy Impacts on Dairy Farmers.

The financial health of dairy farmers is also affected by actions and decisions of government.

At the federal level, the 2014 farm bill adopted a radical change in the programs intended to help dairy farmers. The principal new program (the Margin Protection Program or MPP) makes payments to dairy farmers when gross margins fall below $4. But as the above discussion notes, gross margins haven't been below $4 very often. (Farmers were given the option of "buying up" to higher guaranteed margins, in 50 cent increments up to $8, but this required premium payments, and few Maryland farmers opted for the buy-up.)

In general, and nationwide, dairy farmers are disappointed that the MPP payments have remained low (zero for most farmers). A MPP is triggered if the two month average margin falls below the insured level. In 2015, margins were higher than $7.50 for all six of the two month periods, meaning that only farmers who bought up to the $8 maximum coverage received any MPP payments during the year. In Maryland, only one farmer opted for $8 coverage in 2015. In 2016, the March-April margin was $7.15, and the May-June margin was $5.76. In Maryland, two farmers opted for $7.50 coverage (triggering a payment in March-April) and 19 farmers had coverage levels above $6 (triggering a payment in May-June). The other 95 percent of Maryland's 400+ dairy farmers have never qualified for an MPP payment, even in the low milk price months of March-June 2016.

At the state level, dairy farmers are faced with a state requirement that limits the spreading of manure during winter months, and therefore requires (for most farmers) a substantial investment in manure storage facilities. In a series of meetings with state officials, including Maryland Agriculture Secretary Joseph Bartenfelder, during the summer, dairy farmers were briefed on these requirements and on programs that may provide some cost-share subsidies to partially offset the costs.

<u>Fewer and fewer dairy farms in Maryland</u>

The trend toward fewer and fewer dairy farms in the state continues. The state Department of Health and Mental Hygiene measure of farms licensed to sell milk has fallen by 44 percent, from 750 in 2002 to 424 in 2016. Over the same period, milk production has dropped by about 25 percent. The forces behind these trends – increasing output per cow and increasing cows per farm – will probably continue for the foreseeable future.

Year	**Number of dairy farms in Maryland**	**Maryland Milk production (mill. lbs)**
2002	750	1301
2003	710	1232
2004	667	1162
2005	649	1161
2006	631	1093
2007	582	1045
2008	561	1029
2009	555	1004
2010	524	999
2011	505	970
2012	496	979
2013	482	972
2014	455	987

2015	443	983
2016	424	980 (est.)

Source: Farm numbers -- Maryland Department of Health and Mental Hygiene
Milk production – quarterly milk production reports (NASS online)

The reduction in numbers of farms comes primarily from consolidation of existing herd. Since 2002, farm numbers have dropped by 40 percent – to 60 percent of the initial level; but milk production has only dropped by a quarter – to 76 percent of initial level. Or (the same point illustrated differently) – total milk production in 2016 will be about the same as in 2011, but with 81 (16 percent) fewer dairy farms.

The decline in the number of Maryland dairy farms is likely to continue at about the same rate over the next year, about 10-25 farms exiting the industry.

Dale Johnson,
University of Maryland
Farm Management
Specialist
Analysis August 2016

2013-2015 Average of Maryland Dairy Farms

Income, Expenses, and Profit per FARM

	Average 31 Farms	Highest 10 Farms*	Lowest 10 Farms*	Non-organic 24 Farms	Organic 7 farms
Average number of cows	132	160	126	148	76
Total cwt milk sold	24,800	31,055	22,981	30,222	6,209
Schedule F line					
Farm income					
1a&b Sales of livestock bought	4,535	3,604	10,454	1,564	0
1c Cost or other basis of line 1	2,783	2,417	6,211	1,094	0
1e Subtract line d from line c	1,752	1,187	4,243	470	0
2 Sales of farm products					
a. Milk sales	553,068	698,952	504,277	652,945	210,632
b. Crop sales	16,623	14,457	15,181	21,214	882
c. Cattle sales	50,267	73,567	34,519	56,725	34,270
Total 3+4+5+6+7+8 other income	47,054	39,766	82,472	58,336	8,373
9 Gross Income	668,763	827,930	640,691	789,690	254,158
Farm expenses					
10 Car and truck expenses	579	1,027	207	534	736
11 Chemicals	13,433	15,099	4,559	17,351	0
12 Conservation expenses	3,145	1,359	8,391	4,062	0
13 Custom hire	25,310	38,535	18,556	29,184	12,027
14 Depreciation	56,237	51,614	65,166	66,312	21,694
15 Employee benefits	2,392	1,321	4,218	3,089	0
16 Feed	157,413	158,646	197,407	190,312	44,615
17 Fertilizer and lime	20,241	36,610	14,505	23,856	7,845
18 Freight and trucking	24,855	26,910	25,396	31,116	3,387
19 Gasoline, Fuel, and oil	23,555	24,252	26,266	27,484	10,086
20 Insurance (other than health)	9,325	10,935	9,155	11,466	1,985
21a+21b Interest	14,814	11,226	15,111	16,548	8,869
22 Labor hired	36,851	60,030	37,242	46,241	4,657
23 Pension and profit-sharing	0	0	0	0	0
24a+24b Rent or lease	20,982	24,186	19,296	24,878	7,626

25 Repairs and maintenance	43,460	49,020	43,033	51,024	17,528
26 Seeds and plants	20,194	28,438	13,311	23,854	7,642
27 Storage and warehousing	31	96	0	40	0
28 Supplies purchased	27,915	34,307	27,278	32,531	12,089
29 Taxes	4,853	5,967	4,182	5,633	2,180
30 Utilities	12,734	13,482	11,915	14,738	5,866
31 Vet., breed., and med.	23,574	25,189	29,126	29,639	2,777
32 Other expenses	15,942	24,589	17,874	18,605	6,811
33 Total expenses	557,825	642,836	592,165	668,485	178,419
34 Net farm profit	110,938	185,094	48,527	121,205	75,738

2013-2015 Average of Maryland Dairy Farms

Analysis August 2016

Income, Expenses, and Profit per COW

	Average 31 Farms	Highest 10 Farms*	Lowest 10 Farms*	Non-organic 24 Farms	Organic 7 farms
Average number of cows	132	160	126	148	76
CWT milk sold per cow	188	194	183	204	82
Schedule F line					
Farm income					
1a&b Sales of livestock bought	34	23	83	11	0
1c Cost or other basis of line 1	21	15	49	7	0
1e Subtract line d from line c	13	7	34	3	0
2 Sales of farm products					
a. Milk sales	4,188	4,365	4,013	4,399	2,777
b. Crop sales	126	90	121	143	12
c. Cattle sales	381	459	275	382	452
Total 3+4+5+6+7+8 other income	356	248	656	393	110
9 Gross Income	5,064	5,171	5,098	5,320	3,350
Farm expenses					
10 Car and truck expenses	4	6	2	4	10
11 Chemicals	102	94	36	117	0
12 Conservation expenses	24	8	67	27	0
13 Custom hire	192	241	148	197	159
14 Depreciation	426	322	519	447	286
15 Employee benefits	18	8	34	21	0
16 Feed	1,192	991	1,571	1,282	588

17 Fertilizer and lime	153	229	115	161	103
18 Freight and trucking	188	168	202	210	45
19 Gasoline, Fuel, and oil	178	151	209	185	133
20 Insurance (other than health)	71	68	73	77	26
21a+21b Interest	112	70	120	111	117
22 Labor hired	279	375	296	312	61
23 Pension and profit-sharing	0	0	0	0	0
24a+24b Rent or lease	159	151	154	168	101
25 Repairs and maintenance	329	306	342	344	231
26 Seeds and plants	153	178	106	161	101
27 Storage and warehousing	0	1	0	0	0
28 Supplies purchased	211	214	217	219	159
29 Taxes	37	37	33	38	29
30 Utilities	96	84	95	99	77
31 Vet., breed., and med.	179	157	232	200	37
32 Other expenses	121	154	142	125	90
33 Total expenses	4,224	4,015	4,712	4,503	2,352
34 Net farm profit	840	1,156	386	817	998

*Analyzing farms on a per COW versus per CWT basis results in a different set of farms in the highest and lowest 10 farms.

2013-2015 Average of Maryland Dairy Farms

Analysis August 2016

Income, Expenses, and Profit per CWT

	Average 31 Farms	Highest 10 Farms*	Lowest 10 Farms*	Non-organic 24 Farms	Organic 7 farms
Average number of cows	132	89	125	148	76
CWT milk sold per cow	188	138	206	204	82
Schedule F line					
Farm income					
1a&b Sales of livestock bought	0.18	0.00	0.01	0.05	0.00
1c Cost or other basis of line 1	0.11	0.00	0.01	0.04	0.00
1e Subtract line d from line c	0.07	0.00	0.00	0.02	0.00
2 Sales of farm products					
a. Milk sales (price per cwt)	22.30	25.88	21.51	21.60	33.92
b. Crop sales	0.67	0.95	0.71	0.70	0.14
c. Cattle sales	2.03	3.02	1.59	1.88	5.52
Total 3+4+5+6+7+8 other income	1.90	1.66	3.38	1.93	1.35
9 Gross Income	26.97	31.51	27.19	26.13	40.93

Farm expenses					
10 Car and truck expenses	0.02	0.05	0.00	0.02	0.12
11 Chemicals	0.54	0.86	0.43	0.57	0.00
12 Conservation expenses	0.13	0.00	0.33	0.13	0.00
13 Custom hire	1.02	1.40	0.89	0.97	1.94
14 Depreciation	2.27	2.45	2.56	2.19	3.49
15 Employee benefits	0.10	0.00	0.17	0.10	0.00
16 Feed	6.35	5.65	7.86	6.30	7.19
17 Fertilizer and lime	0.82	1.11	0.55	0.79	1.26
18 Freight and trucking	1.00	0.86	1.20	1.03	0.55
19 Gasoline, Fuel, and oil	0.95	0.96	1.11	0.91	1.62
20 Insurance (other than health)	0.38	0.51	0.46	0.38	0.32
21a+21b Interest	0.60	0.77	0.71	0.55	1.43
22 Labor hired	1.49	1.06	1.60	1.53	0.75
23 Pension and profit-sharing	0.00	0.00	0.00	0.00	0.00
24a+24b Rent or lease	0.85	1.11	0.81	0.82	1.23
25 Repairs and maintenance	1.75	1.81	1.84	1.69	2.82
26 Seeds and plants	0.81	1.00	0.65	0.79	1.23
27 Storage and warehousing	0.00	0.00	0.00	0.00	0.00
28 Supplies purchased	1.13	1.49	1.24	1.08	1.95
29 Taxes	0.20	0.14	0.18	0.19	0.35
30 Utilities	0.51	0.60	0.49	0.49	0.94
31 Vet., breed., and med.	0.95	0.60	1.23	0.98	0.45
32 Other expenses	0.64	0.67	0.68	0.62	1.10
33 Total expenses	22.49	23.12	24.97	22.12	28.73
34 Net farm profit	4.47	8.39	2.22	4.01	12.20

*Analyzing farms on a per COW versus per CWT basis results in a different set of farms in the highest and lowest 10 farms.

Analysis August 2016

	Average 31 Farms	Highest 10 Farms*	Lowest 10 Farms*	Non-organic 24 Farms	Organic 7 farms
Average number of cows	**132**	**160**	**126**	**148**	**76**
CWT of milk sold per cow	**188**	**194**	**183**	**204**	**82**
Farm income					
Milk sales				**4,399**	

	4,188	4,365	4,013		2,777
Cattle sales	381	459	275	382	452
Other income	495	346	811	539	122
Total income	5,064	5,171	5,098	5,320	3,350
Farm expenses					
Feed purchased	1,192	991	1,571	1,282	588
Seed, fertilizer, chemicals	432	509	324	466	204
Depreciation and repairs	755	628	861	790	517
Labor	297	383	330	332	61
Medical and breeding	179	157	232	200	37
Car, Truck, Fuel, Hauling	371	326	413	398	187
Rent	159	151	154	168	101
Interest	112	70	120	111	117
Custom hire	192	241	148	197	159
Other expenses	536	558	560	559	381
Total Expenses	4,224	4,015	4,712	4,503	2,352
Profit per COW	840	1,156	386	817	998

Analysis August 2016

	Average 31 Farms	Highest 10 Farms*	Lowest 10 Farms*	Non-organic 24 Farms	Organic 7 farms
Average number of cows	132	89	125	148	76
CWT of milk sold per cow	188	138	206	204	82

Farm income					
Milk sales	22.30	25.88	21.51	21.60	33.92
Cattle sales	2.03	3.02	1.59	1.88	5.52
Other income	2.64	2.61	4.09	2.65	1.49
Total income	26.97	31.51	27.19	26.13	40.93
Farm expenses					
Feed purchased	6.35	5.65	7.86	6.30	7.19
Seed, fertilizer, chemicals	2.30	2.97	1.96	2.29	2.49
Depreciation and repairs	4.02	4.26	4.40	3.88	6.32
Labor	1.58	1.07	1.77	1.63	0.75
Medical and breeding	0.95	0.60	1.23	0.98	0.45
Car, Truck, Fuel, Hauling	1.98	1.88	2.31	1.96	2.29
Rent	0.85	1.11	0.81	0.82	1.23
Interest	0.60	0.77	0.71	0.55	1.43
Custom hire	1.02	1.40	0.89	0.97	1.94
Other expenses	2.85	3.42	3.04	2.75	4.66
Total Expenses	22.49	23.12	24.97	22.12	28.73
Profit per CWT	4.47	8.39	2.22	4.01	12.20

Attachment 2
Maryland Licensed Milk Processors

Entity Name	Address	City	State	Zip	County
CHAPELS COUNTRY CREAMERY	10380 CHAPEL RD	EASTON	MD	21601	Talbot
CHERRY GLEN FARM INC	16120 BARNESVILLE ROAD	BOYDS	MD	20841	Montgomery
CHESAPEAKE BAY DAIRY	4111 WHITESBURG RD	POCOMOKE	MD	21851	Worcester
CLEAR SPRING CREAMERY	14322 ST PAUL RD	CLEAR SPRING	MD	21722	Washington
CLOVER HILL DAIRY	27925 WOODBURN HILL RD	MECHANICSVILLE	MD	20659	Saint Mary's
CLOVERLAND FARMS DAIRY	2701 LOCH RAVEN RD	BALTIMORE	MD	21218	Baltimore City
DAIRY MAID DAIRY LLC	259 E 7TH ST	FREDERICK	MD	21701	Frederick
FIREFLY FARMS INC	107 S MAIN ST	ACCIDENT	MD	21520	Garrett
KILBY CREAM INC	785 FIRETOWER RD	COLORA	MD	21917	Cecil
LANCO DAIRY FARMS COOP LLC	14738 WARFORDSBURG RD	HANCOCK	MD	21750	Washington
MARVA MAID LANDOVER	1805 SOUTH CLUB DR	LANDOVER	MD	20785	Prince Georges
MARYLAND & VIRGINIA MILK PRODUCERS	8321 LEISHEAR RD	LAUREL	MD	20723	Howard
MISTY MEADOW FARM CREAMERY	14325 MISTY MEADOW RD	SMITHSBURG	MD	21783	Washington
NESTLE DRYERS ICE CREAM CO.	9090 WHISKEY BOTTOM RD	LAUREL	MD	20723	Prince Georges
NICE FARMS CREAMERY	25786 AUCTION ROAD	FEDERALSBURG	MD	21632	Caroline
POTOMAC FARMS DAIRY	RACE ST & W IND	CUMBERLAND	MD	21502	Allegany
PRIGEL FAMILY CREAMERY	4852 LONG GREEN RD	GLEN ARM	MD		Baltimore
SHEPHERDS MANOR CREAMERY LLC	1126 SLINGLUFF RD	NEW WINDSOR	MD	21776	Carroll
SOUTH MOUNTAIN CREAMERY	8305 BOLIVAR RD	MIDDLETOWN	MD	21769	Frederick
SPRIGGS DELIGHT	6836 TOMMY TOWN RD	SHARPSBURG	MD	21782	Washington
WOODBOURNE CREAMERY	28600 RIDGE RD	MOUNT AIRY	MD	21771	Montgomery

STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

POSITION AND RATIONALE:

The Department of Health and Mental Hygiene (the Department) opposes the sale of raw milk because the consumption of raw milk can cause illness, including severe disease and death; because raw milk has not been shown to provide any health benefits over pasteurized milk; because no regulation or sampling can assure the safety of raw milk; and because applying warning labels or other disclosures to raw milk cannot assure public health. To provide additional detail regarding these concerns:

1. **Raw milk can cause illness, including severe disease and death, particularly in young children.**

   The role of raw milk and other unpasteurized dairy products in the transmission of infectious diseases is well documented. According to the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), raw milk might contain pathogens that cause illness in humans. Pasteurization is the process of heating milk to a high enough temperature for a long enough time to kill disease-causing bacteria. Raw milk was recognized as a source of severe infections over 100 years ago, and pasteurization of milk to prevent these infections is one of the public health triumphs of the 20th century. As a consequence of the widespread adoption of pasteurization, diseases from contaminated milk and milk products that resulted in a significant morbidity and mortality in humans have been substantially reduced in the United States.

   Pathogens such as *Escherichia coli* O157, *Campylobacter jejuni*, and *Salmonella* can contaminate milk during the milking process because they can be shed in the feces of healthy-looking dairy animals, including cows and goats. Illnesses related to raw milk range from gastro-intestinal upset to more severe disease with long-term consequences, such as hemolytic uremic syndrome (which can result in kidney failure) and Guillain-Barré syndrome (which can result in paralysis). These infections are particularly serious in those who are very young, very old, or who have impaired immune systems, and can be fatal. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children.

   Adherence to good hygienic practices during milking can reduce, but not eliminate, the risk of milk contamination. The intrinsic properties of milk, including its pH and nutrient content, make it an excellent vehicle for the survival and growth of bacteria. The only reliable method for reducing the level of human pathogens in milk and milk products is production and processing under sanitary conditions and subsequent pasteurization. Pasteurization is recommended for all animal milk consumed by humans by the CDC, the FDA, the American Academy of Pediatrics, the American Academy of Family Practitioners, the American Veterinary Medical Association, the National Association of State Public Health Veterinarians, and many other medical and scientific organizations.

   In a 2015 CDC report, a total of 81 raw milk-related outbreaks were reported during the years 2007-2012. [1] The vast majority of these outbreaks (81%) were caused by nonpasteurized milk purchased in

[1] Mungai EA, Behravesh CB, Gould LH. Increased outbreaks associated with nonpasteurized milk, United States, 2007-2012. Emerg

states in which the sale of nonpasteurized milk was legal, oftentimes via legal cow share or herd share programs. These outbreaks resulted in 979 illnesses and 73 hospitalizations. Of particular concern was the disproportionate impact on children. Of the 78 outbreaks for which the age of the patients was available, 59% involved at least one child under 5 years old. While no deaths were reported, there were severe health consequences among those afflicted.

According to a March 18, 2016 report by the federal Centers for Disease Control and Prevention (CDC), Miller's Organic Farm located in Pennsylvania, is linked to listeriosis illnesses of individuals in California and Florida, one of whom died after being hospitalized for a Listeria monocytogenes infection. The FDA and CDC then investigated those incidents. In interviews with family members, the investigators learned that both individuals drank raw milk purchased from Miller's Organic Farm. The FDA collected Listeria bacteria from the two infected individuals and, in November 2015, obtained samples of raw chocolate milk from Miller's Organic Farm. The samples were purchased at a raw milk conference in California. Those raw milk samples contained Listeria bacteria matching that collected from the victims, according to the CDC. Reference :*http://www.cdc.gov/listeria/outbreaks/raw-milk-03-16/*

In another recent and tragic example, raw milk obtained through a cow-share program in Oregon infected 19 persons with *E. coli* O157:H7. Of those, 15 (79%) were children younger than 19 years of age. Four children (21%) were hospitalized with kidney failure and hemolytic uremic syndrome, and one, a 2 year old girl, spent several months in the hospital undergoing dialysis and suffered a stroke that left her unable to speak or walk. She subsequently received a kidney transplant from her mother and continues to suffer the consequences of her infection. Four of the farmer's children own children were also ill, including one with hemolytic uremic syndrome. *E. coli* O157 isolated from human patients, animal manure, cattle rectal swabs, the milking station, and the raw milk itself were matched by DNA fingerprinting.

There have been numerous cases where persons, including children, drank raw milk unknowingly or not by choice. One of the sick individuals involved with the April 2012 Oregon cow-share outbreak was a young women who unknowingly drank the raw milk while at a friend's home. In September 2006, one child sickened with E.Coli O157:H7 was exposed to the contaminated raw milk only once when it was served to him as a snack while visiting a friend.

The reported outbreaks represent only the tip of the iceberg. For every outbreak and illness that is reported, many others occur that are not reported; the actual number of illnesses associated with raw milk and raw milk products is likely much greater.

2. No sampling can guarantee that raw milk is safe for consumption.

It is not feasible to perform bacteriological tests on every batch of raw milk to determine the presence or absence of all pathogens and thereby ensure that it is free of infectious organisms.
The pathogens of concern to human beings found in raw milk can come from animals that appear to be completely healthy and can be shed intermittently. Therefore, there is no practical sampling strategy could assure safe raw milk.

Infect Dis. 2015 Jan;21(1):119-22. doi: 10.3201/eid2101.140447. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4285278/

3. **Warning labels, waivers, disclosures, and registrations do not assure public health concerns.**

   The Department analyzed a number of regulatory applications such as warning labels, waivers, disclosures, and registration to determine whether these measures might address public health concerns. The Department has concluded that no warnings or consumer right-to-know strategies could guarantee that raw milk is safe for human consumption. Raw milk-associated outbreaks continue to occur, predominantly in states that permit regulated sales of raw milk, including states requiring warning labels.[1]

In 2014, after the Legislative Session, the Health and Government Operations Committee, the Committee requested the Johns Hopkins University to conduct a review of the benefits and risks of drinking raw cow's milk and pasteurized milk. The published report, entitled, "A Literature Review of the Risk and Benefits of Consuming Raw and Pasteurized Cow's Milk", concluded by discouraging the consumption of raw milk: "The risks of consuming raw milk instead of pasteurized milk are well established in the scientific literature, and in some cases can have severe or even fatal consequences." The review also concluded that, "The potential benefits on the other hand, are still unclear and would benefit from further investigation. We are left with a large uncertainty about the potential benefits of raw milk but with a clear understanding of the microbial hazards from consuming raw milk." This report is attached.

In August 2009, the Court of Special Appeals of Maryland ruled that the distribution of raw milk through a herd share program is deemed a "sale of raw milk". The sale of raw milk is clearly prohibited in Maryland in both Maryland law and the Code of Maryland Regulations.

In summary, because raw milk clearly causes human illness, particularly in children and other vulnerable populations, allowing the sale of raw milk and raw milk products increases the risk of illness, including potentially severe and fatal illness, in Maryland residents. It is the assessment of the Department that passage of this bill greatly increases the chances of illness associated with raw milk consumption in Maryland residents. The Department, therefore, strongly advises against the consumption of raw milk.

Epidemiologic Evidence Supporting the Ban on the Sale of Raw Milk

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State Public Health Veterinarian
Maryland Department of Health and Mental Hygiene

How Does Milk Become Contaminated And Why Is Pasteurization Important?

Contamination

- Milk can become contaminated both preharvest and postharvest.
- Milk in the mammary gland typically does not contain bacteria.
- As milk is excreted it can become contaminated with commensal microflora on
- the teat skin or on the lining of the teat canal.
- Animals with subclinical mastitis produce milk that is not noticeably different from the milk produced by uninfected animals and may be added to the bulk tank.
- • Animals with clinical mastitis or systemic disease may shed organisms into milk, but typically milk from these animals will have a changed appearance and is withheld from human consumption.
- The dairy farm environment is an important reservoir for many foodborne

pathogens and contamination of milk by this route has been documented.
- Milk may also become contaminated during processing, distribution and storage from environmental or human sources.

Controls to minimize contamination
- To minimize the risk of contamination, controls must be applied at all stages along the continuum.
- Enhanced animal health (such as eradication of certain zoonotic diseases from the US dairy herd) will reduce the opportunity for shedding of pathogens in milk.
- Improved milking hygiene and cow cleanliness may not be able to completely eliminate the risk of contamination but can reduce contamination of milk.
- Enhanced animal health and improved milking hygiene **canno**t fully eliminate the risk of contamination of milk, hence the need for pasteurization.
- Controls can also be applied during processing, distribution and storage (postpasteurization) to ensure reduced opportunity for milk contamination from the environment or from those handling the product.

Pasteurization
- Pasteurization is the process of heating milk for a predetermined time and temperature combination to destroy pathogens.
- Pasteurization is the *cornerstone of milk safety*
  - It improves the safety and lengthens the shelf life of milk by destroying pathogenic and spoilage organisms.
  - It is not the same as sterilization of milk.

- **The incidence of milkborne illness in the United States has been sharply**
- **reduced as a result of pasteurization.**
- ○ In 1938, milkborne outbreaks constituted twenty-five percent (25%) of all disease outbreaks due to infected foods and contaminated water.
- ○ The most recent information reveals that milk and fluid milk products continue to be associated with less than one percent (<1%) of such
- reported outbreaks.

Reference
LeJeune JT and PJ Rajala-Schultz. Unpasteurized milk: A continued public health threat. Clinical Infectious Diseases 2009;48:93-100.

Policy Analysis conducted by the CDC: Do restrictions on raw milk sales reduce outbreaks associated with raw milk?

Approach: All reported outbreaks associated with dairy products (raw or pasteurized) during 1973-1992 included in analysis.
- Outbreaks associated with raw milk were compared to the outbreaks associated with pasteurized dairy products.
- The number of outbreaks and the number of cases associated with unpasteurized products were compared between states that permit the sale of raw milk and states that do not permit the sale of raw milk.

Findings:

- From 1993-2006, 122 outbreaks associated with dairy products

	Outbreaks	Number Of Patients	Number of Hospitalizations	Hospitalization Rate	Deaths
Pasteurized	**48**	**1223**	**30**	**2.45%**	**1**
Unpasteurized (raw)	**73**	**1571**	**202**	**12.8%**	**2**

Conclusion: Disease associated with raw milk outbreaks is more severe than disease associated with milk products contaminated post-pasteurization.

- The incidence of outbreaks and cases associated with raw milk in states where raw milk sales are allowed is 2.85 times and 1.91 times greater (respectively) than in states where raw milk sales are not allowed.

For all reported outbreaks associated with dairy products, 1993-2006	Incidence Density in State where Sale Permitted	Incidence Density in States where Sale Prohibted	Incidence Density Ration (95% Confidence Interval) THIS IS A MEASURE OF RISK
Outbreaks	55/2.2b = 2.5*	15/1.7B = 0.88*	**2.85 (1.67-5.2)**
Cases	1016/2.2b = 46.14*	414/1.7B = 24.18*	**1.91 1.7-2.14)**

*per 100 million person-years

Conclusion: Outbreaks associated with raw milk are more likely to occur in states where raw milk sales are legalized.

Reference

Adam Langer, DVM, MPH, DACVPM
Centers for Disease Control and Prevention
Presented at the International Association of Food Protection Timely Topics Symposium: Raw Milk Consumption: An Emerging Public Health Threat? February 17, 2009
Available at: http://www.foodprotection.org/meetingsEducation/TimelyTopics09.asp

THE NATIONAL PICTURE

Between 1998 and 2011, a total of 119 outbreaks, 2,147 illnesses, and 2 deaths were attributed to consumption of raw milk, raw colostrum, and raw milk products. Outbreaks have been associated with raw cow milk and raw goat milk, as well as cheese made from raw milk. Herd-shares, retail sales, and direct farm sales have been implicated in outbreaks.

Raw milk and other raw products made from raw milk contribute to significantly more outbreaks than pasteurized milk and milk products. The Centers for Disease Control and Prevention (CDC) estimates that the risk of an outbreak from raw milk is 150 times greater than the risk from pasteurized milk. Although only 1-3%

of the U.S. population is believed to drink raw milk, more than 50% of all dairy outbreaks can be attributed to raw milk and raw milk products. If the risks from raw and pasteurized dairy products were equal, or if raw dairy products were actually safer, raw dairy related outbreaks should account for 1-3% of the total number of outbreaks, and not more than 50% as documented.

People under age 20 represent approximately 60% of raw milk illnesses during outbreaks reported to CDC. This is approximately three times more than for pasteurized milk. Raw milk is also more likely to cause hospitalization from the most dangerous foodborne pathogens such as *E. coli* O157:H7. In contrast, *E. coli* O157 outbreaks have not been attributed to pasteurized milk in the U.S. Between 2005-2012, there have been 15 *E. coli* O157 outbreaks in the U.S. associated with raw milk consumption. The 15 outbreaks resulted in 116 illnesses that included 44 (38%) hospitalizations, and 28 (24%) cases of hemolytic uremic syndrome (HUS). Hemolytic uremic syndrome causes life-threatening anemia and can cause kidney failure requiring dialysis. Of the 28 patients with HUS, 27 (96%) were under the age of 18 years old.

These data were compiled from CDC foodborne disease outbreak surveillance tables, an online outbreak database published by the Center for Science in the Public Interest (CSPI), public health reports such as the Morbidity and Mortality Weekly (MMWR), peer-reviewed manuscripts, and CDC Line List of dairy outbreaks from 1973-2005 produced in response to a Freedom of Information Act (FOIA) request to CDC by the Farm to Consumer Legal Defense Fund, and summarized on the website www.realrawmilkfact.com

Recent Wisconsin outbreak, 38 people sickened, 2014

September 2014, 38 people at a High School football team dinner in Wisconsin became ill after consuming raw milk contaminated with *Campylobacter jejuni* from a Grade "A" permitted dairy farm. Those who were sickened ranged in age from 14 to 49 and included 33 students and five coaches. Sixteen (16) of the thirty eight (38) sought medical attention and ten (10) were hospitalized. Some of the adults and students didn't know that raw milk was being served.
Reference: http://www.foodsafetynews.com/2014/12/wisconsins-campy-outbreak-blamed-on-raw-milk/#.VgXINE2FPcs

Recent Utah outbreak, 45 people sickened, 2014

In August 2014, 45 people were ill after consuming raw milk or raw cream obtained from either the Ropelato Dairy Farm or from the farm's retail store. To date 45 cases of Campylobacter infection have been reported in persons ranging from the ages of 2 to 74. Utah public health officials are still investigating this cluster of illness associated with the consumption of unpasteurized milk and cream.

Recent Oregon outbreak with severe clinical outcomes associated with raw milk obtained through a herdshare, 2012

In April 2012, raw milk obtained through a cow-share program in Oregon was responsible for a total of 19 persons ill with *E. coli* O157:H7. Of the 19 affected, 15 (79%) were in children younger than 19 years of age. Four children (21%) were hospitalized with kidney failure and HUS. One of the children, a two year old girl, spent several months in the hospital undergoing dialysis. In addition, she had a stroke, which left her unable to speak or walk. This young girl has subsequently received a kidney transplant (from her mother) and continues to suffer the consequences of her infection. Four of the farmer's children were also ill, including one with HUS.

E. coli O157 isolated from human patients, animal manure, cattle rectal swabs, the milking station, and the raw milk itself were matched by DNA fingerprinting.
References:
Summary of the Foundation Farm raw milk-associated E. coli O157:H7 outbreak. Public Health Division of the Oregon Health Authority, April 20, 2012. Available at: http://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/ecoli/Documents/foundationfarm2012_outbreak.pdf.
News Desk. Young E. coli Victim Receives Kidney Transplant from Mother. Food Safety News, September 11,2103. Available at: http://www.foodsafetynews.com/2013/09/young-e-coli-victim-receives-kidney-transplantfrom-mother/#.UuvJaT2zFnG

Recent Tennessee outbreak with severe outcomes, 2013
In late 2013, nine children became ill with *E. coli* O157 after drinking raw milk from a local dairy. Five of the nine children (56%), all younger than seven years old, required hospitalization. Three (33%) developed HUS. The strain of *E. coli* O157 that caused their illnesses was matched to animal waste collected at the implicated dairy.
References:
State Analysis Links cluster of Illnesses to Raw Milk Consumption. Tennessee Department of Health, November 21, 2013. Available at: http://news.tn.gov/node/11697
http://www.realrawmilkfacts.com/PDFs/Raw-Dairy-Outbreak-Table.pdf

Outbreaks and illnesses associated with Organic Pastures Dairy, California

Early 2012: At least 10 cases of campylobacteriosis between January and the end of April were linked to consumption of raw dairy products from Organic Pastures Dairy.

November 2011: Organic Pastures was implicated in an *E. coli* outbreak when five children who were sickened with the same strain of *E. coli* all reported drinking raw milk from Organic Pastures, with no other common exposure. Environmental samples from Organic Pastures facilities revealed the same strain of *E. coli* that had infected these children.

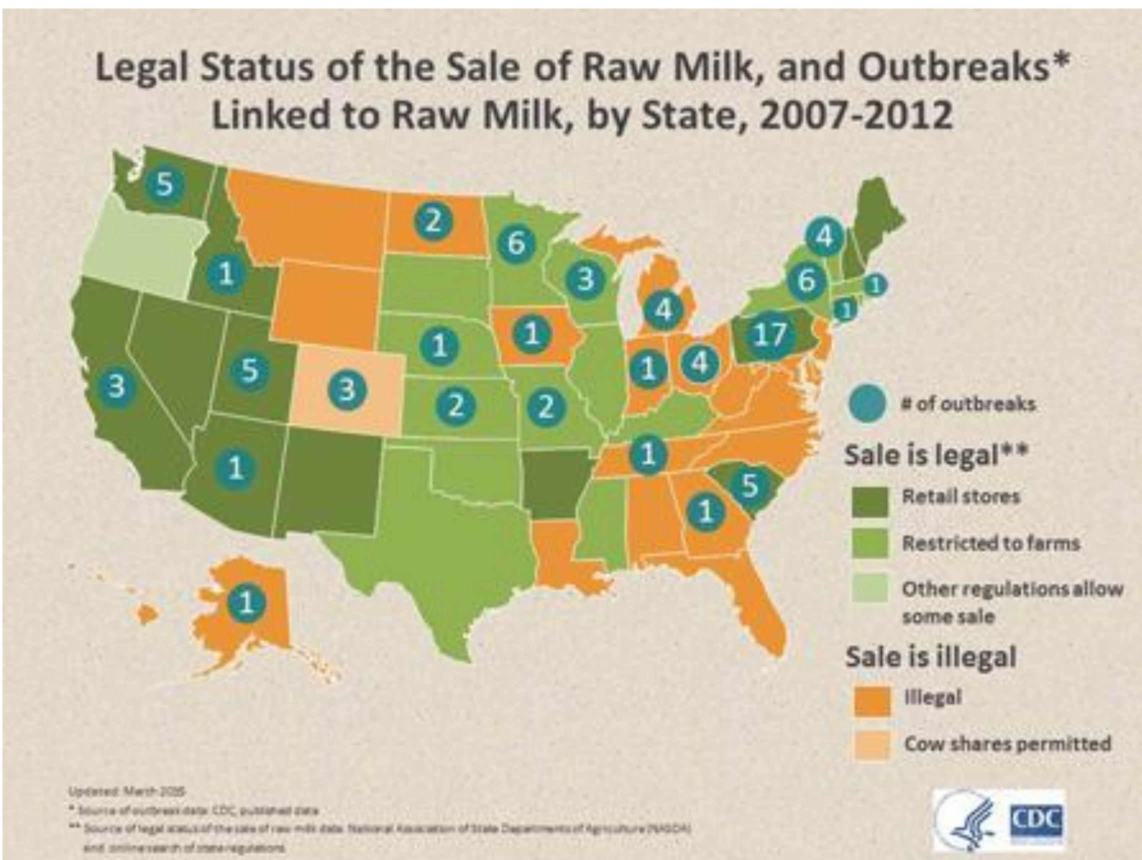
Products from Organic Pastures were subject to three other recalls and linked to two other outbreaks between 2006 and 2008. In 2006, *E. coli* infections among six children were linked to Organic Pastures' raw milk. Two (33%) of these victims developed hemolytic uremic syndrome, a complication of *E. coli* infection that leads to kidney failure.
References:
CDFA Announces Recall of Raw Milk Products at Organic Pastures of Fresno County. California Department of Food and Agriculture, May 10, 2012. Available at:
http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018
Organic Pastures Raw Milk Recall Announced by CDFA. California Department of Food and Agriculture, November 15, 2011. Available at: http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=11-064
Beecher C. Organic Pastures Faces Another Recall, Quarantine. Food Safety News, September 6, 2012. Available at: http://www.foodsafetynews.com/2012/09/organic-pastures-faces-another-recallquarantine/#. UuwGFj2zFnG

Legal Status of Raw Milk and Outbreaks in the United States

Consumption of raw milk has been found to account for less than 1% of total milk sold in those states that permit the sale of raw milk, according to the CDC. Although consumption is relatively low, raw milk continues to cause outbreaks of illness disproportionate to its presence in the market. Many of those persons who have become ill from drinking raw milk are children and teenagers who have battled serious illness and endured lengthy hospital stays. According to the Center for Disease Control and Prevention (CDC) study published in January 2015, Journal of Emerging Infectious Diseases, the average number of foodborne illness outbreaks associated with drinking unpasteurized milk has more than quadrupled in recent years, as states approved more laws allowing retail sale of raw milk. From 2007 to 2012, the study reported 81 raw milk-associated foodborne illness outbreaks nationwide, or an average of 13 per year. The outbreaks, which sickened more than 1,000 people and sent 73 to the hospital, were concentrated in states where raw milk sales are legal. The raw milk outbreaks accounted for about 5% of all foodborne illness outbreaks from a known source from 2007 to 2012. More than 80% of the outbreaks occurred in states where selling of raw milk is legal.

By contrast, an earlier CDC study, covering 1993 to 2006, found an average of only three foodborne illness outbreaks per year associated with raw milk consumption. This study concludes that the legalization of the sale of nonpasteurized milk in additional states would probably lead to more outbreaks and illnesses and recommends that public health officials should continue to educate legislators and consumers about the dangers associated with consuming nonpasteurized milk.

Reference: The Center for Disease Control and Prevention. *Increase in Outbreaks Associated with Nonpasteurized Milk, United States, 2007-2012.* http://www.cdc.gov/foodsafety/rawmilk/nonpasteurized-outbreaks-2012.html



THE PENNSYLVANIA EXPERIENCE

For the period 2007-2011:
During 2007-2011, 15 raw milk-related outbreaks were reported in Pennsylvania

- 233 persons were confirmed with illness
  - **11 (5%) were hospitalized**
  - 45% were under 18 years of age
  - 17% were under 5 years of age
- There were 12 *Campylobacter* outbreaks and three *Salmonella* outbreaks

During 2007-2011, only one outbreak associated with pasteurized milk was reported

- 16 persons with confirmed illness were identified

Reference: *Pennsylvania Epi Notes, Pennsylvania Department of Health. Vol. 2, Iss. 2, Spring 2012.* Published at: www.health.state.pa.us/epinotes.

For the period 2005-2013:
During 2005-2013, Pennsylvania experienced 17 salmonellosis and campylobacteriosis outbreaks associated with retail raw milk. Five producers had more than one outbreak during that period.

One particularly severe outcome was **a case of Guillain-Barre Syndrome** in a 67 y.o. man who had consumed raw milk for a year because of its purported nutritional value. After 2 weeks of illness, the local newspaper reported, "He can't move his arms and legs. He can't talk; he can only mouth words. And he has a breathing tube," his wife said. "The doctors said his situation will eventually reverse itself, but it's going to take a long time and a lot of physical therapy.""

The patient's wife and daughter "suffered diarrhea and stomach aches after drinking the milk…" The wife "recovered in about two weeks… Their daughter was sick for about four days."

References: *Centers for Disease Control and Prevention (CDC). Recurrent outbreak of Campylobacter jejuni infections associated with a raw milk dairy--Pennsylvania, April-May 2013. MMWR Morb Mortal Wkly Rep. 2013 Aug 30;62(34):702.*
Cronin M. Tainted raw milk blamed for Butler County man's paralytic illness. TribLive. April 20, 2010. Available at: http://triblive.com/x/valleynewsdispatch/s_677255.html#axzz2rp3OuIUC

2012 Family Cow Dairy Outbreak:
In 2012, one of the largest outbreaks associated with raw milk consumption occurred from exposure to raw milk produced by and sold on site at the Family Cow Dairy. A total of 148 confirmed and probable cases of *Campylobacter* were identified:

- There were 81 confirmed cases, including:
  - 70 from PA, 6 from MD, 3 from WV, and 2 from NJ
  - The median age of patients was 31 years (2-74 years)
    - 25 (31%) of the confirmed cases were <18 years old
  - **10 (12%) were hospitalized**
    - No deaths or Guillain-Barre Syndrome are known to have resulted
- There were 67 probable cases from 4 states

Reference: *Longenberger AH, Palumbo AJ, Chu AK, Moll ME, Weltman A, Ostroff SM. Campylobacter jejuni infections associated with unpasteurized milk—multiple states, 2012. Clin Infect Dis 2013;57:263–6.*

Miller's Organic Farm Outbreak

According to a March 18, 2016 report by the federal Centers for Disease Control and Prevention (CDC), Miller's Organic Farm located in Pennsylvania, is linked to listeriosis illnesses of 2 individuals in California and Florida, one of whom **died** after being hospitalized for a Listeria monocytogenes infection.

The FDA and CDC then investigated those incidents. In interviews with family members, the investigators learned that both individuals drank raw milk purchased from Miller's Organic Farm. The FDA collected Listeria bacteria from the two infected individuals and, in November 2015, obtained samples of raw chocolate milk from Miller's Organic Farm. The samples were purchased at a raw milk conference in California. Those raw milk samples contained Listeria bacteria matching that collected from the victims, according to the CDC. Both illnesses occurred in 2014. Reference :*http://www.cdc.gov/listeria/outbreaks/raw-milk-03-16/*

A Literature Review of the Risks and Benefits of Consuming Raw and Pasteurized Cow's Milk

A response to the request from The Maryland House of Delegates' Health and Government Operations Committee

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Executive Summary

A bill entitled "House Bill 3, *Health - Milk Products - Raw Milk - Consumer-Owned Livestock*" was introduced to the Maryland House of Delegates during the 2014 session of the General Assembly. In response to concerns regarding the public health and safety of allowing the sale of raw milk directly to consumers, the Health and Government Operations Committee requested a review of the benefits and risks of drinking raw cow's milk and pasteurized (i.e. heat-treated) milk. This review aims to provide an objective evaluation of the claims that health benefits of raw milk outweigh any potential risks.

We examined the scientific literature for research regarding the health benefits and risks of raw and pasteurized liquid bovine milk. Based on a rigorous search strategy, we identified more than 1000 scientific articles for consideration in our review. We then reviewed abstracts of these articles to narrow the study database to articles that fit our scope. After eliminating articles that were not informative to the questions posed, our screening process resulted in the inclusion of 81 articles from the peer-reviewed literature.

Based on our review of the scientific evidence, we conclude that drinking raw milk carries an increased risk of foodborne illness as compared to drinking pasteurized milk. We identified several articles that detected a relationship between drinking raw milk and reduced allergies among rural children and infants. The underlying cause for this relationship, however, has not been identified. While some articles noted nutritional deficiencies in pasteurized milk, these can be overcome by eating a well-balanced diet. Overall, our review identified no evidence that the potential benefits of consuming raw milk outweigh the known health risks.

Based on our findings, we discourage the consumption of raw milk. The risks of consuming raw milk instead of pasteurized milk are well established in the scientific literature, and in some cases can have severe or even fatal consequences. The potential benefits on the other hand, are still unclear and would benefit from further investigation. We are left with a large uncertainty about the potential benefits of raw milk but with a clear understanding of the microbial hazards from consuming raw milk.

We believe the scope of the review and the employed search methods are unbiased and representative of the available scientific literature; only future research will remove current uncertainties. While future research could inform decision-making on the legalization of raw milk, we believe that from a public health perspective, it is a far safer choice to discourage the sale of raw milk. Regardless, we believe that the potential health risks of consuming raw milk should be clearly communicated, especially to vulnerable populations such as pregnant women, children, and the elderly.

Introduction

Cow's milk has been a staple of the American diet ever since the medical community publicized its nutritional benefits in the 1920s (Mendelson 2011). However, health concerns over cow's milk began as early as the mid-19th century, when the public began to focus on unhygienic conditions of cows and dairy processing plants. Foodborne illnesses from consuming milk were common during this time, and were mostly due to bacterial contamination (Garber 2008; Gillespie et al. 2003). Foodborne illnesses are often limited to ephemeral symptoms such as nausea, vomiting, and diarrhea, but can also include more serious and chronic complications, such as hemolytic uremic or Guillain–Barré syndromes; in some cases illnesses can lead to death (U.S. Food and Drug Administration 2012a).

In response to the public's concerns, regulators and hygienists improved the practices of caring for and milking cows as well as how milk was distributed to consumers (Gould et al. 2014; Leedom 2006). At a similar time, a heat-treatment process that could kill microbes, known today as pasteurization, was introduced to further ensure milk safety. Pasteurization requires heating milk to a specific temperature for a minimum period of time, and then quickly cooling it back down to refrigeration temperatures (4°C) (De Buyser et al. 2001; Walstra et al. 2006). Many heat-time combinations are effective (**Table 1**). Classic pasteurization involves heating milk to 63°C for 30 minutes. However, as pasteurization became widely accepted and dairy plants became more industrialized, higher temperature-short time pasteurization (HTST; 72°C for 15 seconds) and ultra-high temperature pasteurization (UHT; 135°C for 2 seconds) became commonplace (Mendelson 2011; Walstra et al. 2006).

In the mid-1950s states began banning the sale of "raw" (i.e. unpasteurized) milk (Mendelson 2011), and in 1987 the U.S. Food and Drug Administration (FDA) prohibited the interstate shipment and sale of raw milk for human consumption (Langer et al. 2012). These laws, along with more hygienic farm practices, reduced milkborne outbreaks from almost a quarter of all reported intestinal infectious diseases to <1% (Lejeune and Rajala-Schultz 2009). Since its ban, however, demand for raw milk has persisted and grown along with the public's interest in "whole" and "organic" diets (David 2012). There have also been claims that raw milk is cleaner and has a superior taste to pasteurized milk (Lejeune and Rajala-Schultz 2009). For the past 15 years media coverage of raw milk has expanded, reflecting the communication and outreach of raw milk advocates (Mendelson 2011). Currently 30 states permit the sale of raw milk, usually allowing small amounts to be sold directly at local farms or through "cow share" programs (Gould et al. 2014). Some of these efforts have illegally expanded into interstate sales. For example, raw milk produced in Pennsylvania has been sold in Maryland, which has resulted in litigation from the FDA (David 2012). It is currently estimated that 0.5-3.5% of the U.S. population drinks raw milk, with the majority of these people residing on farms (Lejeune and Rajala-Schultz 2009). In recent years, there has been an increase in raw milk availability, which has concerned public health officials, as they believe this may increase the risk of foodborne illness (U.S. Food and Drug Administration 2012b).

The greatest and most widespread concern of overall milk safety is microbial contamination: the presence of infectious bacteria or viruses. Pathogens commonly found in milk include: *Salmonella* species, *Campylobacter jejuni*, Shiga-toxin producing *Escherichia coli* (STEC), and *Listeria* *monocytogenes*. These bacteria are also found naturally in the environment. Cows can be exposed to environmental sources of microbes on the farm, which can cause mastitis, an infection of the udders that can spread pathogens during milking (Lejeune and Rajala-Schultz 2009). Fecal contamination from the cows during milking can also allow high amounts of pathogenic microbes to enter the milk.

During large-scale pasteurized milk production, unprocessed milk is sent from dairy farms to dairy processing plants in bulk tanks where large quantities of milk are stored (Oliver et al. 2005). Bacteria and viruses can grow in these tanks and spread to previously uncontaminated milk. It is at this point in the milk production process, however, that milk is usually pasteurized, and, assuming the heat treatment is performed appropriately, most pathogens will not survive (Oliver et al. 2005; Walstra et al. 2006). Post-pasteurization contamination, however, is possible, usually through microbial biofilms in distribution pipes, unhygienic practices of employees, or the use of unsterilized containers or post-pasteurization equipment (Leedom 2006; Lejeune and Rajala-Schultz 2009; Oliver et al. 2005). The risk of microbial transmission also occurs via dairy workers at all points during milk processing, including the equipment and practices on the farm (Leedom 2006). After milk is distributed, failure to keep milk at refrigeration temperatures can allow pathogenic microbes to multiply, greatly increasing the risk of illness from consuming the milk. Improper storage can be the fault of the dairy distributors, but also retail workers and milk consumers (Gould et al. 2014). So, while pasteurization can reduce microbial contamination, it does not ensure that milk is sterile throughout the supply chain (Lejeune and Rajala-Schultz 2009).

Often, there are systematic differences between the large-scale milk production described above and small-scale dairy farming, where raw milk is commonly sold (Mendelson 2011). These differences may influence the risk of microbial contamination in milk. Cattle on small farms are often not confined to dense, industrial sheds and may graze on nearby grass instead of being fed soy and corn from elsewhere. Raw milk for sale is typically not stored in bulk tanks and the distribution of milk is usually minimal, with most customers purchasing on the farm. While cross-contamination of milk after collection is reduced, the risk of contamination during collection remains (e.g. fecal contamination or mastitis of cow udders). Because small-scale farmers may not be subject to state and federal sanitary regulations and testing, there may be greater likelihood of some raw milk being contaminated with hazardous microbes and thus pose a risk to consumers.

Cow's milk has multiple benefits including its nutritional value (Mendelson 2011). In recent years there have been claims that raw milk can reduce allergic reactions and cure other ailments (Ijaz 2013). Allergies are a symptom of autoimmunity, which is characterized by the immune system attacking its own body (Melnik et al. 2014). The frequency and prevalence of autoimmunological conditions, such as asthma, have been increasing in recent decades, and some believe that living in too sterile of an environment may contribute to this increase. This "hygiene hypothesis" could be the reason why some believe that drinking unpasteurized milk, which contains many natural proteins, antibodies, and microbial communities, may reduce these public health risks (Baars 2013; Hodgkinson et al. 2014). However, recent reports have asserted that these potential health benefits have not been sufficiently investigated (Macdonald et al. 2011).

In the 2014 session of the Maryland General Assembly, a bill was introduced in the House of Delegates that would allow for the limited distribution of raw milk intended for consumption in the state via "cow shares" (Hubbard 2014). The Health and Government Operations Committee requested that the authors conduct a literature review on the benefits and risks of consuming raw milk and pasteurized milk. This review is intended to be an objective evaluation of the claims that health benefits of raw milk outweigh any potential risks. Below is the description of the literature review, a summary of its results, and an interpretation of the findings.

Methods

Our charge from the Maryland House of Delegates was to review the scientific literature concerning the risks and benefits of both raw and heat-treated (i.e. pasteurized) milk. Due to time and resource limitations, the scope of our review was limited to direct comparisons of health risks for raw and pasteurized fluid bovine milk. Articles discussing nutrition, spoilage (from an aesthetic perspective), or taste were excluded from the review, except when such articles also discussed other health risks. We considered these topics less pressing, as they are not, in the context of milk consumption, primarily public health concerns. While overall nutrition is important to the public's health, vitamins and proteins found in milk are found in other staple foods (Macdonald et al. 2011; Mendelson 2011), and thus milk is not essential to an individual's diet. Spoilage and taste are more economical and consumer-preference concerns and so were not considered health benefits. We also excluded literature that focused exclusively on non-bovine milk or other dairy products such as cheese, buttermilk and yogurt. Many of these products undergo a fermentation process, and the U.S. Food and Drug Administration considers some cheeses made from raw milk safe (Gould et al. 2014).

Our literature search was conducted in PubMed, the most relevant database for English health-focused scientific literature. Relevant articles were found using specific search terms, (**Appendix A)**. While there may be additional relevant articles that were not included in our search results, there is no reason for us to believe that our search method significantly biased the search returns. We therefore consider our review representative of the scientific literature. We reviewed all titles and abstracts of returned database articles and determined whether they were pertinent to the topic of raw and pasteurized milk public health benefits or risks. Articles considered relevant were then grouped into categories based on the type of public health risk and what dairy products were evaluated. We fully reviewed all articles within our aforementioned scope and that were published in the last 15 years (i.e. after 1998).

Articles and documents recommended for this review by interested citizens (and forwarded to us by the Committee) were also considered. These articles went through the same review process as described above unless they were already identified through the database search results.

Results

Selection of articles for review

Our search was conducted in the PubMed database on July 27, 2014. Of the 1,006 articles returned, 659 were not considered relevant and so were not fully reviewed. These excluded articles often focused on the accuracy of new microbiological assays to detect bacteria in milk products, as opposed to persistence of natural bacteria concentrations in milk. Other studies focused on rural and impoverished international settings where raw milk is the only type of bovine milk available for consumption. Other articles focused only on human breast milk, soymilk, or changes in raw milk composition based on dairy feeding practices. Still others focused on public health risks that were not relevant to the U.S. such as tick-borne encephalitis in milk, which is currently only a concern for central and eastern European countries. This last set of articles could have been included, as they could potentially become risks of U.S. milk consumption in the future.

The remaining 347 articles considered relevant to the charge given by the Maryland House of Delegates were further separated into categories. These categories included non-bovine/non-fluid milk, public health benefits, and public health risks. Complete information on these sub-categories is available in **Appendix B**. As mentioned above, we restricted our review's scope to direct comparisons of public health concerns for raw and pasteurized bovine fluid milk. Of the 172 articles within this scope, some were not reviewed because it was difficult or impossible to access the article or because the article had not been translated into English. A total of 48 were therefore additionally excluded. Finally we restricted our review to articles published in the last 15 years. After all exclusions, 81 articles were fully reviewed (list available in **Appendix C**). **Figure 1** depicts our review process.

Two additional articles that were not returned by our search but were frequently referenced by papers retrieved were also included in our review (Langer et al. 2012; Latorre et al. 2011).

Some of the reviewed articles also mentioned nutrients and other milk components. While these topics were not in our scope, details from these articles were included in our review. Some fully reviewed articles were determined to be outside of our aforementioned scope or were articles from magazines and other non-peer-reviewed sources that simply reiterated information from other primary scientific articles. These articles are therefore not mentioned in the following results.

Our review of the included articles is organized into the following sections: outbreak reviews, microbiological hazards in milk, allergies, lactose intolerance, and milk consumption, non-microbial hazards in milk, and other public health risks, and milk nutrition.

Outbreak reviews

Almost every article reviewed on the topic of milk-related outbreaks directly stated that pasteurization substantially reduces the risk of microbial contamination and should always be strongly recommended or required (e.g. (Langer et al. 2012) (Lejeune and Rajala-Schultz 2009) (Gould et al. 2014) (David 2012)). Many studies have investigated microbial risks by reviewing outbreaks of infectious intestinal diseases reported to health agencies in the United States and other countries. As infections from pathogenic bacteria and viruses are sporadic, epidemiologists rely on determining causes of outbreaks through retrospective analyses of surveillance data. (Langer et al. 2012) provides one of the most extensive reviews of outbreaks from both nonpasteurized and pasteurized dairy products. This article identified 121 outbreaks from 1993-2006 associated with dairy products through the Centers for Disease Control and Prevention's (CDC) Foodborne Disease Outbreak surveillance system. 60% of these outbreaks were from nonpasteurized dairy products. Only 36% of total cases (i.e. infected individuals) from all the outbreaks were from nonpasteurized dairy products, but among these cases there was a higher proportion hospitalized; 13% as opposed to the 1% hospitalization rate from pasteurized dairy product cases. Individuals affected by nonpasteurized outbreaks were more likely to be young children and to reside in states that permit the sale of nonpasteurized milk. The authors found that half of the pasteurized dairy product outbreaks were caused by norovirus, a pathogen with a human reservoir and therefore likely contaminated products post-pasteurization. This study highlighted the high proportion of nonpasteurized outbreaks, especially considering that consumption rate of nonpasteurized dairy products ranges from 1-3.5% of all dairy products. The authors estimate that the relative risk of individual illness is almost 150 times greater per unit of nonpasteurized dairy product, compared to pasteurized.

Similar findings were observed in other reviews of outbreaks. (Lejeune and Rajala-Schultz 2009) mentions numerous additional raw milk outbreaks reported to the CDC since 2006. (Newkirk et al. 2011) looked at U.S. milkborne outbreaks from 1990-2006 and found that 55.4% of the 83 outbreaks were associated with unpasteurized milk. (Oliver et al. 2009) found that from 2000-2008, 8 of 10 U.S. milkborne outbreaks were due to consuming raw milk. (Leedom 2006) mentions a study that reviewed 23 foodborne outbreaks from 1980-1982 caused by *Campylobacter* species; 14 were associated with raw milk. (Gillespie et al. 2003) reported milkborne outbreaks in England and Wales from 1992-2002. Fifteen of the 27 outbreaks during this time period were from unpasteurized milk, mostly due to *Salmonella* species, *Escherichia coli* strain VTEC O157 and *Campylobacter jejuni*. Finally, (De Buyser et al. 2001) reviewed reported outbreaks from France, U.S., Finland, Netherlands, UK, Germany, and Poland. Of the 22 milkborne outbreaks considered, 10 were from raw milk, and of the 27 cheese-associated outbreaks, 21 were from cheese made from raw milk.

When considering these outbreak reviews, it is important to emphasize the difference in consumption rates of raw and pasteurized dairy products. As only a small fraction of U.S. and European populations consume raw dairy products, the proportion of associated illnesses is considerably large. While nothing short of a clinical trial could remove all the potential confounding that underscores any outbreak review, these studies do indicate that raw milk carries a substantially larger risk of pathogenic microbial contamination and subsequent human illness, when compared to pasteurized milk.

Microbiological hazards in milk

(Grant et al. 2002a) conducted a survey of bacteria prevalence in milk samples in the United Kingdom from 1999-2000. Investigators surveyed 258 of the 754 approved dairy processing plants in the UK for bulk raw and pasteurized milk. Analysis of samples revealed that raw milk had far higher prevalence of coliforms, *E. coli*, and *Listeria* species. A few bulk raw milk samples also contained the pathogenic *E. coli* strain O157, as well as *Salmonella* and *Campylobacter* species; almost none were detected in pasteurized milk.

A study performed in Italy investigated bacterial levels in raw milk purchased from vending machines (Tremonte et al. 2014). The Italian Ministry of Health requires that raw milk purchased from vending machines be stored at 4°C for no more than 72 hours, and should be boiled before consumption. This study showed that total bacteria increased significantly in raw milk during the 72hrs of storage at 4°C. Boiling was able to sanitize the milk, resulting in undetectable bacterial counts. Interestingly, microwaving the milk at 900 watts for 75 seconds also sanitized the milk to undetectable microbial levels, but did not recapitulate the drastic loss of whey protein that results from boiling. This study draws attention to heating milk as important for sanitation, but suggests that microwave treatment should be investigated as an alternative to boiling (Tremonte et al. 2014).

Although outbreak records and microbial milk analyses are useful, it is still difficult to precisely quantify the bacterial risk of consuming raw versus pasteurized milk. A recent study by (Giacometti et al. 2012) attempted to address this by performing a quantitative microbial risk assessment for campylobacteriosis, caused by *Campylobacter jejuni,* and for hemolytic uremic syndrome (HUS), caused by verocytotoxin-producing *E. coli,* from consuming bottled raw milk in northern Italy. The investigators performed a full exposure assessment, from milking to consumption, considering variation in refrigeration, storage, and heating of raw milk. The investigators found that there was annual risk equivalent to 1-2 cases of campylobacteriosis and 0.01-0.02 HUS cases for every 10,000-20,000 consumers. The investigators were confident that the overall risk would increase if the entire population of Italy was considered, and estimated that 2-11 cases of HUS caused by consuming raw milk occurred in the country between 2007-2011.

The FDA performed a similar risk assessment for *Listeria monocytogenes* in multiple ready-to-eat foods (Whiting et al. 2003). When directly compared, unpasteurized milk had almost a 7 times greater risk of infection per serving than pasteurized milk, although this difference was not statistically significant. However when considering the frequency of consumption, far more listeriosis cases were estimated annually for pasteurized milk than for unpasteurized milk (90.8 vs. 3.1). This calculation was made assuming that raw milk accounts for only 0.5% of all fluid milk consumed in the U.S., and the authors noted that the number of cases attributed to raw milk would increase substantially if raw milk was more frequently consumed. A recent publication updated this risk assessment and calculated a significantly lower overall risk for raw milk, but also found that, when compared to pasteurized milk, the risk per serving was ~117 times greater (Latorre et al. 2011).

A number of specific pathogenic bacteria were examined in other articles; they are discussed below. Please note, when we refer to “genetic material,” there is no proof an actual living microorganism was present. For example, microbial genetic material can still be found after heat-treatment has killed a pathogen in milk. Although live bacteria are able to be detected, it is done using other methods not involving genetic material.

Listeria monocytogenes is a gram-positive aerobic non-spore-forming bacterium. Although rare, listerial contamination of dairy products can cause serious illness. These bacteria can thrive in refrigeration temperatures (4°C) and can lead to listeriosis, bacteremia, meningitis, and death for fetuses, children, the elderly, and the immune-compromised. (Baek et al. 2000) reported that in a survey of food products in South Korea, 4.4% of raw milk products were contaminated with *Listeria* species genetic material, while none were found in pasteurized milk and cheese. This study also mentions that *Listeria* species have been found in pasteurized milk in other countries, for example 1.1% of samples in a United Kingdom survey, but that these were likely due to post-pasteurization contamination. (Mathew and Ryser 2002) investigated growth of *Listeria* bacteria that was artificially added into raw and pasteurized milk. The authors found the bacteria were much less likely to grow in raw milk, possibly because of the competing microflora. Another study reported similar results, where four different strains of *Listeria monocytogenes* were artificially incubated in raw or pasteurized milk for 24 hours at 4°C (Pricope-Ciolacu et al. 2013). These strains displayed improved virulence when incubated in pasteurized milk, and decreased virulence when incubated in raw milk. These results indicate that the milk environment can impact the virulence of this pathogen, and underscores the importance of preventing post-pasteurization contamination.

Escherichia coli are gram-negative bacteria commonly found in the intestines of birds and mammals. Only a small subset of this group of bacteria is pathogenic to humans (e.g. *E. coli* strain O157). For European children under the age of 3, this strain of *E. coli* has caused illnesses solely from drinking raw milk (Baars 2013). While pasteurization will kill all *E. coli* bacteria, (Peng et al. 2013) investigated whether subpasteurization, or "thermization", would still be effective in order to retain the claimed health benefits of raw milk. The authors found that thermization did not kill all *E. coli* but, but no pathogenic *E. coli* survived. (Alhelfi et al. 2012) showed that contaminated milk, whether raw or pasteurized, will see proliferation of *E. coli* O157 if allowed to reach room temperature for 2 hours, reemphasizing the need to properly store milk at refrigeration temperatures. (Massa et al. 1999) also found that storing contaminated raw milk at 8°C, for 1-2 weeks allows *E. coli* O157 to survive and even proliferate.

Campylobacter jejuni are gram-negative bacteria that are ubiquitous throughout the environment. They can be present in milk due to fecal contamination during milking or through mastitis in udders. These bacteria can cause campylobacteriosis and in some cases Guillain-Barré syndrome. (Doyle and Roman 1982) inoculated *C. jejuni* bacteria into unpasteurized and pasteurized milk. The authors found that *C. jejuni* bacteria levels decreased more rapidly in unpasteurized milk than pasteurized, most likely due to competing microflora. The authors do note the need to pasteurize milk, as *C. jejuni* can be found in unprocessed milk.

Yersinia entercolitica can grow at refrigeration temperatures. Although they are usually not a concern, they can cause gastroenteritis in susceptible populations such as children. (Soltan-Dallal et al. 2004) found that 1.6% of raw milk samples from northern Iran tested positive for *Y. entercolitica* genetic material while none of the HTST pasteurized milk samples tested positive.

The investigators recognized that other studies have found these bacteria in pasteurized milk samples, but this was usually a result of post-pasteurization contamination.

Helicobacter pylori are common parasite infections in humans, usually acquired during childhood from a variety of sources including drinking water and unpasteurized sheep's milk. (Fujimura et al. 2002) collected bovine milk samples across Japan and found 72.2% of raw bovine milk and 55% of pasteurized milk contained genetic material for the parasite. However, investigators could only isolate live *H. pylori* in one raw milk sample. The investigators concluded that *H. pylori* could not survive pasteurization, but that post-pasteurization contamination is possible.

Staphylococcus aureus bacteria cause a large number of human infections and can be found throughout the environment. Food handlers and animals can act as reservoirs, and the bacteria can cause mastitis in cows. (Rodriguez-Rubio et al. 2013) assessed the effectiveness of exogenous lytic enzymes to act as antimicrobials on these bacteria in milk. They found the enzyme CHAPSH3b was particularly effective at destroying these bacteria, more so in raw milk than pasteurized milk. The investigators concluded this was because high temperatures destroyed CHAPSH3b and thus recommended that the enzyme only be included after pasteurization of milk was complete.

A type of bacteria known as *Mycobacterium avium* subspecies *paratuberculosis* (MAP) raised some concerns during the 2000s. MAP bacteria can cause a chronic gastrointestinal illness in cattle known as Johne's disease, and there is currently an unresolved association between MAP and Chron's disease in humans. A number of studies have evaluated the presence of MAP in raw and pasteurized milk. Two systematic reviews of the MAP literature found mixed findings, but overall observed that while pasteurization can inactivate MAP, viable bacteria can still be found in milk after pasteurization (Eltholth et al. 2009; Waddell et al. 2008). Five articles in our review found MAP genetic material in pasteurized milk, but no viable bacteria (Ayele et al. 2005; Gao et al. 2002; O'Reilly et al. 2004; Skovgaard 2007; Stabel 2000), while three studies were able to detect viable MAP bacteria in pasteurized milk (Gao et al. 2002; Grant et al. 2002b; McDonald et al. 2005).

Another *Mycobacterium* species, *M. bovis*, can cause tuberculosis in cattle and in humans drinking contaminated milk. (de la Rua-Domenech 2006) notes that while pasteurization prevents against such risky contamination, there is a growing concern as raw milk consumption increases in the United Kingdom. The author concludes that more rigorous cattle inspections will be required to mitigate the growing risk. Fortunately, in the early 20th century great efforts were made to remove *M. bovis* from U.S. cows and these bacteria rarely found in U.S. milk today (Lejeune and Rajala-Schultz 2009). However if the bacteria species again invaded U.S. cattle, the risk of tuberculosis from consuming raw milk would rise significantly. (de Kantor et al. 2010) noted recent outbreaks of *M. bovis* in parts of San Diego, California, but these were likely due to eating unpasteurized soft cheeses imported from Mexico.

Arcobacter species are considered emerging enteropathogens, with *A. butzleri* being the most prevalent. These bacteria produce similar symptoms to campylobacteriosis but are more persistent in the natural environment. (Giacometti et al. 2014) studied growth and survival of *A. butzleri* and *A. cryaerophilus* that were added "post-processing" to raw, pasteurized, and UHT milk and were then stored for six days. They found at refrigeration temperatures that both species remained viable in all types of milk. At room temperature, *A. butzleri* levels increased in pasteurized and UHT milk but became non-viable in raw milk. The authors note that this decrease of these bacteria in raw milk was likely due to competition from other microflora. However, since storing milk at room temperature is never recommended these findings are not relevant. The authors concluded that contamination is mostly a concern during "post-pasteurization" as effective pasteurization will likely remove most if not all *Arcobacter* species.

Aeromonas bacteria cause gastroenteritis, and are commonly isolated from a variety of food products. These species are able to grow at refrigeration temperatures, thus posing a threat to human health if present in milk. (Melas et al. 1999) tested many raw and pasteurized milk samples from Northern Greece, and found that 40% of raw milk samples were positive for live *Aeromonas* bacteria, including *A. hydrophila*, *A. caviae*, and *A. sobria*. *Aeromonas* species were not detected in any pasteurized milk samples.

Coxiella burnetti are found worldwide and can cause an illness commonly referred to as "Q fever". While these bacteria are mostly a hazard for individuals in direct contact with farm animals, there is some concern about exposure through raw milk. However the CDC considers this exposure rare. (Eldin et al. 2013) tested raw, thermized, and pasteurized milk for presence of *C. burnetti* genetic material and then tested potential cultures in mice via oral exposure. There were significantly more raw milk samples with the bacteria's genetic material, although some pasteurized milk still tested positive. However none of the mice in the study displayed any illness. The authors consider that pasteurization likely kills *C. burnetti* but may not completely remove its harmless genetic material.

Certain types of bacteria are able to form endospores, a dormant state where bacteria are resistant to extreme conditions such as heat. Endospore-forming bacteria include *Bacillus*, *Paenibacillus* (De Jonghe et al. 2010; Huck et al. 2007; Scheldeman et al. 2004), and *Clostridium botulinum* (Lindstrom et al. 2010). The bacteria genus *Bacillus* contains several pathogenic species. (De Jonghe et al. 2010) detected heat-resistant toxins from *B. amyloliquefaciens* and *B. subtilis* in raw milk, which can cause food poisoning. (Banyko and Vyletelova 2009) found similar concentrations of *B. cereus* and *B. licheniformis* in raw and pasteurized milk, and based on genetic fingerprinting determined that most contamination is occurring at points post-pasteurization for pasteurized milk. In (Huck et al. 2007), investigators isolated some of the same strains of *Bacillus* and *Paenibacillus* bacteria in both pasteurized and raw milk, suggesting that these bacteria are not killed during HTST pasteurization. Some *Paenibacillus* strains have even been isolated from UHT-pasteurized milk (Scheldeman et al. 2004).

There is a growing concern that milk, due to its wide distribution, storage in bulk tanks, rapid shelf life, and high consumption rates among humans, could be a prime target for bioterrorist attacks. (Newkirk et al. 2011) discusses this topic at length and mentions the potential for very potent pathogens such as *Clostridium botulinum* bacteria, which produce both endospores and deadly neurotoxins, to be used as a weapon. While these bacteria are not commonly found in milk, there are concerns they could be intentionally introduced as part of a bioterrorist plot. (Weingart et al. 2010) found that HTST pasteurization of raw milk removed 99.99% of isolated botulism neurotoxins and 99.5% of the neurotoxin complexes, the latter being the more dangerous form. (Perdue et al. 2003) grappled with the possibility of an anthrax attack on the milk production system. Anthrax is an infection spread by endospores from *Bacillis anthracis*. This study showed that anthrax spores are highly heat resistant. Two rounds of pasteurization could kill most spores, but up to 1% survived. These investigators determined that while pasteurization certainly seems to reduce the threat of an intentional outbreak, it would not prevent it. However these investigators note that failing to pasteurize bulk tank milk could significantly elevate the risk of an effective and potentially life-threatening bioterrorist attack.

An important problem in public health is the increasing prevalence of antibacterial resistance. Antibiotics are widely administered to dairy cows to prevent mastitis, which may result in bacteria developing drug resistance in our dairy products. Many of the antibiotics used in animals are the same ones used to treat infections in humans. Therefore, human diseases caused by these resistant bacteria could not be treated with conventional drugs. (Manie et al. 1999) characterized the prevalence of antibiotic resistant bacteria in pasteurized and raw milk samples in South Africa. When looking at total aerobic bacteria, a higher level of tetracycline resistance was seen in raw milk than in pasteurized milk. However, resistance to oxacillin, vancomycin, and methicillin were higher in pasteurized milk than in raw milk. The authors state that the bacteria detected in pasteurized milk may be due to post-pasteurization contamination. The mixed results from this study do not lead to a conclusion regarding the risks of raw versus pasteurized milk, but this study highlights important issues regarding antibiotic resistant bacteria. While another article claims the risk of antibiotic-resistant bacteria is currently not a concern for dairy products, the authors also argue that, if resistance began to occur on dairy farms, there would be a much greater concern for individuals consuming raw milk (Oliver and Murinda 2012).

Allergies, lactose intolerance, and milk consumption

In recent years there have been claims that drinking raw milk can attenuate the effects of lactose intolerance. However, studies have shown that pasteurization does not substantially change the lactose content in milk (Ijaz 2013; Lejeune and Rajala-Schultz 2009). Recently a group of researchers undertook a randomized control pilot study to observe the effects of raw milk on lactose intolerance and malabsoprtion (Mummah et al. 2014). The study compared 16 adults who each drank organic raw whole milk, organic pasteurized whole milk and plain soymilk over different intervals of time. Study participants were blinded to the milk they were drinking and the order of drinks was randomized for each participant. Individuals drinking raw milk unexpectedly showed higher lactose malabsoprtion (i.e. greater hydrogen excretion during a breath test) when compared to pasteurized milk. Furthermore, self-reported symptoms of lactose intolerance were not significantly different between raw milk and pasteurized milk. The authors concluded that raw milk does not reduce lactose intolerance, but recommended that additional studies with larger study groups should be conducted.

There have also been claims that raw milk consumption protects against the development of allergies. A meta-analysis of the literature on this topic supports these claims (Macdonald et al. 2011). The most interesting and compelling of these works was a case-control study on school-age children residing in rural areas of Germany, Austria, and Switzerland (Loss et al. 2011). Investigators used a questionnaire, took milk samples from a subset of participants' homes, and directly assessed the prevalence of asthma, atopy, and hay fever among the participants. Raw milk consumption had a substantial and statistically significant inverse association with all three allergic conditions when compared to pasteurized milk (usually UHT). From milk samples the researchers found that the inverse association with asthma was related to higher whey protein, lactalbumin, and lactoglobulin concentrations in raw milk. Total fat content and viable bacteria concentrations had no relationship to any of the allergenic conditions. While this study may suffer from selection bias, and does not measure life-long exposure to raw and pasteurized milk, its findings are significant and warrant further study. Future comparisons of allergic conditions comparing UHT milk with lower temperature pasteurized milk would also be informative.

Another article reviewed other studies investigating the relationship between unprocessed cow's milk and childhood allergies (von Mutius 2012). Two studies in different populations showed similar associations to (Loss et al. 2011). One report found higher immunoglobulin E (IgE) in cord blood from mothers who drank boiled milk during pregnancy as opposed to those who drank unboiled raw milk. This study also found higher toll-like receptor (TLR) expression in infants of mothers who drank unboiled milk. These findings support a more subdued autoimmunological response, which could explain the reduced allergic reactions observed in the children exposed to raw milk (von Mutius 2012). (Baars 2013) & (Perkin 2007) describe small epidemiological studies that have found similar trends. While the findings from these epidemiological studies are compelling, their results have been heterogeneous, with varying associations of raw milk and allergic symptoms (e.g. asthma, atopy, allergenic rhinitis, etc.). The reasons for this heterogeneity are still unclear.

These epidemiological findings have spurred experimental studies that further investigate how milk composition affects immunological responses. Heat treatment of milk can simultaneously denature some protein structures and aggregate or create others (Baars 2013). One recent study examined caseins and whey proteins from cow's milk given to mice (Shandilya et al. 2013). Mice were injected with raw, pasteurized, or sterilized (heated to 120 °C for 20 minutes) milk. Mice exposed to pasteurized milk had more IgE and IgG in the serum, while those exposed to raw or sterilized milk did not. The authors believed these observations were related to changes in the structure of caseins and whey proteins. These findings may be related to milk content associations with allergies found in (Loss et al. 2011) and (von Mutius 2012).

This biological pathway, however, is not consistently observed. In a recent study, mice were fed water, raw milk, UHT milk, or gamma-sterilized milk, which kills viable bacteria but will not alter protein content (Hodgkinson et al. 2014). Mice fed raw milk had a relatively higher IgE response as well as higher mast cell and interleukin-10 concentrations than mice fed pasteurized milk. Most importantly, mice fed raw milk had the most severe allergen response of all experimental groups. These mice however were exposed for only a short period of time, and the high interleukin-10 concentrations observed may indicate that allergic regulation occurs after long-term exposure to raw milk. Interestingly, this study also showed that mice fed raw milk had more active immune responses than those fed gamma-sterilized milk, implying that viable bacteria, and not proteins, are the more important components of raw milk. The importance of microbial diversity in milk has also been hypothesized elsewhere (Baars 2013). Other research has focused on the role of fatty acids, and that homogenization or dairy-farming factors independent of pasteurization may have a significant influence on allergic responses (Baars 2013; Perkin 2007). More research is needed to better understand the relationship between raw milk and allergies.

It is important to note that the epidemiological studies in this section were almost always limited to rural populations. Since individuals living on farms are the most frequent consumers of raw milk, it is not certain whether these findings can be extrapolated to children who live in more urban settings. Children living in rural areas are usually directly or indirectly exposed to farm animals, which may be associated with lower prevalence of allergies (Loss et al. 2011). Urban residents who have little or no contact with farm animals may have a qualitatively different immunological response to raw milk consumption. To our knowledge, such a population has yet to be evaluated to address this research question.

Furthermore, every article we reviewed that evaluated the relationship of raw milk to allergies or lactose intolerance cautioned against consuming raw milk. The authors of each of these studies recognize that the potential exposure of pathogenic microbes in raw milk may be far more harmful than any possible benefits raw milk may provide. Some of the authors state that this line of research will be most helpful by identifying the components of raw milk that are beneficial to reducing allergies. These authors believe this information can be used to determine a way to process milk that maintains these components while still removing hazardous pathogens.

Non-microbial hazards in milk and other public health risks

Only a few articles focused on non-infectious or allergy-related public health risks. One study looked at concentrations of estrogenic hormones in milk. Estrogen is naturally secreted in lactating cows. One study found that concentrations of estrogen in raw and pasteurized milk were related to cow pregnancy status, with cows in their third trimester secreting the most estrogen (Malekinejad et al. 2006). Estrogen concentrations were also associated with the fat content of the milk, with whole milk containing more estrogen than skim milk. Raw milk did have significantly higher concentrations of estrogen than pasteurized milk, but only in autumn samples, which may imply a seasonal effect in hormone secretion. Another article considered antibiotics in milk (Oliver and Murinda 2012). Antibiotics are usually given to cows to prevent mastitis. The article states that higher residues of antibiotics are found in raw milk, and that pasteurization will reduce concentrations. A smaller, recent study of antibiotic residues in animal products found very low levels of tetracycline antibiotics in two of three analyzed pasteurized milk samples (Baron et al. 2014); the same study noted low-level residues of acetaminophen in all pasteurized milk samples tested. Another study performed a meta-analysis on the association of raw milk consumption and the risk of cancer, however no association was found (McDonald et al. 2005). Evidence of raw milk having protective effects on diabetes, osteoporosis, and arthritis incidence is also lacking (Ijaz 2013).

Milk nutrition

As stated above, articles devoted solely to comparing the nutritional content of raw versus pasteurized milk were not considered. Some articles, however, did mention nutrition along with public health risks and are summarized here. One review article provided a summary of previous nutrition literature (Lejeune and Rajala-Schultz 2009). Lactoferrin and lysoszymes, milk proteins that can prevent bacterial proliferation, do not significantly differ between raw or pasteurized milk, and only slight differences are found when milk is HTST or UHT pasteurized. Bovine immunoglobulins as well as oligosaccharides and bacteriocins, all of which can prevent bacterial infections, were not different between pasteurized and raw milk samples. However, lactoperoxidase, a bacteriostatic enzyme, was reduced by 30% when pasteurized, and concentrations decreased after higher-temperature pasteurization.

Both the review above and a meta-analysis study compared the vitamin concentrations in raw versus pasteurized milk (Lejeune and Rajala-Schultz 2009; Macdonald et al. 2011). Vitamins D, E and K do not appear to decrease substantially after pasteurization of milk. Vitamin A, of which milk is an important source, actually increased in concentrations after pasteurization. Vitamin B12 and E were found to significantly decrease after pasteurization, however milk is not considered an important source of either of these vitamins. Vitamin B2, also known as riboflavin, did have lower concentrations in pasteurized milk when compared to raw milk and this difference was statistically significant. While milk is a popular source of riboflavin and its loss in pasteurized milk is substantial, there are many other common foods that could supplement any potential vitamin deficiency in consumers of pasteurized milk.

Articles submitted by proponents

Proponents of the recent bill sent us a number of articles for consideration. Some of these have been included in the results above. Please see **Appendix D** for a complete listing of the articles we received as well as reasons we included or excluded these articles from our review. Many articles did not fit our pre-specified scope for our literature review, or did not compare raw and pasteurized milk. We also excluded information that came from non-peer-reviewed secondary sources, such as media outlets.

We would like to note that the research on the microbiome and its effects on human health is in its infancy and that there is no direct evidence to suggest that microbial exposures have a net benefit to the human health. While we agree there should be scientific investigations into the effects of milk on the human microbiome, we do not believe claims regarding the microbiome are currently scientifically relevant to raw milk (Ijaz 2013; von Mutius 2012).

Discussion

There are inherent risks in consuming both raw and pasteurized milk; pasteurization is not a sterilization technique and post-pasteurization contamination can occur (Lejeune and Rajala-Schultz 2009). The articles we reviewed, however, clearly suggest that the risk of microbial hazards in raw milk is substantially higher than in pasteurized milk. Further, raw milk is more likely to contain pathogens that are harmful to susceptible populations such as young children, the elderly, and individuals with chronic illnesses. Some of the articles we reviewed seem to imply that infection rates between raw and pasteurized milk are similar or are lower for raw milk. Such an interpretation however does not take into account the substantial differences in consumption frequency. Current estimates are that raw milk is consumed by no more than 3.5% of the U.S. population (Committee on Infectious Diseases and Committee on Nutrition of the American Academy of Pediatrics 2014; David 2012). If this proportion were to increase, then the number of infectious outbreaks caused by consuming raw milk would also rise. These infection rates would likely be greater than current rates for pasteurized milk.

Our results show that heat-treatment of milk creates no noticeable difference in lactose intolerance. Drinking raw milk early in life or during pregnancy, however, does seem to be associated with lower prevalence of allergies. The biological mechanism for this proposed relationship is still unclear, and may be due to whey proteins, bovine immunoglobulins, or microorganisms in raw milk (Hodgkinson et al. 2014; Melnik et al. 2014; von Mutius 2012). Each of the articles we reviewed from our database search that focused on this topic explicitly stated such results do not support drinking raw milk. Most of these articles also stated they do not recommend drinking raw milk, as the risk of microbial contamination is too serious.

A few articles reviewed the risks of other contaminants or changes in the nutritional value of milk. These findings were overall mixed and none demonstrated that raw milk had clear public health benefits compared to pasteurized milk.

Formally evaluating whether the public health benefits of raw milk "outweigh" any health risks would require a comprehensive risk assessment that included all potential hazards (i.e. every pathogenic microbe) as well as all potential health benefits. Ideally, this risk assessment would simultaneously compare the risks and benefits of pasteurized milk. No such analysis has been performed. To our knowledge, only one risk assessment of *Listeria monocytogenes* has formally compared raw and pasteurized milk, and this assessment admittedly had a high uncertainty (Whiting et al. 2003). Reviewing meta-analyses, such as the one performed by (Macdonald et al. 2011), are useful, but to our knowledge no meta-analysis has considered all health risks and benefits simultaneously.

Based on our review of the scientific literature, we believe that there is no scientific evidence supporting the claim that the benefits of raw milk outweigh any health risks. The risk of microbial contamination in food products is measurable, and has been a concern throughout recent times (Scallan et al. 2011). The sources of microbial contaminants have not diminished in the last century and the opportunity for new microbial contaminants resistant to antibiotics is real (Mendelson 2011; Oliver and Murinda 2012). Pasteurization has been shown to reduce the risk of almost all microbial and other contamination in milk products.

While a few studies have shown an interesting association between raw milk and reduced allergies, this has not been proven to be a causal relationship, nor has a biological pathway been confirmed (van Neerven et al. 2012). Further, the evidence implies that this association may only be observed if milk is consumed by pregnant mothers or young children, populations that are also very susceptible to infectious organisms sometimes present in milk. Changes in nutritional value due to pasteurization appear to be marginal and would only become a health concern if an individual were not consuming a well-balanced diet (Macdonald et al. 2011). From a health and safety perspective, it seems more appropriate to defer to pasteurizing milk rather than assume that the risk of microbial contamination is negligible.

Further scientific investigation of raw milk is warranted, ideally to identify the beneficial components of raw milk and how to preserve these during processing. Many of the articles that focused on public health benefits of raw milk such as (Loss et al. 2011) restricted their comparisons to HTST and UHT pasteurized milk. These intensive heat treatments can denature proteins in milk such as caseins and beta-lactoglobulin (Walstra et al. 2006), which have been identified as potential sources of reduced allergic reactions from drinking raw milk (Baars 2013). These modern types of pasteurization may also lead to the "cooked" flavor in milk that some find unpleasant (Walstra et al. 2006). Classic pasteurization (i.e. 63°C for 30 minutes), which is now uncommon in industrialized milk production, does not create such irreversible changes and so may still be able to maintain the healthy components of raw milk while removing harmful pathogens (Lejeune and Rajala-Schultz 2009; Walstra et al. 2006). We believe future studies should compare health benefits of raw milk with milk that is mildly pasteurized. Homogenization is also not required for pasteurization and forgoing it could also help retain beneficial components of milk, such as caseins and whey proteins (Ijaz 2013; Perkin 2007; von Mutius 2012). There are also other forms of milk processing, such as food irradiation, high pressure, carbon dioxide, and filtration, which can be as effective as pasteurization at removing pathogens but do not require heat treatment (Elwell and Barbano 2006; Loaharanu 1996; Ruiz-Espinosa et al. 2013). Whether these varying food safety techniques also alter the claimed health benefits of raw milk should be further investigated.

It is important to reiterate the systematic differences between most raw and pasteurized milk production in the U.S. and how they complicate the public health argument for one or the other (Mendelson 2011). Today most pasteurized milk is produced at an industrial scale, with farms containing thousands of cows fed corn and soy predicts, and milk sent to dairy processing plants in bulk tanks. Dairy farmers at these industrial farms have the opportunity to be more lax about hygienic practices. Further, the potential for cross-contamination of milk before or after pasteurization is substantial due to these potential factors: a large number of workers, biofilms in distribution pipes, and unsterilized equipment (Mendelson 2011; Oliver et al. 2005).

On the other hand, milk that is intentionally sold unpasteurized is often produced on small farms with grass-fed cows and sold to local consumers (Baars 2013). While hygienic practices are not ensured in this setting, these farmers may be more concerned for each individual animal's health and the health of their customers. They thus may strive to prevent microbial or other contamination. We believe in the benefit of consuming milk and other food products on a local scale, as it is both environmentally sustainable and can support the local economy. We also recognize this can be difficult to achieve given the stringent FDA standards of milk production and processing. We are convinced, however, that there are opportunities for small-scale farmers to feasibly provide milk that is free of microbial contaminants. Such options could include: purchasing and maintaining co-operative pasteurization equipment, implementing other food safety processing techniques mentioned above, maintaining strict hygienic standards for cows and workers, and performing microbial tests on milk intended for consumption (Baars 2013).

We believe that our report provides an unbiased comparison of the public health literature on raw and pasteurized milk. While we understand the position of raw milk advocates about the low number of reported foodborne illnesses caused by raw milk, we believe they take an important misstep by failing to account for the low prevalence of raw milk consumption in the United States. If consumption of raw milk increased, then the number of illnesses would quickly outpace those attributed to pasteurized milk. Even more illnesses would occur if raw milk was sold using the aforementioned industrialized production system, as has been seen in California (Garber 2008). Advocates also claim that raw milk may actually be safer than other non-dairy food products, as fewer illnesses are reported or estimated (Ijaz 2013). While there may be some validity in this statement, one must take into account the severe underreporting of all foodborne illnesses including those from pasteurized and raw milk, as well as the high frequency of milk consumption. It is believed that the number of individuals actually succumbing to foodborne illness from consuming raw milk is likely far higher than the numbers reported in outbreaks (Scallan et al. 2011).

We would be remiss to ignore in this review the continuing disagreements of raw milk proponents and federal regulatory agencies (Mendelson 2011). While we understand the positions of both groups, we strongly believe that both parties would gain much by being willing to discuss and compromise on their positions.

In conclusion, given the scientific evidence, we do not recommend the consumption of raw milk. If raw milk sales became legal in Maryland, we would strongly recommend that a labeling system be implemented and that farm safety and hygienic practices be required. We would also recommend restricting pregnant women and children from drinking raw milk due to their increased susceptibility to microbial hazards.

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Temperature	Time (s)
63°C (145°F)	1800
72°C (161°F)	15.0
89°C (191°F)	1.0
90°C (194°F)	0.5
94°C (201°F)	0.1
96°C (204°F)	0.05
100°C (212°F)	0.01

Table 1. Temperature and time combinations for fluid milk pasteurization approved by the U.S. Food and Drug Administration. Adapted from (Lejeune and Rajala-Schultz 2009).

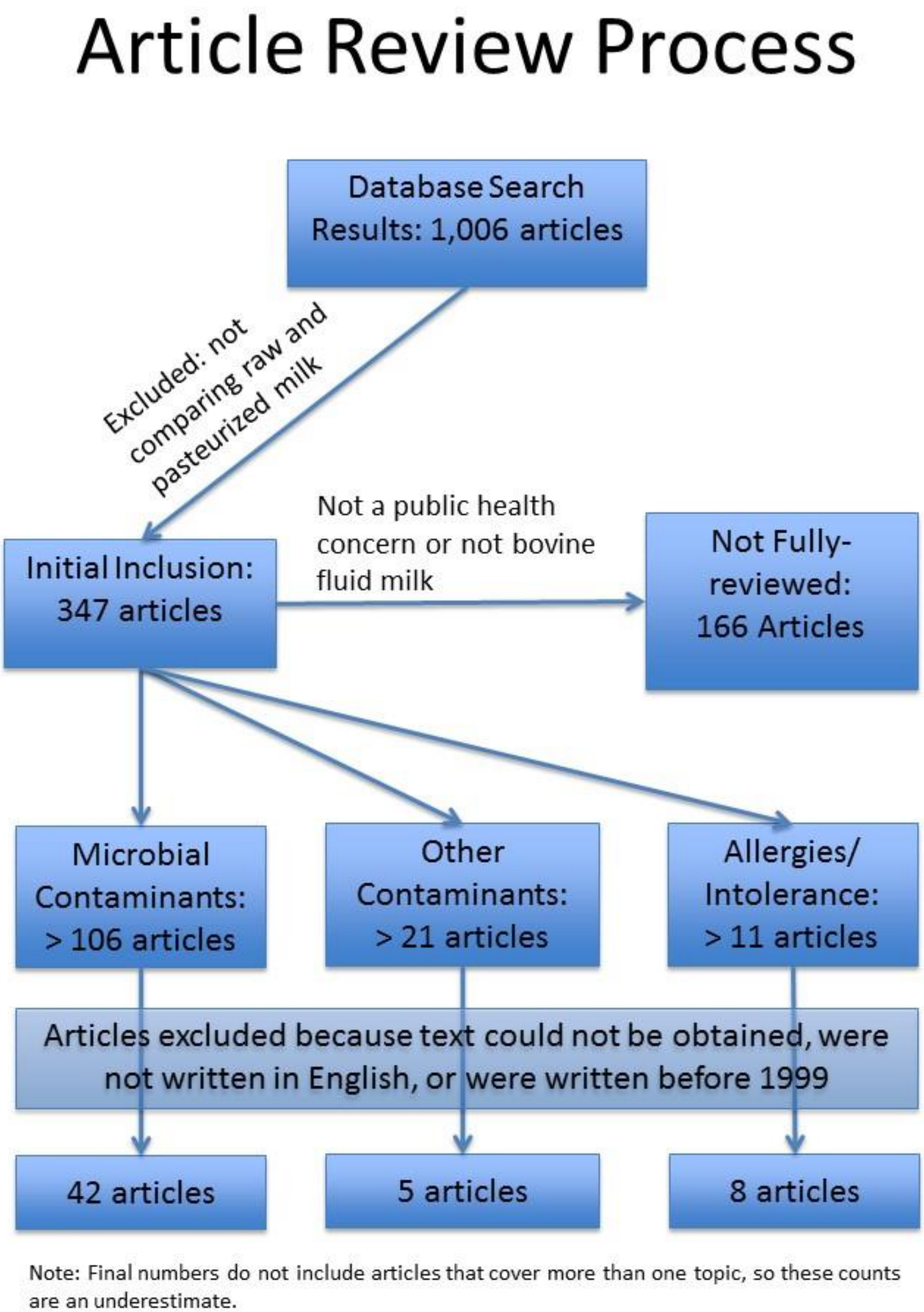

Figure 1. Database search review process

Appendices

***Appendix A**: Search terms for the PubMed database*

("Pasteurization"[Mesh] OR Pasteuriz*[tw] OR Pasteuris*[tw] OR boiled[tw] OR boiling[tw] OR "Sterilization"[Mesh] OR steriliz*[tw] OR sterilis*[tw] OR UHT[tw] OR Ultra-high-temperature[tw] OR processed*[tw] OR microwaved*[tw])

AND

(raw[tw] OR unpasteuriz*[tw] OR unpasteuris*[tw] OR unsteriliz*[tw] OR unsterilis*[tw])

AND

("Milk"[Mesh] OR milk[tw] OR "Dairy Products"[Mesh] OR Dairy[tw])

***Appendix B**: List of categories created for articles "initially included"*

Categories in which articles were fully reviewed (if text was available)

- Review articles (n=43): articles covered a broad range of topics comparing unpasteurized and pasteurized milk and dairy products.
- Microbial Contamination (n=106): Articles primarily focused on potential pathogenic bacteria presence and persistence in fluid bovine milk.
- Other Contaminants (n=21): Articles focused primarily on chemical and fungal contaminants in milk, such as antibiotics, metals, and aflatoxin.
- Allergies/Intolerance: Articles focused on the effects of milk (unpasteurized and pasteurized), usually atopic allergic reactions or lactose intolerance.

Categories in which articles were not considered for full review

- Developing Country Articles (n=35): Articles that focused, primarily on the adverse health effects of consuming raw milk in rural impoverished areas, most commonly in African and South/Central American countries. These articles were not considered due to the likely confounding of unhygienic practices in milking, distribution and storage when comparing raw and pasteurized milk.
- Outbreaks & Case-studies (n=26): Articles that focus on microbial outbreaks with dairy products being the vehicle of transmission. These articles did not directly compare raw and pasteurized milk.
- Microbiome (n=5): Articles that considered the potential benefits on intestinal microflora by consuming raw or pasteurized milk.
- Nutrition and Flavor (n=43): Articles that compared nutritional content and flavor structure of both raw and pasteurized milk.
- Shelf-life & Spoilage (n=8): Articles that compared how long unpasteurized and pasteurized milk could be stored.
- Cheese Health Risks (n=30): Articles that focused solely on the health risks (e.g. pathogenic microbial contamination) of consuming raw versus pasteurized cheese products.
- Cheese Health Benefits (n=10): Articles that focused solely on the health benefits (e.g. nutrition and flavor) of consuming raw versus pasteurized cheese products.
- Goat Milk (n=7): Articles that were restricted only to comparisons of raw versus pasteurized goat milk.
- Other Dairy products (n=2): Articles that focused solely on dairy products that were not fluid milk or cheese (e.g. buttermilk).

Appendix C: *List of articles fully reviewed from PubMed Database Search*

1. Child Health Alert. 2009. Unpasteurized milk--still a health threat. Child health alert 27:5.
2. U.S. Centers for Disease Control and Prevention.. 2013. Vital signs: Listeria illnesses, deaths, and outbreaks--united states, 2009-2011. MMWR Morbidity and mortality weekly report 62:448-452.
3. Committee on Infectious Diseases and Committee on Nutrition of the American Academy of Pediatrics.. 2014. Consumption of raw or unpasteurized milk and milk products by pregnant women and children. Pediatrics 133:175-179.
4. Alhelfi NA, Lahmer RA, Jones DL, Williams AP. 2012. Survival and metabolic activity of lux-marked escherichia coli o157:H7 in different types of milk. The Journal of dairy research 79:257-261.
5. Alisky J. 2009. Bovine and human-derived passive immunization could help slow a future avian influenza pandemic. Medical hypotheses 72:74-75.
6. Ayele WY, Svastova P, Roubal P, Bartos M, Pavlik I. 2005. Mycobacterium avium subspecies paratuberculosis cultured from locally and commercially pasteurized cow's milk in the czech republic. Applied and environmental microbiology 71:1210-1214.
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16. de la Rua-Domenech R. 2006. Human mycobacterium bovis infection in the united kingdom: Incidence, risks, control measures and review of the zoonotic aspects of bovine tuberculosis. Tuberculosis (Edinburgh, Scotland) 86:77-109.
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80. Ward TR. 2008. Daniel boone, yogi berra, the tsunami, and raw milk. Journal of environmental health 70:42-43.
81. Weingart OG, Schreiber T, Mascher C, Pauly D, Dorner MB, Berger TF, et al. 2010. The case of botulinum toxin in milk: Experimental data. Applied and environmental microbiology 76:3293-3300.

***Appendix D**: Articles Submitted by Bill Proponents*

Status	**Citations**
Included	
Found through original PubMed database search	(Doyle and Roman 1982; Loss et al. 2011; van Neerven et al. 2012)
Relevant to our literature review scope	(Baars 2013; Brown et al. 2012; Ijaz 2013; Perkin 2007; Walstra et al. 2006; Whiting et al. 2003)
Excluded	
Not related to milk	(Borody et al. 2014; Desch and Motto 2007; Ganguli and Walker 2011; 2012)
Limited to non-fluid dairy products	(Sanaa et al. 2004)
Limited to milk nutrition	(Haug et al. 2007; Oberleas and Prasad 1969; Patton 1999; Ward and German 2004; Zurera-Cosano et al. 1994)
Limited to cow treatment, not pasteurization	(Dhiman et al. 1999; Said et al. 1989).
Did not distinguish between raw and pasteurized milk	(Baker et al. 2007; Kothary and Babu 2001; Waser et al. 2007)
Not peer-reviewed literature	(Green 2014; Gumpert 2013, 2014; Hartke 2012; Michigan Fresh Unprocessed Whole Milk Workgroup 2012)

Testimony of

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Office of Food Safety

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Before the

Health and Government Operations Committee

Maryland House of Delegates

February 2, 2016

Honorable Chairman Hammen, Vice Chair Pendergrass, and Members of the Committee, thank you for the opportunity to submit written testimony in which we will discuss the public health and food safety concerns of consuming raw milk and the importance of pasteurization. There is and has been a lot of misinformation published or otherwise communicated by various parties to the general public at large about raw milk and pasteurized milk. We very much welcome this opportunity to discuss with this Committee the reality of the dangers of raw milk consumption and the safety and healthfulness of pasteurized milk consumption.

Much of what I will present here today has been stated previously in our testimony provided to several other states.

RAW MILK IS INHERENTLY DANGEROUS

Raw milk is inherently dangerous and may contain a whole host of pathogens including Enterotoxigenic *Staphylococcus aureus, Campylobacter jejuni* (*C. jejuni*), *Salmonella* species, *Escherichia coli (E. coli* O157:H7, Enterohemorrhagic *E .coli* - EHEC, Enterotoxigenic *E. coli* - ETEC*)*, *Listeria monocytogenes, Mycobacterium tuberculosis*, *Mycobacterium bovis* (*M. bovis*), *Brucella species* (*B. abortus* being mainly associated with cattle and *B. melitensis* being mainly associated with goats), *Coxiella burnetii* and *Yersinia enterocolitica* to name but a few. Incidence rates for the presence of these pathogens in raw milk reported in the literature are variable. As one might expect, there are variations in incidence rates between countries and even within regions of countries. There are also variations in incidence rates reported for the three main commercial milks (bovine [cow], ovine [sheep] and caprine [goat]). Van Kessel et al. (1)

reported in 2004 on the prevalence of *Salmonellae* and *Listeria monocytogenes* in bulk tanks on U.S. dairies. They reported a 2.6% incidence rate for *Salmonellae* and a 6.5% incidence rate for *Listeria monocytogenes*. They commented that "although the prevalence of these organisms was low, inappropriate handling of raw milk could result in bacterial growth and substantially increase the potential risk to consumers of raw milk and raw milk products." These incidence rates were reported even with very low standard plate counts (SPC, total bacterial counts) at <5,000 cfu's /ml (less than 5000 colony forming units per milliliter) being reported for the vast majority of samples analyzed for the pathogens. In 2008, Van Kessel et al. reported (38) that raw milk samples taken from farm bulk tanks had SPC's which ranged from 197 - 3,248 colony-forming units(CFU)/ml and coliform counts which ranged from 3-164 CFU/ml, indicating very high quality; yet 11% of all samples were positive for the presence of *Salmonella*. It is important to note these clear illustrations of the fact that a simple standard plate count (or "bacteria count") is not an indication of the safety of milk. A low standard plate count clearly does **not** mean that milk will be pathogen-free. Furthermore, even though Van Kessel et al. in 2004 characterized the incidence rate as "low," the mere possibility of *Salmonella* contamination often leads to food recalls even where *Salmonella* may not be present in all of the food recalled. For example, in 2009, hundreds of firms recalled products made with certain peanuts and peanut products because of the possibility that they may have been contaminated with *Salmonella*.

The notion that compliance with quality standards means that raw milk is safe is not a new notion. Indeed, that argument was made to FDA during the rulemaking process for 21 CFR 1240.61, which requires that all milk and milk products in final package form intended for direct human consumption that move in interstate commerce be pasteurized. In addressing that argument in the preamble to 21 CFR 1240.61, FDA stated, "supporters of certified raw milk pointed to standards such as total bacterial counts as proof of safety, but the high incidence of disease associated with certified raw milk is strong evidence that these standards are unreliable indexes of safety," and further stated that "In FDA's view, "certification" does not provide a reliable index of whether milk or milk products are contaminated with pathogenic bacteria," and finally "FDA concludes that the certification process alone provides no assurance that raw milk is free of *Salmonella* and other harmful organisms." *See* 52 Federal Register (FR) 29512.

As reflected in the preamble of 21 CFR 1240.61, FDA concluded in 1987 that the available record "demonstrate[d] an association between the consumption of raw milk and the outbreak of disease." *See* 52 FR 29511. FDA also found that the record demonstrated "an association between the consumption of certified raw milk and the outbreak of disease, particularly among consumers who are young, elderly, or infirm." *See* 52 FR 29511. As FDA noted at the time, its findings paralleled the conclusions of a study published in the Journal of the American Medical Association that "the role of unpasteurized dairy products, including raw and certified raw milk, in the transmission of disease has been established repeatedly." Particularly persuasive to FDA were statistics collected by the California Department of Health Services ("CDHS") on the incidence of *Salmonella dublin* ("*S. dublin*") infections. *Id.* at 29511-12. FDA summarized these statistics as follows:

"[CDHS] has reported that 50 percent of all the S. dublin infection cases reported in California in 1984 involved the use of certified raw milk. According to CDHS, no other risk factor has been prevalent among cases. For example, even though S. dublin is host adapted to cattle, only a small percent (15 percent or less) of cases report use of either lightly cooked or uncooked beef or beef products. CDHS concluded that the relative risk of contracting S. dublin is 158 times greater for those Californians who consume certified raw milk than for those who do not drink any form of raw milk. CDHS considered this relative risk extremely large and among the largest obtained in any epidemiologic investigation." Clearly, "certification" of raw milk is of no utility with respect to public health protection.

Many of the above-mentioned microorganisms can cause very serious, sometimes life altering and sometimes even fatal disease conditions in humans. With pregnant women, *Listeria monocytogenes*-caused illness can result in miscarriage, fetal death, or illness or death of a newborn infant. Enterohemorrhagic *E.coli* (EHEC) infection has been linked to hemolytic uremic syndrome (HUS), a condition that can cause kidney failure and death. If infected with EHEC, young children are particularly susceptible to contracting HUS as unfortunately has recently happened in this country.

Raw milk should not be consumed by anyone, at any time, for any reason. FDA's opinion in this matter is entirely consistent with that of the American Medical Association, which holds as policy the position that "all milk sold for human consumption should be required to be pasteurized" (H-150.980, Milk and Human Health). The aged, infirm, young and immuno-compromised are most at risk for severe infections from pathogens that may be present in raw milk.

Yet, oftentimes, we hear arguments made by raw milk advocates that these are the very people who should consume raw milk because of its alleged curative or medicinal properties. Claims that raw milk has miraculous disease-curing properties are not supported by the scientific literature. The scientific literature is, however, rife with reports of foodborne illness attributed to the consumption of raw milk, including an article by Werner et al. (2) which reported on the incidence of *Salmonella* Dublin infections in California between 1971-1975. During that time, the mean annual incidence of *Salmonella* Dublin infections in California increased five-fold. Investigations of the cases showed an association with raw milk consumption and that all of the implicated raw milk came from just one dairy. Eighty-nine of the 113 victims were hospitalized and 22 of them died. Almost half of the patients had serious underlying, non-infectious diseases such as leukemias and lymphomas. As we know, the immune system of such persons is often compromised as a result of the treatments they are receiving.

In 1997, Keene et al. (3) reported on a prolonged outbreak of *E.coli* O157:H7 which was caused by the consumption of raw milk sold at Oregon grocery stores. Outbreaks began in 1992 and continued until June of 1994. When the dairy that was the source of the raw milk was identified, it was discovered that 4 of the 132 animals in the herd were initially positive for *E.coli* O157:H7. Despite public warnings, new labeling requirements and increased monitoring of the culprit dairy, illnesses continued until June 1994, when retail sales were finally stopped. The authors concluded that without restrictions on distribution, *E.coli* O157:H7 outbreaks caused by raw milk consumption can continue indefinitely, with infections occurring intermittently and unpredictably.

Proctor and Davis (4) reported on *E.coli* O157:H7 infections in Wisconsin between 1992-1999. During that timeframe, there were 1,333 cases, even though the disease only became reportable in Wisconsin in April 2000. The highest age-specific mean annual incidence, at 13.2 cases per 100,000 population, occurred in children aged 3-5 years old. Among case patient identifiable exposures, consumption of raw milk/milk products was among the top three causes most frequently noted. Kernland et al. (5) reported on the causes of HUS in childhood in Switzerland. Among the causes was the consumption of raw milk, which resulted in the authors concluding that pasteurization of raw milk is likely to have a positive influence on the incidence of HUS. Allerberger et al. (6) reported on a specific incident in Austria in which two children contracted *E.coli* O157:H7 infection and subsequently developed HUS after consuming raw milk. The authors concluded that "it is prudent to remind them (parents and teachers) that children should not be given unpasteurized milk."

When one reads all of the literature available on the association between *E.coli* O157:H7, HUS and raw milk, one wonders whether children themselves would choose to drink raw milk if they knew that raw milk might make them very ill, cause them to lose their kidneys, or even kill them. Given a child's enthusiasm for life, I doubt very much that they would. Since children cannot and do not know about such matters, however, it is incumbent upon those of us who do know and are responsible for protecting them to ensure that the likelihood of their contracting foodborne disease from any food, including the milk that they drink, is an ever-diminishing prospect. Our collective actions should tend to make the food supply safer overall and not result in a lessening of the level of protection which we afford ourselves as a society.

Permitting raw milk sales or the operation of so-called "cow share" schemes to occur within any given jurisdiction will not result in the maintenance or further strengthening of our food safety systems. To the contrary, permitting such sales and schemes will inevitably result in an increased incidence of foodborne illness. Indeed, a farm operating a cow-sharing scheme in the state of Washington and which was engaged in the unlawful interstate distribution of raw milk, was determined to have produced milk which was adulterated with *E.coli* O157:H7 and to have caused an outbreak of foodborne illness. There were eighteen victims identified in that outbreak, which represented 13% of those who reported consuming raw milk originating from the culprit farm. Unfortunately, the median age of the victims was just 9 years. Five of these victims, aged between 1-13 years, were hospitalized and four of these unfortunate children developed HUS. Seventeen of the victims were farm "shareholders" or the children of "shareholders" and one other victim, a child of ten years of age, was a friend of a "shareholder". The Centers for Disease Control and Prevention (CDC) issued, on March 2, 2007, a report on this outbreak in its Morbidity and Mortality Weekly Report (MMWR). That MMWR report may be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a3.htm.

On the day of the publication of this MMWR, March 2, 2007, the state of Pennsylvania issued a press release announcing that a Pennsylvania farm engaged in the practice of selling raw milk had been determined to be responsible for an outbreak of Salmonellosis in that State. The CDC has since issued an MMWR describing the Pennsylvania outbreak in 2007. It may be found at http://www.cdc.gov/mmwR/preview/mmwrhtml/mm5644a3.htm .

An outbreak of foodborne illness involving *E.coli* O157:H7 also occurred in California in 2006. This outbreak was determined by California to likely have been caused by a dairy owned by a raw milk advocate. The evidence linking these illnesses to this dairy was strong enough to prompt California authorities to order the milk to be recalled. According to California authorities, all of the victims in this outbreak were children. FDA had previously issued a warning letter to this same dairy farm on February 24, 2005, for the unlawful distribution of unpasteurized milk, buttermilk, butter, cream and colostrum in interstate commerce, in finished form for human consumption, an action which is in violation of the Public Health Service Act, Title 42, U.S. Code, Sections 264 (a) and 271 (a) and Title 21, Code of Federal Regulations, Section 1240.61 (a). A copy of this warning letter is available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075299.htm .

E.coli O157:H7 is not the only pathogen of concern for the very young. Schmid et al. (7) reported on *Campylobacter jejuni* infections in Dubuque, Iowa over a twelve-month period. Forty-six of 53 victims participated in the case control study. Twenty-one of the 46 cases occurred in children less than ten years of age. The age-specific attack-rate was highest for children aged one to four years. Fifteen of the 46 had consumed raw milk in the week before the onset of their illness. Twelve of the 15 who had consumed raw milk were less than 10 years old. The authors concluded “eliminating the consumption of raw milk will depend on educational efforts.”

In order to protect the public health, raw milk should not be permitted to be sold for human consumption, nor should people be allowed to attempt to skirt laws banning direct raw milk sales by operating so-called “cow share” schemes. The CDC agrees with FDA in this regard. In the March 2, 2007, MMWR discussed above, CDC stated that “State milk regulations and methods for their enforcement should be reviewed **and strengthened** to minimize the hazards of raw milk" (emphasis added).

House Bill 79 which is now before this body for consideration would operate to weaken Maryland laws governing public health protection. House Bill 79 significantly relaxes the current regulation by permitting "distribution of raw milk and raw milk products from milk producers directly to the final consumer if the consumer has acquired an ownership interest in the animal or herd from which the raw milk is produced." Such animal or herd share operations, as described above, do not protect public health. Allowing any type of raw milk sales directly to consumers does increase the probability of serious harm occurring to Maryland consumers, especially children, the aged, infirm and immunocompromised, and this bill would actually increase the probability of a state-wide outbreak occurring within Maryland. House Bill 79 also would significantly distance Maryland's regulation of raw milk from the advice being given by the CDC, FDA, and many notable others. In a press release issued jointly by both CDC and FDA on March 1, 2007, the agencies noted that in addition to CDC and the FDA, "the American Medical Association, the American Academy of Pediatrics (AAP), the National Conference on Interstate Milk Shipments, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials and other organizations have endorsed the pasteurization of milk and prohibition of the sale of raw milk and products containing raw milk." On May 9, 2014, CDC (41) recommended, "To protect the health of the public, state regulators should continue to support pasteurization and consider further restricting or prohibiting the sale and distribution of raw milk and other unpasteurized dairy products in their states."

In the January, 2014 issue of *Pediatrics*, the AAP (39) published its updated policy statement regarding human consumption of raw milk: "In summary, the AAP strongly supports the position of the FDA and other national and international associations in endorsing the consumption of only pasteurized milk and milk products for pregnant women, infants, and children. The AAP also endorses a ban on the sale of raw or unpasteurized milk and milk products throughout the United States, including the sale of certain raw milk cheeses, such as fresh cheeses, soft cheeses, and soft-ripened cheeses. This recommendation is based on the multiplicity of data regarding the burden of illness associated with consumption of raw and unpasteurized milk and milk products, especially among pregnant women, fetuses and newborn infants, and infants and young children, as well as the strong scientific evidence that pasteurization does not alter the nutritional value of milk. The AAP also encourages pediatricians to contact their state representatives to support a ban on sale of raw milk and milk products."

It is not only the very young, the aged, infirm and immunocompromised that can fall victim to the pathogens which may be present in raw milk. Anyone can be a victim, including healthy young adults, as was reported by Blaser and Williams (8) when they described how 19 of 31 college students developed an acute gastrointestinal illness caused by *C. jejuni* infection after a visit to an Oregon farm. It was determined that 3 others had an asymptomatic infection. Twenty-two of 25 students who had consumed raw milk for the first time became infected.

Raw milk advocates have claimed that "it is not even clear that tuberculosis (TB) can be contracted from milk products." (Weston A. Price Foundation PowerPoint presentation available on-line entitled "Raw Milk and Raw Milk Products") These advocates are wrong. It is clear to the medical community, to scientists, food technologists and those otherwise familiar with milk and milk products and the history of pasteurization that TB can be contracted from raw milk and raw milk products. Prior to the advent of pasteurization, *M. bovis* was reported to cause between 6-30% of all TB cases in the United States. (Karlsen and Carr) (9). De la Rua-Domenech has also recently produced a very useful review on human *M. bovis* infections (10) which might be of further interest to this Committee.

STATISTICS ON DISEASE OUTBREAKS ASSOCIATED WITH RAW MILK OR RAW MILK PRODUCTS

In 2015, Mungai et al. from CDC (44) reported that the number of outbreaks associated with nonpasteurized (raw) milk increased 400%, from an average of 3.3 outbreaks per year to an average of 13.5 outbreaks per year during 1993 to 2006.

In 2012, Langer et al. from CDC (37) reported that during 1993 to 2006, of the 121 dairy-associated outbreaks with known pasteurization status, 73 outbreaks were associated with unpasteurized products. These 73 unpasteurized dairy outbreaks resulted in 1,571 cases, 202 hospitalizations, and 2 deaths (37). Seventy-five percent (55 outbreaks) of the unpasteurized dairy outbreaks occurred in 21 states where raw milk sale is legal. Langer et al. (37) made several key conclusions, including: 1) legal intrastate sale of unpasteurized dairy products is associated with a high risk for dairy-related outbreaks; 2) the rate of outbreaks caused by unpasteurized dairy products was about 150 times greater than outbreaks linked to pasteurized dairy; and 3) unpasteurized dairy outbreaks led to much more severe illnesses in, and disproportionately affected, younger people (under age 20).

In CDC's May 9, 2014 Letter to State and Territorial Epidemiologists and State Public Health Veterinarians, titled "The Ongoing Public Health Hazard of Consuming Raw Milk" (41), CDC stated that CDC data shows that the rate of raw milk-associated outbreaks is 2.2 times higher in states in which the sale of raw milk is legal compared with states where sale of raw milk is illegal. "From 2007 to 2012, the CDC National Outbreak Reporting System received reports indicating 81 outbreaks of infections due to consumption of raw milk resulting in 979 illnesses , 73 hospitalizations and no deaths. Most infections were caused by Campylobacter, Shiga toxin-producing *Escherichia coli*, or *Salmonella* bacteria, pathogens that are carried by cattle that appear healthy. The number of outbreaks increased during this time, from 30 in the three year span 2007–2009 to 51 in 2010–2012. Eighty-one percent of outbreaks were reported from states where the sale of raw milk was legal in some form; only 19% occurred in states where the sale of raw milk was illegal. The reported outbreaks represent only the tip of the iceberg. For every outbreak and illness that is reported, many others occur that are not reported; the actual number of illnesses associated with raw milk and raw milk products is likely much greater. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; 59 % of outbreaks involved at least one person aged less than 5 years."

Also, CDC's 2011 and 2012 data for foodborne disease outbreaks (42, 43) indicate that of the thirty-seven (37) outbreaks caused by *Campylobacter* linked to food, unpasteurized (raw) milk was responsible for the largest number of outbreaks. Among the 18 *Campylobacter* outbreaks with a known food vehicle in 2011, 15 (83%) were attributed to unpasteurized (raw) dairy products. Among the 19 *Campylobacter* outbreaks with a known food vehicle in 2012, 10 (53%) were attributed to unpasteurized (raw) dairy products.

In January 2014, Robinson et al. from the Minnesota Department of Health (40) reported that analysis of routine surveillance data reportable in Minnesota between 2001 and 2010 involving illnesses caused by enteric pathogens revealed that 3.7% of patients with sporadic, domestically acquired enteric infections had reported raw milk consumption. Severe illness including HUS among 21% of *Escherichia coli* O157–infected patients reporting raw milk consumption was noted, and 1 death was reported. Children were disproportionately affected and 76% (age 5 years and under) were served raw milk from their own or a relative's farm. The study suggests that farm family members, particularly young children, who consume raw milk are susceptible to illness from it. During the 10 year study period, the number of patients with sporadic laboratory-confirmed infections who reported consuming raw milk was 25 times greater than the number of raw milk–associated outbreak cases among Minnesota residents. Thus, sporadic cases of illness associated with consuming raw milk far outnumber cases associated with recognized outbreaks. An estimated 20,502 Minnesotans, or 17% of raw milk consumers, may have become ill with enteric pathogens during the study period after consuming raw milk. Robinson et al. states that this finding suggests that outbreaks represent a small number of the illnesses associated with raw milk consumption and that the risk for illness associated with consuming raw milk is far greater than determined based on the occurrence of recognized outbreaks. Robinson et al. also states that "Raw milk consumers, potential consumers, and policy makers who might consider relaxing regulations regarding raw milk sales should be educated regarding illnesses associated with raw milk consumption."

CDC's MMWR for the week of March 2, 2007, which I discussed above, reported that from 1998 to May 2005, 45 outbreaks of foodborne illness implicated unpasteurized milk, or cheese made from unpasteurized milk. Those outbreaks accounted for 1,007 illnesses, 104 hospitalizations, and two deaths. The CDC also noted that between 1973-1992, 87% of the raw milk outbreaks occurred in those states which allowed for raw milk sales to consumers while consumption of raw milk was estimated to have been less than 1% of the total milk sold in those states.

Raw milk advocates have claimed that "between 1984 and 2002, reports of outbreaks associated with raw milk produced in the U.S. are almost non-existent." (Weston A. Price Foundation PowerPoint presentation available on-line entitled "Raw Milk and Raw Milk Products") This is not the case. FDA's review of outbreaks for this period indicates that there were 35 outbreaks attributed to raw milk, an average of two outbreaks per year. FDA's recent review of CDC data indicates that the average annual number of outbreaks associated with the consumption of raw milk has more than tripled (340%) from an average of 5 outbreaks during 1993 to 2006 to an average of 17 outbreaks during 2010 to 2012. The average annual number of illnesses associated with the consumption of raw milk increased 62% from 112 average number of illnesses during 1993-2006 to 182 average number of illnesses during 2010-2012.

When considering these statistics, it is important to consider that not all outbreaks are actually recognized and that, even when they are recognized, not all of them are reported to CDC. Additionally, it is impossible to capture all of the incidences of individual illness. Generally, for each outbreak reported, there is a much greater incidence of unreported sporadic illness from a food, such as raw milk.

PASTEURIZATION

Pasteurization is required for all milk and milk products in final package form intended for direct human consumption that move in interstate commerce. (21 CFR 1240.61) The only exceptions to this requirement are for certain cheeses and those exceptions are not absolute, but are tied to certain other requirements relative to the manner in which any raw milk cheese must be ripened. In promulgating 21 CFR 1240.61, FDA made a number of findings relative to raw milk, including that "[r]aw milk, no matter how carefully produced, may be unsafe" (52 FR 29514, Aug. 10, 1987).

The case that prompted FDA to promulgate 21 CFR 1240.61 was Public Citizen v. Heckler, 653 F. Supp. 1229 (D.D.C. 1986). In its holding, the federal district court concluded that the record presented "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified." Id. at 1238. The court stated that the evidence FDA has accumulated concerning raw milk had “conclusively shown…. raw milk is unsafe" and that "[t]here is no longer any question of fact as to whether raw milk is unsafe". Id. at 1241.

Pasteurization will destroy all of the pathogens that I have mentioned thus far and others that I have not mentioned. For example, pasteurization is also destructive of *Mycobacterium paratuberculosis,* the causative organism of Johne’s disease in cattle. Clearly, pasteurized milk can never rationally be considered more hazardous than raw milk, contrary to the claims of raw milk advocates. In fact, it is universally agreed within the scientific community that pasteurization has made milk a much safer food for human nutrition.

Raw milk advocates have mentioned that *Bacillus cereus* and *Clostridium botulinum* spores may survive pasteurization, labeling these microbes as "heat-resistant pathogens." Microbial endospores are indeed very resistant to heat and chemical treatments, but the vegetative cells of these microbes are not heat resistant and will be destroyed by pasteurization.

B. cereus spores are quite common in milk, raw or otherwise, and are thus a common cause of spoilage concerns within the dairy industry. However, the presence of *C. botulinum* spores in milk is not a very common occurrence. Before either of these microbes can pose food safety concerns with milk or milk products, very high population levels must be reached, a condition that does not ordinarily occur in the collection and processing of milk and milk products. Interestingly, in alleging that consumers are avoiding commercial milk because it is pasteurized (which is not true insofar as FDA is aware), raw milk advocates also claim that consumers do not like the fact that cows are allegedly kept in confinement and fed rations designed to enhance milk production, a situation which they claim causes poor health and disease. In support of such a notion, raw milk advocates claim that Dutch researchers found much lower rates of *Salmonella* infections in dairy herds and cows with access to pasture, but they neglect to mention, or are perhaps unaware, of other Dutch research (Slaghuis et al.) (11) that indicates that cows fed on pasture during the summer had **higher** levels of *B. cereus* spores in their milk than cows which were housed during the summer. Thus, it appears that raw milk advocates are somewhat selective about the research which they choose to discuss when it comes to the subject of cattle feeding and its impact upon milk microflora. In any event, microorganisms may be found in milk from both cows fed on pasture and cows fed rations, and pasteurization is required in both cases.

CLAIMS ABOUT RAW MILK AND PASTEURIZED MILK

Raw milk advocates are wont to claim that pasteurization, in addition to killing any pathogens which might be present, also destroys the nutritive value of milk. Nothing could be further from the truth.

Because there is so much misinformation currently circulating about raw milk and pasteurized milk, I developed a presentation which was given at the biennial meeting of the National Conference on Interstate Milk Shipments at Columbus, Ohio in May 2005 by Ms.

Cynthia Leonard, M.S., who is a member of my Division. In that presentation, we addressed several of the more common and egregious fallacies about pasteurization. Due to the constant and heavy demand for that presentation, we have placed it on the FDA website. It can be found at:
http://www.fda.gov/food/foodborneillnesscontaminants/buystoreservesafefood/ucm165048.htm .

In addition to the fallacies that we addressed in the presentation, we have been made aware of several other erroneous statements being made by raw milk advocates about raw milk and pasteurized milk, and it may be useful for me to address some of these here:

RAW MILK IS NOT A "MAGIC FOOD FOR CHILDREN"

Relatively recently, a raw milk advocate claimed that "raw milk is a magic food for children." There is nothing magical about the possibility of contracting foodborne disease from raw milk, having that progress into hemolytic uremic syndrome, ending up having to fight for your young life as best you can and (if you are fortunate enough to survive), and having to suffer lifelong complications from your illness, knowing all the while that your life likely has been shortened as a result of your illness.

Raw milk advocates have mischaracterized scientific literature in the past and indeed, where we have seen them do so, we have exposed their errors. Their mischaracterization of the article on the PARSIFAL study (Waser et al.) is therefore not at all surprising and, indeed, the journal article on the PARSIFAL study has been mischaracterized by raw milk advocates since it first appeared. The study is about farm milk, not raw milk. The authors of the study took great pains to explain as much in their Clinical and Experimental Allergy article. The authors clearly state also in the article that "[t]he present study does not allow evaluating the effects of pasteurized vs. raw milk consumption because no objective confirmation of the raw milk status of the farm milk samples was available." They go on to say that "[a]bout half of the parents indicated that they usually did not boil the milk before consumption but no differential effects were observed between those boiling and those not boiling the milk. This might be a result of biased parental answers or may indicate that pasteurization is not of key importance because compounds other than microbes play a role." They also go on to say that "raw milk may contain pathogens such as Salmonella or EHEC and its consumption may therefore imply serious health risks." Finally, the authors state that "[a]t this stage, consumption of raw farm milk cannot be recommended as a preventive measure." The study does not indicate, as some raw milk advocates claim, that raw milk prevents allergies and asthma in children.

RAW MILK DOES NOT KILL PATHOGENS

The claim that raw milk per se kills pathogens and thus is safe is simply incorrect. Milk contains certain indigenous enzymes to which antimicrobial properties have been ascribed, and milk may contain certain strains of bacteria that might be able to produce anti-bacterial compounds known as bacteriocins, but these enzymes and microbes (if present) do not render raw milk safe. With raw milk, the temperature of storage, coupled with the nature and composition of the microflora initially present and simple microbial competition and outgrowth, play an important part in the determination of which microbes will grow and which will not. Some micro-organisms are more fastidious than others. Some do not grow well in cold temperatures, whereas others do. Some pathogens can survive and grow at refrigeration temperatures.

Another version of the claim that raw milk kills pathogens is that “pathogens can multiply in pasteurized milk and other foods but not in raw milk.” That too is untrue. In support of this claim, we have seen raw milk advocates cite a 1982 study by Doyle and Roman (12) and selectively present data from that study which, at first glance, appears to support the raw milk advocates’ claim. However, the authors of that study found and reported in that same article that “[s]urvival of the eight *Campylobacter* strains in refrigerated unpasteurized milk varied greatly.” Furthermore, the authors stated that “one strain of *C. jejuni*, bovine isolate FRI-CF147B, survived exceptionally well in unpasteurized milk at 4º C. A less than 2-log reduction in cells occurred after 14 days, indicating that under the appropriate conditions, large numbers of campylobacters may survive in raw milk for several days.” The authors also determined that “[i]nactivation of *Campylobacter* strains in unpasteurized milk paralleled but was greater than the inactivation of strains in sterile milk.” Note that the authors report **an inactivation** in sterile (not merely pasteurized) milk. Finally, the authors concluded: “The presence and possible persistence of *C. jejuni* in raw Grade A milk reaffirms the need for pasteurization.” Thus, far from providing a support for raw milk advocates, the Doyle and Roman study clearly advocates pasteurization of raw milk.

PASTEURIZATION DOES NOT DESTROY THE ENZYMES IN MILK

The claim that pasteurization destroys all the "built-in safety systems" or "enzymes that kill pathogens" also is simply not supported by the scientific literature. For example, it has been claimed that pasteurization inactivates lactoferrin. Lactoferrin is an iron-binding protein believed to have dual roles; the one being a facilitator of iron absorption and the other a bacteriostatic role. Paulsson et al. (13) determined that "unheated and pasteurized bLf (bovine lactoferrin) preparations showed similar antibacterial properties and caused an effective metabolic inhibition with a moderate bacteriostasis." They further stated that "pasteurization seems to be the method of choice (when making a lactoferrin product) because it did not alter either the bacterial interactive capacity or the antibacterial activity of bLf." Tomita et al. (14) discussed how a pasteurization process was developed for lactoferrin in order to apply active lactoferrin usage to various products. Plainly, lactoferrin is not destroyed or inactivated by pasteurization.

Similarly, lactoperoxidase, an enzyme which is integral to the lactoperoxidase system of milk preservation, has been described as being "inactivated" by pasteurization, when actually lactoperoxidase is a very heat stable enzyme which is not destroyed by minimum legal pasteurization conditions, although some literature indicates moderate inactivation. In fact, because it will survive pasteurization intact, measurement of residual lactoperoxidase activity has been proposed as a means of indicating if a heat treatment applied to milk has exceeded high temperature short time (HTST) pasteurization conditions. Contrary to the claim that the lactoperoxidase system can be an alternative to pasteurization, the lactoperoxidase system is not, and could never be an alternative to pasteurization. (Some researchers do consider that it might possibly be used synergistically with pasteurization to extend the shelf life of dairy products).

The lactoperoxidase system, which requires the addition of hydrogen peroxide and thiocyanate ion to milk to be activated, functions as a bacteriostatic mechanism generally, i.e., it serves to keep microbial populations from growing and spoiling milk. It is used in regions of the world where it is difficult, if not impossible, to cool milk, due either to a lack of electricity or cooling equipment. It is reported by some researchers to be bactericidal to certain enteric pathogens. Seifu et al. (15), in 2005, published an excellent review article on lactoperoxidase, which may be of further interest to this Committee. The claim that lysozyme, which, in conjunction with lactoferrin does have a bactericidal effect, is destroyed by pasteurization is also simply not true. In excess of 70% of bovine milk lysozyme will survive normal HTST conditions, as reported by Griffiths (16).

With respect to indigenous dairy enzymes in general, Stepaniak (17), in 2004, published an excellent review article of the literature available to which I would refer anyone interested in learning what the current science is on the effect of pasteurization on milk enzymes.

Claims have been made by raw milk advocates that Immunoglobulin G (referred to as "IgG antibodies" by raw milk advocates) is destroyed by pasteurization. However, Kulczycki (18) reported in 1987 that his research on bovine IgG suggested "the possibility that pasteurization of milk (and condensed milk) may not destroy the receptor-binding ability of IgG, but instead might enhance its binding by causing aggregation of the bovine IgG."

PASTEURIZATION DOES NOT CAUSE LACTOSE INTOLERANCE

Raw milk advocates have also claimed that pasteurized milk causes lactose intolerance (which is an inborn error of metabolism), despite the fact that all milks, raw or pasteurized, contain lactose and that pasteurization does not change the concentration of lactose. A person who is lactose intolerant has a reduced ability to synthesize the enzyme Beta-galactosidase, which hydrolyzes the disaccharide lactose into its monosaccharide constituents, glucose and galactose. Any such person might be expected to experience the symptoms of lactose intolerance when consuming either raw or pasteurized milk.

Recently, a new version of this fallacy has been brought to our attention. A raw milk advocate has begun to claim that raw milk does not cause lactose intolerance because it contains bacteria (which he describes as being "bifido and lacto") which he believes create their own lactase (beta-galactosidase) when consumed, thus allegedly preventing the symptoms of lactose intolerance. Among the numerous difficulties with this proposition is the fact that the Bifidobacteria in the gastrointestinal tracts of humans are different to those found in animals (Gavini et al.) (24) and thus the milk from animals also. Furthermore, if Bifidobacteria consumed as a therapeutic or prophylactic measure are to be of any benefit, they must be consumed in appreciable quantities (as might be found, for example in a fermented milk product containing an adjunct Bifidobacteria culture) and be of human origin in order to withstand transit through the intestinal tract (Arunachalam) (25). Finally, it has actually been proposed that the Bifidobacteria present in bovine milk be used as indicator organisms to gauge the extent of fecal contamination of milk. (Beerens et al.) (26). Thus, far from being of any health benefit, the Bifidobacteria present in raw milk are considered by scientists to be an indication of the extent to which it has been contaminated with manure.

Although many potential health benefits have been ascribed to Bifidobacteria in the literature, curing lactose intolerance is not among them. (Arunachalam) (22). De Vrese et al. (27) published a useful paper entitled "Probiotics- compensation for lactase insufficiency" wherein they synopsize some of the research done on the utility of Bifidobacteria as promoters of lactose hydrolysis and state that Bifidobacteria "affected lactose digestion less than did lactobacilli or had no effect at all."

Although we are uncertain just what the raw milk advocate in question is referring to when he mentions "lacto bacteria," if we assume that he is referring to *Lactobacillus* species, it is true that several *Lactobacillus* species are generally considered to be probiotic and that among the possible benefits suggested as being conferred by consumption of fermented dairy products containing appreciable quantities of Lactobacilli are reduced symptoms of lactose intolerance, as reported by De Vrese et al., Holzapfel and Schillinger, McBean and Miller, Savaiano et al. (27, 28, 29, 30) However, *Lactobacilli* typically are but a small portion of the microflora in milk.

RAW MILK IS NOT A PROBIOTIC FOOD

While making the above claims and perhaps because of them, this same raw milk advocate has described his milk as being "probiotic." Raw milk is certainly not a probiotic food, as that term is defined within the FAO/WHO Guidelines for the Evaluation of Probiotics in Food, which was published in 2002 (31), and it is scientifically improper to describe raw milk as being probiotic. That document defines probiotics as being "[l]ive microorganisms which when administered in adequate amounts confer a health benefit on the host". According to FAO/WHO, in order for that term to be used, stringent requirements must be met, including strain identification, functional characterization, a safety assessment, efficacy studies, and comparison with standard treatments as well as labeling requirements. None of that has been done for raw milk.

PASTEURIZATION DOES NOT DESTROY MILK PROTEINS

Raw milk advocates claim that pasteurization either destroys the proteins of milk or that it renders milk proteins more allergenic, even though the milk proteins that cause allergic reactions (including lactoferrin) in dairy-sensitive people are present in raw milk as well as pasteurized milk. Interestingly, these same sorts of claims were addressed directly over twenty years ago by Coveny and Darnton-Hill (19) when they wrote in their article entitled "Goat milk and infant feeding" that "there are some who feel that pasteurization is unnecessary and even detrimental. Concern appears to centre (sic) on possible increased allergenicity and nutrient losses. However, studies show that the sensitizing capacity of cow's milk is retained or – more usually – reduced after heat treatment (cites) while pasteurization minimizes the heat destruction of nutrients (cite). There would appear to be little advantage therefore in the use of raw milk."

Caseins, the major family of milk proteins, are largely unaffected by pasteurization (Farrell and Douglas) (20). Any changes which might occur with whey proteins are barely perceptible.

PASTEURIZATION DOES NOT DESTROY VITAMINS AND MINERALS IN MILK

With respect to vitamins, the claims about the destructive capacity of pasteurization have been many and varied and virtually none of what has been said is accurate. Milk is a good source of the B-complex vitamins thiamine, folate and riboflavin. Pasteurization will result in losses of each of these of anywhere between zero to 10 percent, which most would consider to be merely a marginal reduction (17), (21). Pasteurization does not cause appreciable losses of the fat-soluble vitamins, A, D, E and K (21). Milk does contain a small amount of Vitamin C, but it is not considered to be a good dietary source of that vitamin. Pasteurization will result in a loss of anywhere from 0-10% of the Vitamin C present (21). Most vitamin C losses in milk occur during storage and such will occur whether milk is pasteurized or not.

With respect to the minerals present in milk, raw milk advocates have made several different claims about the allegedly destructive impact of pasteurization. FDA has not been able to substantiate any of these claims. In fact, the scientific literature that we have reviewed thus far contradicts most of the claims being made. Where raw milk advocates indicate that "no significant change" occurs with sodium, potassium and magnesium, FDA would agree, however. Williamson et al. (22) and Zurera-Cosano et al. (23).

RAW MILK IS RAW MILK

Finally, raw milk advocates have recently begun to claim that only raw milk produced at large commercial dairy farms, which is intended to be subsequently pasteurized, is unsafe and that raw milk produced at small farms is safe. The history of raw milk outbreaks, however, does not support such claims. Additionally, literature indicates that somatic cell counts, which are a measure of dairy herd health (with lower counts being better), tend to be lower in larger, high intensity dairy farming operations as reported by Windig et al., Norman et al., Berry et al. and Oleggini et al. (32, 33, 34, 35).

Another variation on this theme that we sometimes encounter is the claim that raw milk is safe if it originates from "certified" dairies. That is simply not correct. As is discussed above and as was stated in Public Citizen v. Heckler, 653 F Supp. 1229 (D.D.C. 1986), there exists "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified." Id. at 1238.

SUMMARY

Raw milk, even a "certified" raw milk, is inherently dangerous and should not be consumed. Raw milk continues to be a source of foodborne illness and even a cause of death within the United States. Despite the claims of raw milk advocates, raw milk is not a magical elixir possessing miraculous curative properties. Pasteurization destroys pathogens and most other vegetative microbes which might be expected and have been shown to be present in milk. Pasteurization does not appreciably alter the nutritive value of milk. Claims to the contrary by raw milk advocates are without scientific support. FDA encourages everyone charged with protecting the public health to prevent the sale of raw milk to consumers and not permit the operation of so-called "cow-sharing" or other schemes designed as attempts at circumventing laws prohibiting sales of raw milk to consumers. To do otherwise would be to take a giant step backwards with public health protection.

We would like to thank the Committee for affording us the opportunity to provide this information and trust that the above will prove useful to you in your deliberations. If we may be of any further assistance to the Committee, we will be happy to do so.

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