

Maryland's Dairy Industry: 2014

**A Report
To
Governor Martin O'Malley**

**From

The Maryland Dairy Industry Oversight and Advisory Council**



October 2014

Members of the Dairy Advisory Council

Samuel G. Tressler III – *Chairman*, Dairy farmer, Mount Airy
Gordon Hoover – Land ‘O Lakes Dairy Cooperative
Louis ‘Pete’ DeBaugh – Dairy Farmers of America Cooperative
Ed Kennedy – Cloverland-Greenspring Dairy, Baltimore
Jody Vona – Dairy Maid Dairy, Frederick
Joseph Milazzo – Marva Maid Dairy, Landover
Kim Young – Milk hauler, Frederick
William Chomicki – Maryland & Virginia Milk Producers Cooperative, Laurel
Barbara Wetzel – Consumer, Thurmont
Michael Haines – Dairy farmer, Taneytown
Janet Stiles Fulton – Dairy farmer, Boonsboro
Phyllis Kilby – Dairy farmer, Colora

Non-voting members

Delegate Patrick N. Hogan, Frederick
Senator David R. Brinkley, Frederick
S. Patrick McMillan, Assistant Secretary, Maryland Department of Agriculture
Dr. Robert Peters, University of Maryland College of Agriculture and Natural Resources
Laurie Bucher, Chief, Center for Milk and Dairy Product Safety, Office of Food
Protection, Maryland Department of Health and Mental Hygiene
Barbara Brookmyer, Health Officer, Frederick County Health Department

Staff

Cheryl Eichelberger, Maryland Department of Health and Mental Hygiene
(240) 313-3540; cheryl.eichelberger@maryland.gov
Mark S. Powell, Maryland Department of Agriculture
(410) 841-5775; mark.powell@maryland.gov

Contents

Executive Summary 4

Recommendations and Rationale 7

Attachments begin on Page 10: Economic Outlook, DHMH Statement on Raw Milk, FDA Statement on Raw Milk before the Maryland General Assembly, SHA Presentation on Maryland's new exceptional hauling permit for milk trucks

Executive Summary

Milk truck weight issued addressed by General Assembly in 2014 **Dairy farms continue decline**

The Governor's Dairy Advisory and Oversight Council is charged with improving and sustaining the economic viability of Maryland's dairy industry. With representation appointed by Governor Martin O'Malley, the Council meets to hear from experts in various areas of interest to the industry.

In 2014, the Council focused its attention on issues of milk hauling, raw milk, new federal farm programs created in the 2012 Farm Bill and methods to manage manure under new standards for phosphorus management proposed in the state by Maryland Department of Agriculture. The Council was pleased with and encouraged support of legislation passed in 2014 which allows for hauling up to 95,000 pounds of milk on six axles or up to 88,000 pounds on five axles on state roads during March to June. This legislation, which includes reports compiled by Maryland & Virginia Milk Producers Cooperative with the State Highway Administration on the number of vehicles using the new permits, has been sought by the Dairy Advisory Council for several years. (A copy of the legislation is Attachment D to this report.) States throughout the region have varying allowances for milk haulers, understanding that milk is a perishable commodity which must be hauled from farm to processor in a short amount of time. Milk processing plants in Howard County, Frederick County and Baltimore City are recipients of milk from dairy farmers throughout the state and the region. Trucks carrying milk to plants had been limited to 80,000 pounds. By comparison, other states in the Northeast allow milk trucks to carry up to 97,000 pounds depending upon the state.

Despite the fact that farm milk prices reached record high levels in 2014, the number of dairy farms in Maryland continued to decline. . In 2012, for the first time since records

have been maintained, the number of dairy farms fell below 500 to 496 dairy farms registered with the Maryland Department of Health and Mental Hygiene to sell milk. In 2013, the number of dairy farms declined to 476. In 2014, the number has declined further to 455. Washington County has the most dairy farms with 125, followed by Frederick with 97, Garrett with 63 and Carroll with 45. Other counties with dairy farms: Allegany, 2; Baltimore, 9; Caroline, 5; Cecil, 28; Harford, 24; Howard, 5; Kent, 13; Montgomery, 6; Prince George's, 2; Queen Anne's, 8; St. Mary's, 16; Talbot, 5; Wicomico, 1; and Worcester, 1.

In 2013, Maryland dairy farms produced 972,000,000 pounds of milk. That compares with 1.1 billion in 2004. Greater productivity of the remaining dairy farms kept milk production from declining as precipitously as farm numbers. Although the number of dairy cows declined 50 percent, from 75,000 head in 2004 to 50,000 in 201, milk production only declined 13.2 percent.

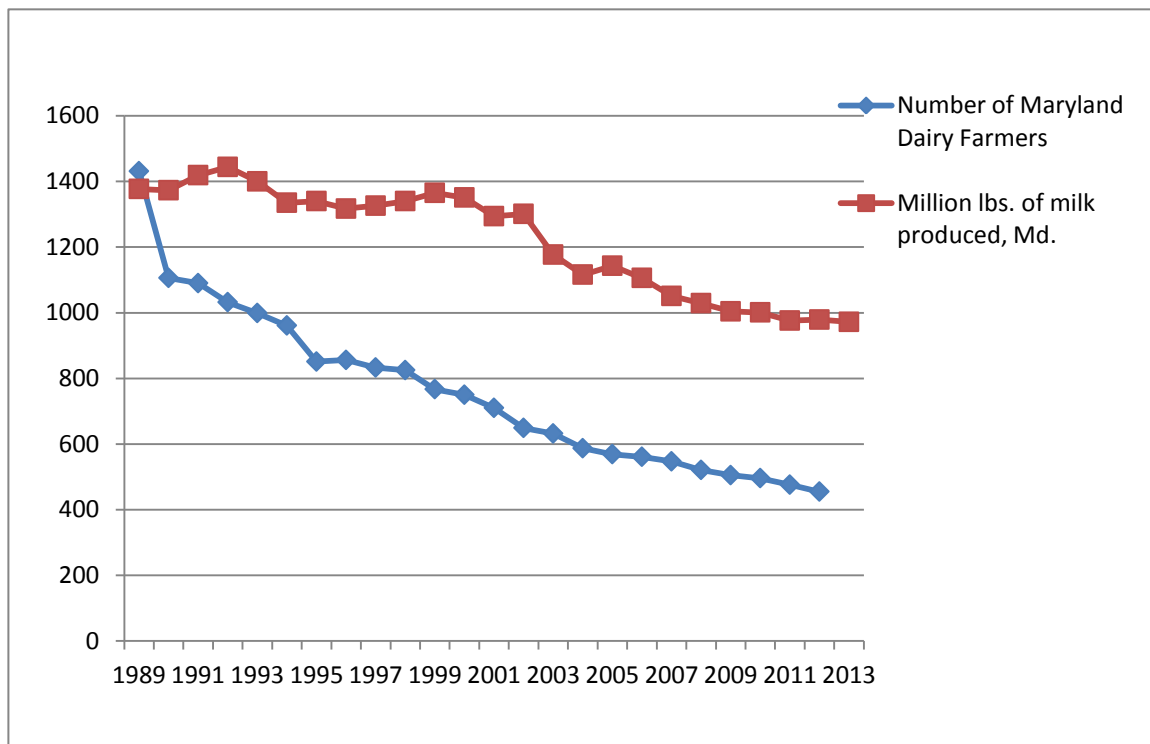
Maryland's current milk processing capacity includes 9 large, commercial dairy processors, and 12 on-farm processors. Maryland dairy product manufacturers annually utilize approximately 3.36 billion pounds of milk according to the Maryland Department of Health and Mental Hygiene and the Federal Milk Market Order. More than 40,000 loads of milk are hauled from farms throughout the Mid-Atlantic to Maryland processors each year. The Mid-Atlantic is a milk deficit area. While in the past the region's dairy farms had provided milk to Southern states, the situation has now reversed. There is increasing demand for milk in the region as Greek yogurt production and other processors expand and locate in the region. Anticipated expansions and plant openings are in New York, Vermont and Pennsylvania.

Also in 2013, Dairy Maid Dairy in Frederick was purchased from the Vona family by the nation's largest dairy cooperative, Dairy Farmers of America. DFA announced the purchase in September and said it fits the cooperative's goal to increase its fluid milk processing capacity in the region. Founded in 1946, Dairy Maid employs 146 at its plant.

The Advisory Council offers three recommendations to Governor Martin O'Malley to support the State's dairy industry.

1. Oppose legislation that would authorize the sale of raw milk
2. Support federal legislation to increase milk truck weight limits on the Interstates.
3. Encourage the MDA Nutrient Management Program to further develop detailed information on temporary storage and help farmers understand how they can store manure on the farm during winter months. Temporary storage is allowed under state regulation and could help farmers in winter months.

Number of Maryland Dairy Farms, Production of Milk in State



2014 Recommendations

Recommendation 1:

The Governor and the General Assembly should not allow the sale of raw milk in the State of Maryland. This is currently the law in our State and this Council believes that it should remain the law.

As discussed in the 2013 report to Governor O'Malley, there is a push from some quarters for the sale of raw milk in the State. The Council however, strongly believes that the health concerns associated with raw milk sales are well documented, and repeats its recommendation against allowing the sale of raw milk. Because raw milk is inherently dangerous and may contain pathogens that can cause human illness, the availability and subsequent consumption of raw milk products increases the risk of illness.

Pathogens in milk can cause very serious, sometimes life altering and sometimes even fatal disease conditions in humans. The only method proven to be reliable in reducing the level of pathogens in milk and milk products is proper pasteurization. The Council, therefore, strongly advises against the consumption of raw milk. Milk that is processed and pasteurized is a healthy, safe food product.

However, in its raw form, there are serious potential health risks.

Attachment B to this report, prepared by the Maryland Department of Health and Mental Hygiene, and Attachment C to this report, prepared by the Food and Drug Administration (FDA), are provided in support of this recommendation.

Recommendation 2:

The Governor and General Assembly should support federal legislation to give states the discretion to increase gross vehicle weight limits on the Interstate Highways..

Maryland House of Delegates Bill 1246 and its companion, Senate Bill 771 established a new Maryland law providing for an exceptional milk hauling permit. The new permit is for six axle carriers with at least 28 feet between the last axle on the tractor and the first axle on the semitrailer or, for five axle carriers with the 28 feet separation carrying milk from farms to processing plants on state roads from March 1 to June 30. The six axle weight limit on state roads for this exceptional permit is 95,000 pounds. The five axle weight limit is 88,000 pounds, up from the standard 80,000 pounds. The State Highway Administration will meet with the Maryland and Virginia Milk Producers Cooperative Association to develop an annual report of the number of milk haulers operating under 90,000 pounds, between 90,000 and 95,000 pounds and over 95,000 pounds.

While this new law will be very helpful in addressing the challenge of transporting farm milk to Maryland dairy processors, it does not apply to interstate highways. In many cases, it would be more desirable and practical for milk haulers to use the interstates to access some of the state's major milk processing plants. It would also open the door to enabling states in the region to harmonize truck weight rules to facilitate more efficient movement of milk throughout the region. This would have the benefit of reducing the number of trucks on the road and the transportation cost to farmers of supplying their customers.

At the federal level, truck weight limits are the responsibility of the Federal Highway Administration. Both Maine and Vermont allow heavier trucks on federal interstates, 100,000 in Maine and 99,000 in Vermont on six axles. The Highway Administration has been studying this to consider the extra weight's effects on roads and bridges. The most recent report to Congress, in 2012, is at this link:

http://ops.fhwa.dot.gov/freight/sw/reports/me_vt_pilot_2012/index.htm#s11 The Federal Highway Administration recommended extending the study. The Maine Department of Transportation completed its own report in 2010 which states that increasing the weight limit on federal interstates in Maine is a ‘net benefit’ for the transportation system. That report is at this link:

<http://www.maine.gov/mdot/truckweights/documents/pdf/MaineDOTTruckWeightPaper091020.pdf>

Recommendation 3:

Encourage the MDA Nutrient Management Program to further develop detailed information on temporary storage and help farmers understand how they can store manure on the farm during winter months.

Many smaller dairy farms throughout the state may not be able to comply with the prohibition of manure spreading during the winter effective July 1, 2016. Some dairies rent their farms with short-term leases and their landlord may not agree to construction of waste storage, even with cost-share funding from the state and federal governments. And, there are many older farmers who may be the last generation to dairy on the farms and are not interested in investing in waste storage. Temporary storage is allowed under state regulation and could help farmers in winter months.

Attachment A

Dairy Situation and Outlook, October 2014

**Howard Leathers
University of Maryland, College Park, MD.**

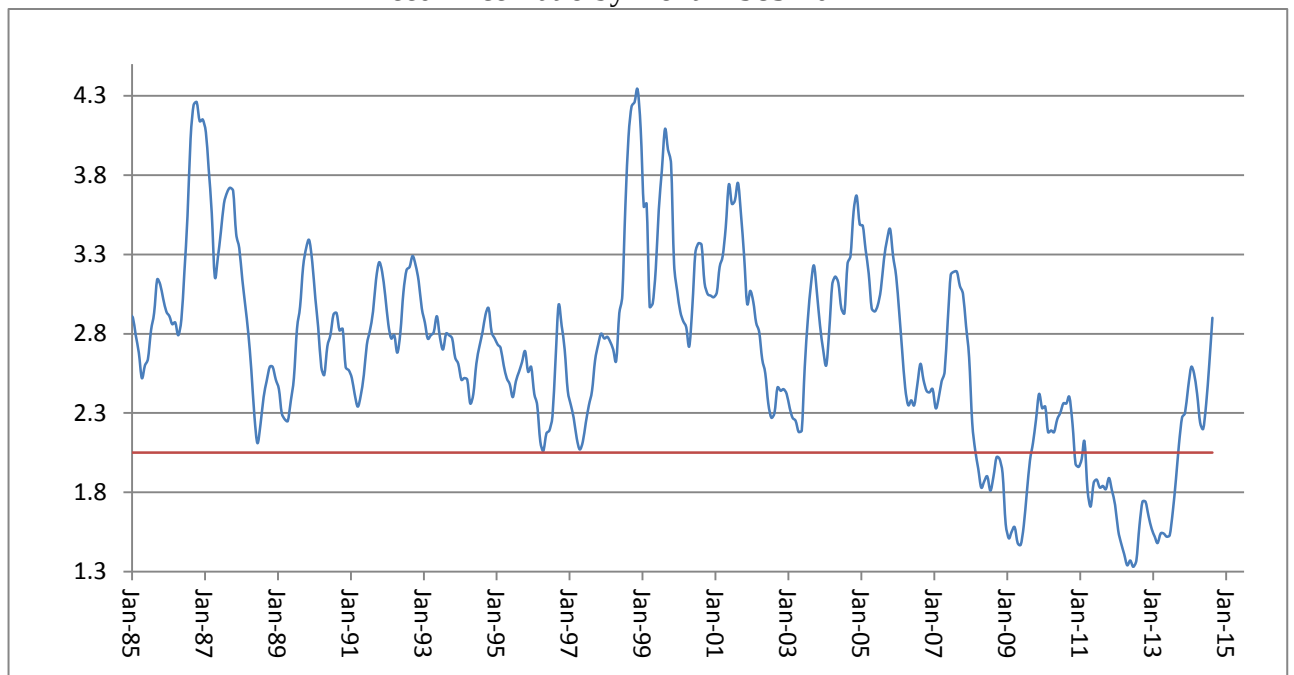
The outlook for Maryland's dairy farmers promises continued challenges, but with some good news in terms of lower feed costs. .

Looking backwards, we can see that the last year has been a good one for dairy farmers.

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 22 years from January 1985 to March 2008, the milk-feed price ratio had never fallen below 2.06. But in the 4+ years from April 2008 to October 2013 it has been below 2.06 in 39 of 54 months.

However, since October 2013, the milk feed price ratio has been consistently above the 2.06 level, and in the summer of 2014, it reached high levels not seen since 2006.

Milk Feed Price Ratio by month 1985-2014



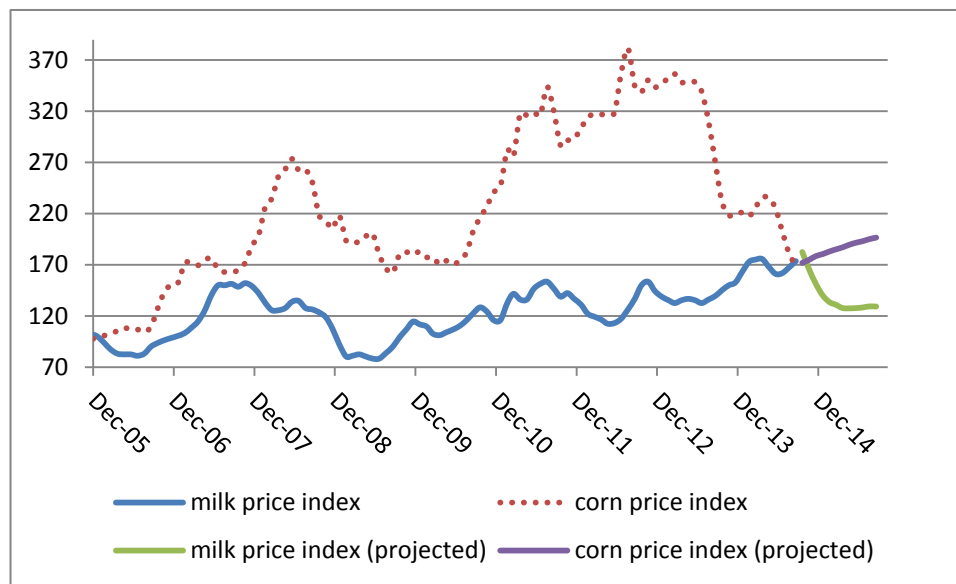
Recently, dairy policy has focused more attention on the “gross margin” or the difference between milk price and feed price (rather than ratio of milk price to feed price, shown above). Of course, the two measures are built upon the same fundamental price measures, so they will show the same general pattern. During the “hard times” of May-July 2012 one measure of the gross margin (all milk price minus 16% feed ration price per cwt of milk produced) was \$4.26. During the recent “strong price” period of February to September of 2014, the gross margin averaged \$14.51 by this measure. 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).

In last year’s report, we anticipated that both milk and feed prices would level off – a situation that was moderately good for dairy farmers. But, in fact, prices took a much more favorable turn than expected. Milk prices continued the upward trend from \$21 in October of 2013 to over \$26 in September of 2014 (a 20% increase). And corn prices dropped even more precipitously from \$4.63 in October 2013 to \$3.38 in September 2014 (a 27% decline).

Looking forward to the upcoming year, we anticipate that relative prices facing farmers will worsen from their current (October 2014) strong levels. Feed prices are expected to stay low, but not to weaken further. Milk prices are expected to decline from current levels as increased milk production begins to show up in the market in response to the current and recent high milk prices. The overall outlook for dairy farm profitability is moderately positive – not as good as summer/fall of 2014, but better than the hard times of late 2012 and early 2013.

The figure below illustrates the stress that has been faced by dairy farmers from 2010 to 2013, and the recent relaxation of that stress in recent months with the sharp decline in corn prices. In fact, by the fall of 2014, the relationship between corn and milk prices has returned to the status that generally existed in years prior to 2006. The projected price lines show that milk prices have peaked and will turn downwards in the year ahead. Corn prices have probably bottomed out, but are not expected to rebound very strongly.

Indexes of Milk and Corn Prices, January 2006 = 100.



The trend toward fewer and fewer dairy farms in the state continues. The 2007 Governor's report contained a prediction that 100-220 Maryland dairy farmers would exit the industry between 2006 and 2015. Now, nine years into that ten-year projection, we find that the number of farms registered with the state Department of Health and Mental Hygiene as licensed to sell milk has fallen by 176, from 631 in 2006 to 455 in 2014.

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	985 (estimate)

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

As expected, the reduction in numbers of farms comes primarily from consolidation of existing herd. Since 2002, farm numbers have dropped by 40% – to 60% of the initial level; but milk production has only dropped by a quarter – to 76% of initial level. Or (the same point illustrated differently) – total milk production in 2014 will be the same or higher than in 2011, but with 50 (10%) 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 15-25 farms exiting the industry.

As we anticipated in last year's report, the 2014 Farm Bill did contain some substantial changes for policies affecting dairy farmers. The biggest change at the farm level is that the new law eliminates the Milk Income Loss Contract (MILC) program. In its place, the law offers dairy farmers a safety net in the form of the "margin protection program" (MPP). Under this program farmers can "lock in" a \$4 per cwt gross margin. As described above \$4 per cwt gross margin is at the very low end of historical experience. But farmers can also "buy in" a higher level of protection by paying the government a (subsidized) premium to lock in gross margins up to \$8 per cwt. This MPP program (or a private insurance (LGM-Dairy) alternative – also available with subsidized premiums -- that farmers can use to lock in a gross margin) should protect most dairy farmers from the worst kinds of possible price movements.

Attachment B



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein M.D., Secretary

Prevention and Health Promotion Administration

Michelle Spencer, MS, Director

Donna Gugel, MHS, Deputy Director

David Blythe, MD, MPH, Acting Director, Infectious Disease Bureau

Ilise D. Marrazzo, RN, BSN, MPH, Director, Maternal and Child Health Bureau

Clifford S. Mitchell, MS, MD, MPH, Director, Environmental Health Bureau

Donald Shell, MD, MA, Director, Cancer and Chronic Disease Bureau

DHMH RAW MILK POSITION PAPER

POSITION AND RATIONALE:

The Department of Health and Mental Hygiene (the Department) opposes the sale of raw milk for human consumption for the following reasons:

1. Raw milk is a high-risk food for all persons, particularly for pregnant women and young, elderly, or infirmed persons.

Raw milk is milk that has not been pasteurized. According to the Center for Disease Control and Prevention (CDC), raw milk might contain pathogens that cause illness in humans. The consumption of raw milk and raw milk products increases the risk of gastrointestinal illness and possible severe complications caused by those pathogens.

Raw milk contains bacteria that are present on the cow's udder and teats, and can be infectious to humans. Further, 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. The U.S. Food and Drug Administration (FDA), using science-based epidemiological evidence, has determined that pasteurization is the only means to ensure the destruction of pathogenic microorganisms that might be present in milk.

Illnesses related to raw milk range from minor gastro-intestinal upset to kidney failure, paralysis, and death. Raw milk has been implicated in illness outbreaks caused by a number of different infectious agents as cited by the CDC's online foodborne disease outbreak database (1998-2010) and realrawmilkfacts.com. Just a few of which are listed below:

- August 2014 – Forty Five (45) people in Utah were confirmed to have *Campylobacter* infections after consuming raw milk linked to the Ropelato Dairy farm. The cases range in age from 2 – 74 years of age.

October 2013 – Nine children in Tennessee had confirmed *Escherichia coli* (*E. coli*) O157:H7 infections after consuming raw milk distributed through a legal herd-share program. Five of the nine children, all younger than seven years old, required

201 W. Preston Street, Baltimore, Maryland 21201
410-767-6742 • Fax 410-333-5995

Environmental Health Bureau

6 St. Paul Street, Suite 1301, Baltimore, Maryland 21202
410-767-8400 • Fax 410-333-8931

Toll Free 1-877-4MD-DHMH

TTY for Disabled Maryland Relay Service 1-800-735-2258

Web Site: <http://phpa.dhmf.maryland.gov>

- hospitalization, and three developed hemolytic uremic syndrome (HUS), a severe kidney disease.
- August 2013 (two persons ill), May 2013 (five persons ill) and January-February 2012 (148 persons ill) – Multiple multi-state outbreaks of *Campylobacter* infections have been associated with drinking unpasteurized milk from the Family Cow Farm in Pennsylvania. The Family Cow Farm sold directly to consumers at its on-farm retail store, in Pennsylvania retail stores, and at multiple drop-off locations. Six of the patients in 2012 were Maryland residents; the 2012 outbreak was the largest outbreak linked to raw milk in Pennsylvania, and one of the largest nationally.
- May 2013 (five persons ill) and February 2013 (31 persons ill) – A total of 36 people in Alaska were confirmed to have *Campylobacter* infections after consuming raw milk distributed through a legal herd-share program from Small Kenai Peninsula Dairy. There was at least one secondary case in an infant who became ill after having close contact with a case-patient who consumed raw milk.
- April 2012 – Nineteen people became ill with *E. coli* O157:H7 infections after consuming raw milk from Foundation Farm in Oregon. Four children were hospitalized with HUS. One of the sick individuals was a young woman who unknowingly drank the raw milk while at a friend's home.
- April 2010 – Redmond Heritage Farms, a raw milk dairy in Utah, caused illness in 10 people due to *Salmonella* Newport in the raw milk. The patients ranged in age from 2 to 56 years of age; one person was hospitalized. The raw milk was legally purchased from the farm and retail stores.
- September 2006 – In California, where raw milk can be purchased in retail outlets, an outbreak of *E. coli* O157:H7 resulted in 6 cases of illness in children; one of the children was exposed to the contaminated milk only once, when it was served to him as a snack while visiting a friend.
- March 2005 – Raw milk cheese that was sold in New York was linked to dozens of individuals who became ill with tuberculosis; a 14-month-old child died.

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 Centers for Disease Control and Prevention (CDC), the risk of dairy-related disease outbreaks in states that allow the sale of raw milk is more than twice the risk in states where the sale of raw milk is prohibited. According to the CDC's 2012 position paper on raw milk, states that have legalized the sale of raw milk are responsible for 75% of the outbreaks caused by raw milk. According to a CDC press release on June 4, 2014, during 2011 and 2012, thirty seven outbreaks caused by *Campylobacter* were linked to foods; unpasteurized (raw) milk was responsible for the largest number of outbreaks.

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

It is not feasible to perform routine bacteriological tests on the raw milk itself 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 that exist in cows and are found in raw milk can come from cows that appear to be completely healthy. According to CDC, there is an increase in raw milk related foodborne outbreaks in state where the sale of raw milk is legal. According to a study done by the

Pennsylvania Department of Agriculture, in Pennsylvania, where the sale of raw milk is legal and regulated, the number of outbreaks associated with raw milk has increased as the number of certified raw milk dairies has increased.

In the last several years, the Department has discussed the possible relaxation of regulations for raw milk with legislators, and has considered the matter carefully. This close review confirms that there are a number of "second-hand" issues that arise if raw milk is sold legally. Examples include: milk that is rejected for commerce because of the presence of drugs or high bacterial counts could be sold as raw milk; milk that has been diluted with water to increase profits could be offered for sale; and milk that was out of temperature and/or otherwise adulterated through mishandling, lack of cleaning, or poor animal health could be sold to an unsuspecting consumer. Without any requirements in the bill, there is no way to ensure that containers which are used for the raw milk are food grade, clean, non-toxic and composed of suitable materials to hold milk.

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 assure public health concerns. The Department concluded that no warnings or consumer right-to-know strategies could guarantee that raw milk is safe for human consumption.

In summary, because raw milk is inherently dangerous and may contain pathogens that can cause human illness, the availability and subsequent consumption of raw milk products increases the risk of illness. Pathogens in milk can cause very serious, sometimes life altering and sometimes even fatal disease conditions in humans. The only method proven to be reliable in reducing the level of pathogens in milk and milk products is proper pasteurization. The Department, therefore, strongly advises against the consumption of raw milk.

Epidemiologic Evidence Supporting the Ban on the Sale of Raw Milk

Prepared by Katherine A. Feldman, DVM, MPH
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 **cannot** 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	12.86%	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 States where Sale Permitted	Incidence Density in States where Sale Prohibited	Incidence Density Ratio (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 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 herd-share, 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-transplant-from-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>

Beecher C. Tennessee E. coli Outbreak Linked to Raw Milk Dairy. Food Safety News, November 22, 2013. Available at: <http://www.foodsafetynews.com/2013/11/raw-milk-dairy-linked-to-e-coli-outbreak-through-tests/#.UurNLT2zFnE>.

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.cdca.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.cdca.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-recall-quarantine/#.UuwGFj2zFnG>

THE PENNSYLVANIA EXPERIENCE

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.

Fifteen of those raw milk-associated outbreaks occurred during 2007-2011, including 12 *Campylobacter* outbreaks and three *Salmonella* outbreaks. During that same time period, only one outbreak associated with pasteurized milk was reported in Pennsylvania (there were 16 persons with confirmed illness). Additional information about the patients identified as part of the 15 raw milk-associated outbreaks includes:

- 233 persons were confirmed with illness
 - 5% were hospitalized
 - 45% were under 18 years of age
 - 17% were under 5 years of age

One particularly severe outcome occurred in a patient paralyzed due to **Guillain-Barre Syndrome**, which can occur following infection with *Campylobacter*. The patient was a 67 year old man who had consumed raw milk for a year because of its purported nutritional value. After two weeks of illness, it was reported that he could not move his arms and legs, could not talk, and had a breathing tube. His wife reported that "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.

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

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 in Pennsylvania. 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.

Attachment C

Testimony of
John F. Sheehan, B.Sc. (Dy.), J.D., Director, Division of Plant and Dairy Food Safety
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
January 28, 2014

Mr. Chair, Madam Vice Chair 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* 0157H:7, 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 relatively recently 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 3 which is now before this body for consideration would operate to weaken Maryland laws governing public health protection. House Bill 3 significantly relaxes the current regulation by permitting the 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 cow share operations, as addressed above, do not protect public health. Allowing any type of raw milk sales or distribution 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 3 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.”

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 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 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.

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/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/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 4° 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 synopsise 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 to the Committee 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.

REFERENCES:

1. Van Kessel et al. J. Dairy Sci. 2004. 87:2822-2830.
2. Werner et al. Br. Med. J. 1979. July 28;2(6184):238-241.
3. Keene et al. J. Infect. Dis. 1997. 176:815-8.
4. Proctor and Davis. WMJ. 2000. Aug;99:5:32-7.
5. Kernland et al. Schweiz Med. Wochenschr. 1997. 127:1229-33.

6. Allerberger et al. *Int. J. Infect. Dis.* 2003. 7:42-45.
7. Schmid et al. *J. Infect. Dis.* 1987. 1 July:156.
8. Blaser and Williams. *JAMA*. 1987. 257:1; 43-6.
9. Karlson and Carr. *Ann. Intern. Med.* 1970. 73:979-983
10. de la Rua-Domenech. 2006. *Tuberculosis*. 86:77-109.
11. Slaghuis et al. *Int. Dairy J.* 1997. 7:4:201-205.
12. Doyle and Roman. *Applied and Environmental Microbiology*. 1982. 44:5:1154-1158.
13. Paulsson et al. *J. Dairy Sci.* 1993. 76:3711-3720.
14. Tomita et al. *Biochem. Cell Biol.* 2002. 80:1:109-112.
15. Seifu et al. 2005. *Trends in Food Science & Technology*. 16:137-154.
16. Griffiths. *J. Food Prot.* 1986. 49:696-705.
17. Stepaniak. *Int. J. of Dairy Technology*. 2004. 57:2/3:153-171.
18. Kulczycki, Jr. *Molecular Immunology*. 1987. 24:3:259-266.
19. Coveny and Darnton-Hill. *Med. J. of Australia*. 1985. 143:508-510.
20. Farrell and Douglas. *Kiel. Milchwirtsch. Forschungsber.* 1983. 35:345-356.
21. Fox. 1995. *Heat-Induced Changes in Milk*, 2nd ed. P.F. Fox, ed. IDF.
22. Williamson et al. *Arch. Dis. Child.* 1978. 53:7:555-563.
23. Zurera-Cosano et al. *Food Chemistry*. 1994. 51:75-78.
24. Gavini et al. *Int. J. Systemic Bacteriology*. 1991. 41:4:548-557.
25. Arunachalam. *Nutrition Research*. 1999. 19:10:1559-1597.
26. Beerens et al. *Int. J. Food Microbiology*. 2000. 54:163-169.
27. de Vrese et al. *Am. J. Clin. Nutr.* 2001. 73:421S-429S.
28. Holzapfel and Schillinger. *Food Research Int.* 2002. 35:109-116.
29. McBean and Miller. *J. Am. Dietetic Assoc.* 1998. 98:671-676.
30. Savaiano et al. *Am J. Clinical Nutrition*. 1984. 40:6:1219-1223.
31. FAO/WHO. Report of a Joint FAO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food. April 30 and May 1, 2002.
32. Windig et al. *J. Dairy Sci.* 2005. 88:335-347.
33. Norman et al. *J. Dairy Sci.* 2000. 83:2782-2788.

34. Berry et al. J. Dairy Sci. 2006. 89:4083-4093.
35. Oleggini et al. J. Dairy Sci. 2001. 84:1044-1050.
36. Waser et al. Clinical and Experimental Allergy. 2007. 37:661-670.
37. Langer et al. Emerging Infectious Diseases. 2012. 18:385-391.
38. Van Kessel et al. Journal of Food Protection. 2008. 71:1967-1973.
39. American Academy of Pediatrics. Pediatrics. 2014. 133:1:175-179.
40. Robinson et al. Emerging Infectious Diseases. 2014. 20:1:38-44.

Attachment D



Motor Carrier Division

October 1, 2014

Summary of Exceptional
Hauling Permit Regulations
for Ag Products & Raw Milk

OVERVIEW

- 2 Categories of Exceptional Hauling Permits - Milk
- 5 Axle Combination Milk Vehicle Specifications
- 6 Axle Combination Milk Vehicle Specifications
- General Conditions Applicable to ALL EHP's
- Approved & Prohibited Routes
- Required Documents to be Carried by Driver at all times
- Statewide Virtual Screening & Evasive/Unsafe Operations
- SHA Administrative Sanctions & Permit Revocation
- Questions

Maryland House Bill 1246

Exceptional Hauling Permit for Agriculture Products & Raw Milk

- Signed into Law May 5, 2014
- Effective October 1, 2014
- Update Effective Oct. 1, 2016
- Transportation Article §24-113.2

**MAXIMUM ALLOWABLE
GROSS and AXLE
WEIGHTS for
EXCEPTIONAL HAULING
PERMITS**



- **95,000 POUNDS GROSS COMBINATION WEIGHT FOR A COMBINATION OF VEHICLES WITH AT LEAST 6 AXLES CARRYING MILK; *OR***
- ***88,000 POUNDS GROSS COMBINATION WEIGHT FOR A COMBINATION OF VEHICLES WITH 5 AXLES CARRYING MILK********

**88,000 POUNDS GROSS
COMBINATION WEIGHT FOR A
COMBINATION OF VEHICLES WITH 5
AXLES CARRYING MILK
(5 AXLE PERMIT FOR MILK
VALID FROM OCTOBER 1st, 2014
to OCTOBER 1st 2016
DURING THE MONTHS OF
MARCH 1st - JUNE 30th ONLY!!)**

General Conditions
Applicable
to ALL types of
SHA Exceptional
Hauling Permits

A maximum of **20,000 pounds** gross weight on a **single axle**

For any **consecutive axle configuration** of two or more axles on individual vehicles in the combination, the maximum gross weight specified in § **24–109(c)** of this subtitle (**Tandem & Formula**)

Be allowed a load limit **tolerance** of only **1,000 pounds for gross** combination weight and **15%** for axle weights.



Twice each year, submit to
and pass a North American
Standard Driver/Vehicle
Level 1 inspection

(This does NOT include the PA annual vehicle inspection)

37 Step North American Standard Level I Roadside Safety Inspection ONLY



- *While operating a combination of vehicles under the authority of an exceptional hauling permit issued under subsection (b) of this section, **a person may not:***
- Violate a **highway restriction** issued by a competent authority;
- Operate the combination of vehicles on the **interstate highway system**, as defined in § 8–101(j) of this article;
- Operate the combination of vehicles if the combination of vehicles exceeds any **tire weight rating or tire speed restriction** adopted under § 25–111 of this article; or
- Fail to comply with the **terms and conditions** of the exceptional hauling permit.

Terms and Conditions

- Must view the SHA Hauling Permit web page (<http://roads.maryland.gov/cvo>) for the list of currently active restrictions prior to any move.
- Snow Emergency Plan restrictions also apply – No permit weights allowed in jurisdictions with active SEP's in place.
- *Holiday restrictions will be in effect for the EHP- Loads will be required to adhere to normal weight limitations (i.e. 80,000 pounds).

ROUTING & RESTRICTIONS





EISENHOWER
INTERSTATE
SYSTEM





RESTRICTED BRIDGES, HIGHWAYS & STRUCTURES





- **Documentation on board.**

- **While operating a combination of vehicles under the authority of an exceptional hauling permit, a person shall have in the person's possession:**



- **(2) For each vehicle in the combination of vehicles, a copy of a valid North American Standard Driver/Vehicle Level 1 inspection report issued within the preceding 180 days that shows no out-of-service violations.**



COMBINATION VEHICLE FOR MILK ONLY

88,000 GROSS

- CARRIES TO A PROCESSING PLANT **FROM MARCH 1 UNTIL JUNE 30** RAW LIQUID MILK THAT IS THE ONLY LOAD ON THE VEHICLE AND IS LOADED FROM BULK LIQUID MILK STORAGE TANKS AT ONE OR MORE FARM LOCATIONS

5 AXLE COMBINATION VEHICLE 88,000 GROSS

28 ≥ FT



6 AXLE COMBINATION VEHICLE FOR MILK ONLY

95,000 GROSS



95,000 GROSS







Ineligible for permit



Ineligible for permit

SHA/MCD

Statewide Virtual Screening Sites



Vehicle ID: 20140804142817-4-920210
Date: 08/04/2014 2:28:17 PM
Weight: 90260 lbs
Speed: 51.8 mph
Length: 50.5 ft
Class: 9
Flags: Over weight gross, over weight bridge, over weight tandems, over weight axle VIOLATION

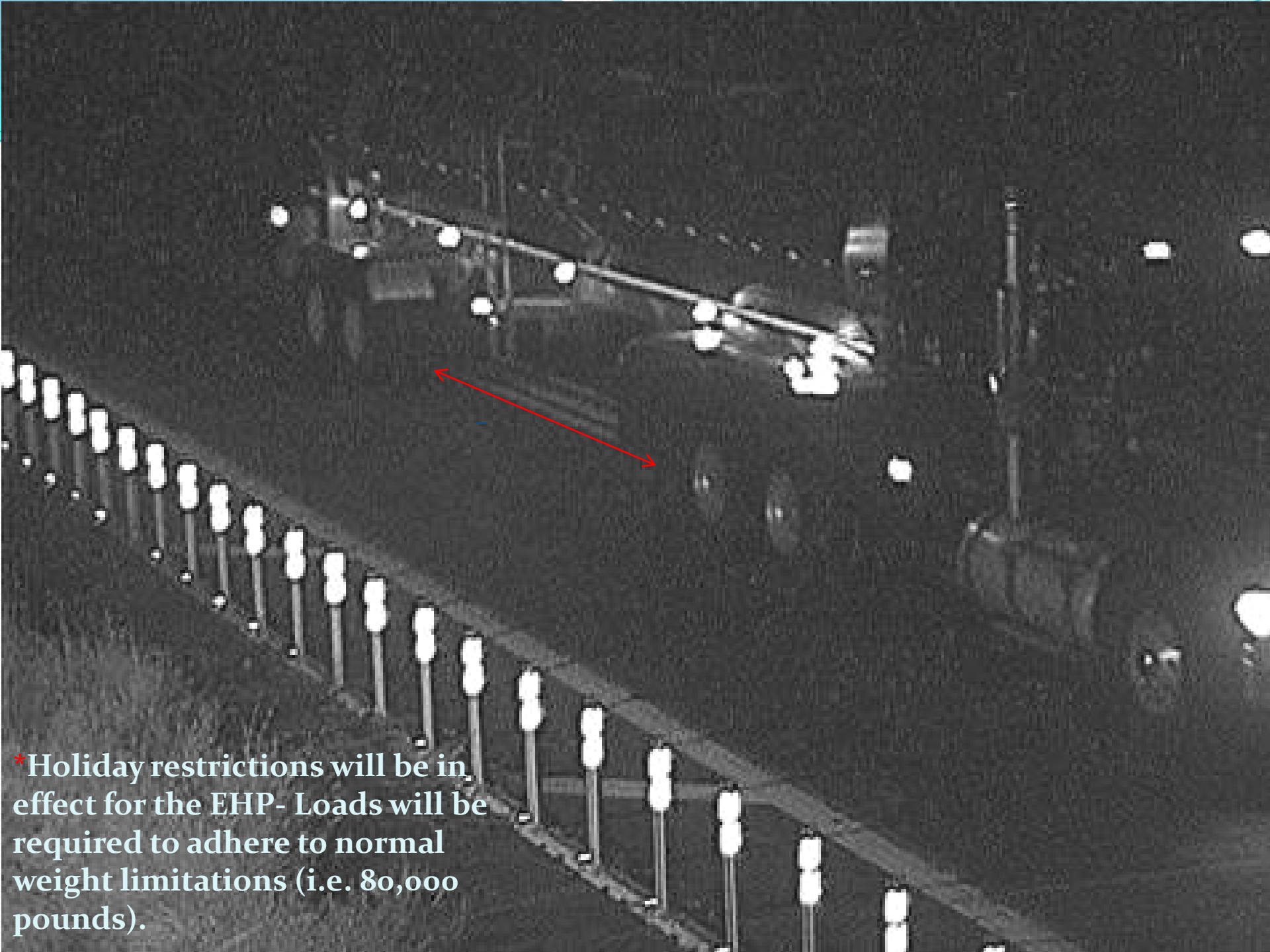
Spacing: 4 27.7 4.2 14.6
Axles: 18.5 19.5 20.3 19.8 12.2
Wt: 18.5 19.5 20.3 19.8 12.2



Vehicle ID: 20140703180153-4-546104
Date: 07/03/2014 6:01:53 PM
Weight: 95270 lbs
Speed: 55.2 mph
Length: 50.5 ft
Class: 9
Flags: Over weight gross, over weight bridge, over weight axle, over weight tandems VIOLATION

Spacing: 4 29.2 4.3 13
Axles: 20.2 19.7 21.6 21.3 12.5
Wt: 20.2 19.7 21.6 21.3 12.5





*Holiday restrictions will be in effect for the EHP- Loads will be required to adhere to normal weight limitations (i.e. 80,000 pounds).

EHP Enforcement



Administrative Sanctions



Administrative Sanctions

- A violation of this section, regulations adopted to implement this section, or the terms and conditions of an exceptional hauling permit issued under subsection (b) of this section shall:
- Void the authority granted under the exceptional hauling permit;
- Subject the vehicle to all weight requirements and tolerances specified in this article; and
- For a violation of a weight restriction specified in this section that exceeds 5,000 pounds, subject the exceptional hauling permit to immediate confiscation by an officer or authorized civilian employee of the Department of State Police, an officer of the Maryland Transportation Authority Police, or any police officer.

Administrative Sanctions

- On notification of the confiscation of an exceptional hauling permit, the State Highway Administration shall review the confiscation, verify the violation of a weight restriction, and, if the State Highway Administration determines that a violation did occur, revoke the permit.
- An owner or operator of a combination of vehicles may appeal the revocation of an exceptional hauling permit to the State Highway Administrator or the Administrator's designee.





SHA Hauling Permit Section Office
7491 Connelley Drive
Hanover, Maryland 21076

Associated Fees

An applicant for an exceptional hauling permit shall pay to the State Highway Administration:

\$250 for the issuance of a new annual permit or the annual renewal;

or

\$30 for the issuance of a 30–day permit;

\$1,000 for the reinstatement of a permit that was revoked under subsection (f)(3) of this section for a first violation; and

\$5,000 for the reinstatement of a permit that was revoked under subsection (f)(3) of this section for a second or subsequent violation within the prior 24 months.

A fee paid under this subsection is nonrefundable.



Questions?