Report

of the

Raw Milk Policy Working Group

March 2011

Department of Agriculture, Trade, and Consumer Protection
State of Wisconsin

State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection
Ben Brancel, Secretary

March 2011

Dear Secretary Brancel:

I am pleased to present you with the report and recommendations of the Raw Milk Policy Working Group.

The working group was asked to explore and evaluate the legal and regulatory alternatives under Wisconsin law that would be necessary to protect public health if dairy farmers are allowed to sell raw milk to consumers on their farms.

Although the members of the Raw Milk Policy Working Group held strong and divergent opinions, they also shared ownership in the issue and a stake in the outcome. The facilitated process we used provided a forum for the group's respectful and reasoned discussion, and produced a wealth of practical information and ideas. The thoughtful recommendations illustrate the value of bringing together the dairy stakeholders to lend their expertise and perspective to such an important topic for Wisconsin.

The working group recognized there is an inherent health risk associated with drinking raw milk. The group reached consensus on a comprehensive regulatory framework that includes food safety regulations, best management practices, and education initiatives that will reduce, but not eliminate the health risks to consumers drinking raw milk. The report contains the background information the group reviewed and the key discussion points that led to the group's recommendations.

I was honored to chair this fine group of dedicated citizens as they worked respectfully and productively through the difficult issues to produce their recommendations.

Sincerely,

Richard Barrows, Chair
Raw Milk Policy Working Group

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Assignment

In January 2010, Secretary Rod Nilsestuen of the Wisconsin Department of Agriculture, Trade, and Consumer Protection appointed a 22-member working group representing a broad range of stakeholders in Wisconsin's dairy industry. Secretary Nilsestuen asked the working group to:

> Explore and evaluate the legal and regulatory alternatives that would be necessary to protect public health if dairy farmers are to be allowed to sell raw milk on their farms in Wisconsin.

The working group met 12 times between January 2010 and March 2011. The group identified the actions that would be necessary to help reduce the risk of foodborne illness to consumers drinking raw milk. These actions comprise a comprehensive framework of food safety regulations, best management practices, and education initiatives.

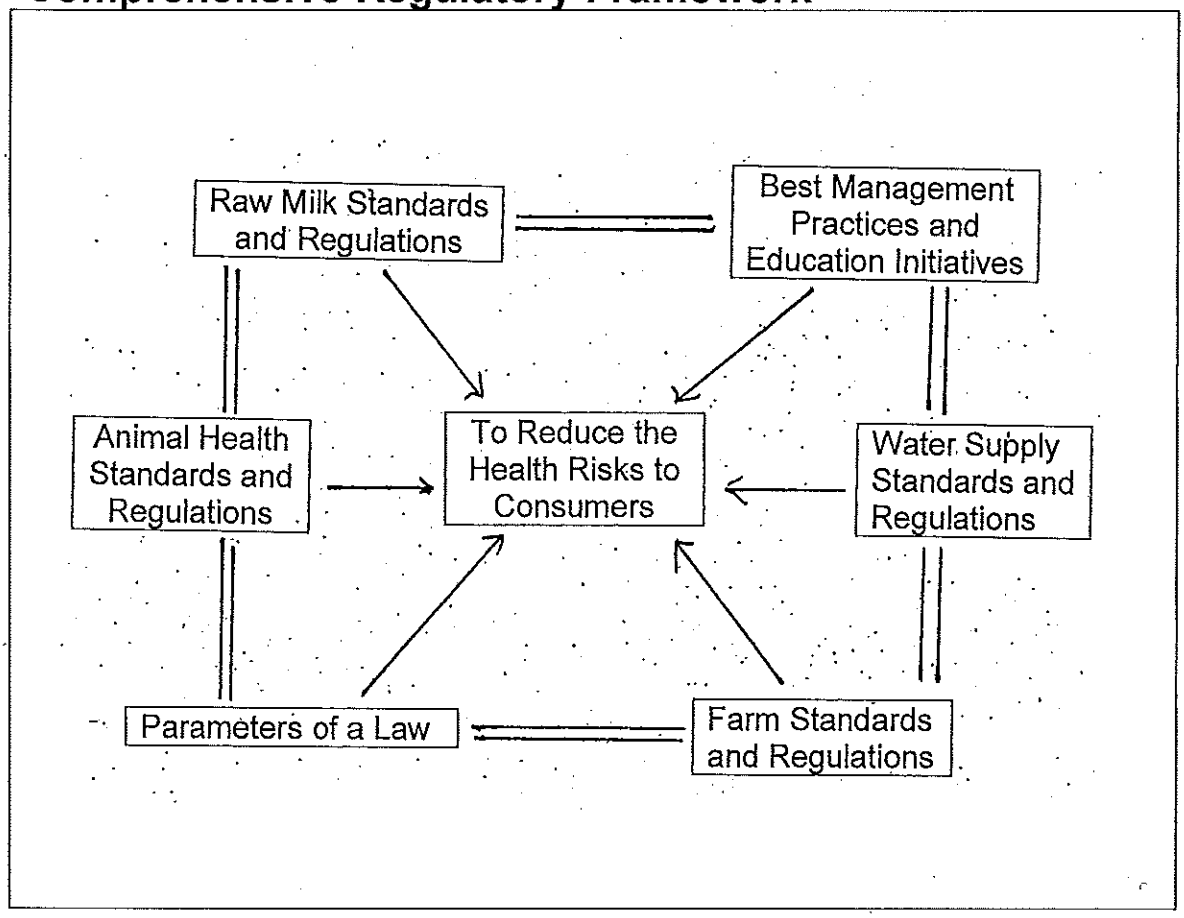
The Raw Milk Policy Working Group was not asked to endorse or reject a public policy to legalize raw milk sales, but rather to evaluate regulatory options necessary to reduce the risk of foodborne illness for consumers drinking raw milk.

Comprehensive Regulatory Framework

The comprehensive regulatory framework developed by the Raw Milk Policy Working Group includes recommendations in six general areas:

1. Parameters of a law
2. Animal health standards and regulations
3. Raw milk standards and regulations
4. On-farm water standards and regulations
5. Farm standards and regulations
6. Best management practices and education initiatives

Comprehensive Regulatory Framework



This Executive Summary includes the key recommendations made by the Raw Milk Policy Working Group. The summary does not include all of the working group's recommendations. All of the working group recommendations are included in the chapters found in the body of this report.

Summary of Key Recommendations

Parameters of a Law

Key recommendations:

- Raw milk may be purchased and sold only at a licensed raw milk farm where it is produced.
- Only fluid, raw cow's milk would be legal to sell on a farm.

- The sale and distribution of raw milk to wholesalers or other third-party distributors should be prohibited. The resale or redistribution of raw milk by the consumer purchasers should also be prohibited.

- The producer permitted to sell raw milk must be required to follow the generally-applicable state and federal food safety; packaging, labeling, and weights and measures laws associated with food production. Producers must be required to follow the generally-applicable state and federal laws prohibiting the sale of adulterated or misbranded food.

- All farms selling raw milk should be treated the same and must follow one set of laws, the same set of laws governing the sale of raw milk. There should not be different requirements for different sizes of farms or herds or different categories of farms or herds as it pertains to the sale of raw milk.

- Raw milk producers should not be exempt from any liability for personal injury or damages incurred by a raw milk consumer.

- On farms where the cows are milked by hand it should be illegal to sell raw milk to consumers.

Animal Health Standards and Regulations

Key recommendations:

- To receive an annual permit to sell raw milk on the farm, the producer should be required to test his or her cows for three animal diseases: 1) tuberculosis, 2) brucellosis, and 3) *Streptococcus agalactiae.*

- Prior to selling raw milk on the farm, as a pre-requisite to receive an annual raw milk permit, all the cows on the farm must test free of tuberculosis and brucellosis and negative for *Streptococcus agalactiae.*

- To continue to receive an annual permit to sell raw milk on the farm, when new cows enter the herd, they must be tested and test free of tuberculosis and brucellosis and test negative for *Streptococcus agalactiae.*

- After receiving an initial raw milk permit and to continue to receive an annual permit to sell raw milk, the producer should be required to test all the cows on the farm for tuberculosis and brucellosis once every three years, or if the producer wishes to establish a certified or accredited tuberculosis and brucellosis free herd, the cows must be tested once every two years.

- After receiving an annual permit to sell raw milk on the farm, the producer should be required to test the raw milk for *Streptococcus agalactiae* when a weekly test for somatic cell count exceeds 400,000 cells/mL.

Raw Milk Standards and Regulations

Key Recommendations for Standard Plate Count, Somatic Cell Count, and Coliform Bacteria Testing:

- The producer should be required to send a sample of the raw milk to a certified laboratory to be tested once each week to determine standard plate count, somatic cell count, and the coliform bacteria count. The raw milk must meet these test standards each week:

  - ≤ 20,000 cfu/mL for standard plate count

  - ≤ 400,000 cells/mL for somatic cell count

  - ≤ 10 cfu/mL for coliform bacteria

- Prior to selling raw milk on the farm, as a pre-requisite to receive a permit to sell raw milk, the producer should be required to demonstrate the raw milk has been tested by a certified laboratory and verify the test results show the standard plate count, somatic cell count, and coliform bacteria count meet the test standards required.

Key Recommendations for Testing for Antibiotic Drug Residues:

- Producers holding an annual permit to sell raw milk should be required to sample and test it for antibiotic drug residues in every lot of raw milk produced for every day raw milk goes into a container for sale to a consumer.

- Every time the raw milk is sampled and tested, the test results must be negative for antibiotic drug residues using the approved Food and Drug Administration tests.

- Prior to selling raw milk, as a pre-requisite to receive a permit to sell raw milk permit, the producer should be required to sample and test the raw milk and verify the raw milk tests are negative for antibiotic drug residues.

Key Recommendations on Testing Raw Milk for Pathogenic Bacteria:

- The producer should be required to send a raw milk sample to an International Standards Organization (ISO) accredited laboratory to be tested once each month for each of these four bacteria:

  - *Campylobacter*
  - *Salmonella*
  - *Listeria*
  - *E. coli* O157:H7

- The monthly test results for each of the four bacteria should be negative or the test result showing no bacteria have been detected.

- Prior to selling raw milk, as a pre-requisite to receive a permit to sell raw milk, the producer should be required to demonstrate the raw milk has been tested by an ISO accredited laboratory and the test results show no *Campylobacter, Salmonella, Listeria,* or *E. coli* O157:H7 has been detected in the raw milk sample.

Key Recommendations for On-farm Raw Milk Sampling Procedures:

- The producer should be required to follow specific on-farm sampling procedures when collecting raw milk to be tested for standard plate count, somatic cell count, coliform bacteria, antibiotic drug residues, *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7 and when collecting water samples to be tested for coliform bacteria.

- Prior to selling raw milk, as a pre-requisite to receive a permit to sell raw milk, the producer should be required to establish and document a business relationship with certified and ISO accredited laboratories to perform the raw milk and water tests for the producer.

- The raw milk producer should be required to be a licensed Bulk Milk Weigher and Sampler to take raw milk and water samples on the farm.

- The raw milk producer should be required to follow specific laboratory protocols for sampling and shipping the raw milk and water samples to the laboratory to be tested. The producer is required to keep certain sampling and testing records.

Key Recommendations on Temperature Controls for Raw Milk:

- Within two hours after milking begins and the first drop of raw milk enters the bulk tank until the raw milk is sold to a consumer, the temperature of the unpasteurized milk on the farm must be maintained ≤ 40° F.

- The producer should be required to empty, wash, and sanitize the bulk milk tank at least every 48 hours.

Key Recommendations for Time Controls on Raw Milk:

- The producer should be required to sell the raw milk within 48 hours after milking begins.

- The label for containers holding raw milk for sale to consumers should be required to include a numerical code that establishes the hour within 48 hours the raw milk must be sold to consumers.

- The label for containers holding raw milk for sale should be required to include safe handling instructions stating either "Best used within 48 hours of purchase," or "Drinking raw milk within 48 hours after purchase may help reduce the risk of foodborne illness."

Key Recommendations on Filling Containers with Raw Milk:

- The producer should be required to use specific kinds of containers and lids to hold and cap the raw milk for sale to consumers.

- The raw milk producer should be only person allowed to fill the container with raw milk for sale on the farm, unless the container is filled mechanically in which case a machine fills the container.

- The producer should be required to clean and sanitize the milking equipment and bulk milk tank using specific procedures.

- There should be three discreet processes for filling containers with raw milk that would be legal for producers to use on the raw milk farm. The three processes are:

  - Filling the container by hand from the bulk tank and giving it to the consumer to take home once the container is filled.
  - Filling the container by hand from the bulk tank and then refrigerating it for the consumer to pick up and take home within a specified time period.
  - Filling the container mechanically and refrigerating the container for the consumer to pick up and take home within a specified time period.

- The producer should be required to follow specific standards and procedures for storing the containers and lids and the location of the refrigerator on the farm.

- During the filling and capping of containers, the temperature of the raw milk should be required to be maintained at ≤ 40° F.

- If the producer chooses to mechanically fill the containers, the producer should be required to hold a dairy processing plant license.

Key Recommendations on Labeling Raw Milk Containers:

- Containers filled with raw milk for sale should be required to be labeled and the labels should include specific language about the raw milk product and the place where it is produced.

- The labels should be required to include specified safe handling instructions and warning statements. The label should be required to include a numerical code to allow it to be traced back to the farm where it was produced.

- The producer selling raw milk should be required to comply with all the current federal and Wisconsin state laws on food advertising and labeling which prohibit food misbranding, deceptive advertising, misrepresentation, and deceptive labeling. The producer should be required to also comply with food safety laws on advertising claims related to health and nutrition.

- The labels for the containers should be required to be approved prior to the time the producer is granted a raw milk permit.

On-Farm Water Standards and Regulations

Key Recommendations:

- The raw milk producer should be required to test the farm's well water or water source for coliform bacteria prior to selling raw milk as a pre-requisite to receive a raw milk permit and annually thereafter. The coliform bacteria test results must meet the Wisconsin drinking water standard for safe and potable water.

Farm Standards and Regulations

Key Recommendations on Licensing Raw Milk Farms:

To sell raw milk on the farm directly to consumers:

- Producers should be required to hold a raw milk permit. Producers must meet specific standards as pre-requisites to receive a permit and begin selling raw milk on the farm.

- Producers should be required to meet specified raw milk farm permit requirements and standards including both the current Grade A farm standards and a new set of farm standards designed for producing raw milk on the farm for direct sale to consumers.

Key Recommendations on Raw Milk Farm Standards:

- Producers should be required to meet the Raw Milk Farm Standards outlined by the working group. These standards should be required to be met prior to receiving a permit to sell raw milk on the farm.

- The Raw Milk Farm Standards should be required to include two major components:

    - The existing set of dairy farm standards used for the Grade A dairy farm permit, with one exception – the producer is not required to sell his or her milk to a dairy plant processor.

- A new set of farm standards necessary to regulate the new and different activities that will occur on farms producing and selling raw milk to consumers. Some of the newly created farm standards address the new requirements for raw milk, water, and animal health testing; bottling and labeling raw milk containers; and temperature and time controls.

Key Recommendations on On-farm Incident Response Plans:

- The producer should be required to write a plan of action to respond to any incident that requires immediate action to address a known or imminent health risk for consumers who have purchased raw milk that may be contaminated.

- When an imminent health risk to consumers is known, the producer should be required to:

  - Stop selling raw milk to consumers
  - Dispose of and/or divert the raw milk
  - Notify his or her customers of the problem
  - Notify the county or local public health department and DATCP
  - Begin to investigate the cause of the problem on the farm
  - Cooperate with public health and agriculture authorities to identify and solve the problem

- The producer should be required to keep certain records as part of the On-farm Incident Response Plan.

Key Recommendations on Raw Milk Farm Inspections:

- Raw milk farms should be required to be inspected routinely by the Wisconsin Department of Agriculture, Trade, and Consumer Protection (DATCP).

- The Raw Milk Farm Standards should be required to be used as the farm inspection standards.

- The number of inspections each year for each farm should be required to be determined by DATCP by the evaluating the farm's performance in relation to a set of specific performance benchmarks. Currently DATCP inspects Grade A farms using an annual inspection frequency schedule based on benchmarks. The current program is known as the Performance Based Farm Inspection program.

- Raw milk farms consistently meeting the identified performance based measures should be required to be inspected less frequently than those raw milk dairy farms meeting fewer of the performance benchmarks.

- Raw milk farms that do not consistently meet the performance benchmarks will be required to be inspected more frequently than farms that consistently meet the benchmarks.

- The number of annual farm inspections should be increased or decreased depending on the consistency of meeting the performance benchmarks. A raw milk farm should have the opportunity to be inspected at the established minimum number of inspections per year if it consistently meets the performance benchmarks.

Key Recommendations on Permit Fees for Raw Milk Farms:

- Raw milk producers should be required to pay an annual fee to hold a permit to sell raw milk on the farm.

- The amount of the fee should be determined consistent with the current DATCP dairy and food industry fee schedule and consistent with the DATCP Policy # 175.

Best Management Practices and Educational Initiatives

Key Recommendations on Best Management Practices:

- The DATCP should be required to write a Best Management Practices Manual for dairy farmers who wish to sell unpasteurized milk to consumers on their farms.

- DATCP should be required to work with the University of Wisconsin and the Wisconsin Department of Health Services in the preparation of the best management practices manual.

Key Recommendations on Education Initiatives:

- Education initiatives for raw milk producers should be developed and include:

- A manual of best management practices for producing and selling raw milk on a farm should be written by DATCP in conjunction with the University of Wisconsin.

- A course curriculum should be written by DATCP in conjunction with the University of Wisconsin for producers to learn key competencies and practices necessary to produce and sell raw milk in a manner that helps reduce the foodborne illness risk to consumers drinking it.

- A producer should be required to pass a competency test prior to applying for a permit to sell raw milk.

- Education initiatives for consumers should include a consumer's guide on the safe handling of raw milk. DATCP should be required to write the consumer's guide, and should seek assistance from the University of Wisconsin as it prepares the guide.

The Report of the Raw Milk Policy Working Group

The first part of the report of the Raw Milk Policy Working Group presents a summary of the background information the working group reviewed and evaluated at its meetings, including information on:

- Wisconsin's current laws on the sale of raw milk
- 2009 Senate Bill 434 legalizing raw milk sales and the Governor's veto
- The working group assignment and its members
- Federal and state dairy and food safety laws and regulations
- Pasteurized and unpasteurized milk
- Inherent risks of producing raw milk
- Public health and raw milk
- Raw milk laws in other states
- Wisconsin's dairy industry

- Themes and challenges of the comprehensive regulatory framework
- The working group consensus on the comprehensive regulatory framework
- Regulatory cost analysis of the comprehensive regulatory framework for producers and consumers

The second section of the report includes the recommendations for a comprehensive regulatory framework, including all the food safety regulations, best management practices, and education initiatives recommended by the working group.

Background Information

Information Reviewed by the
Raw Milk Policy Working Group

Wisconsin's Current Law on Raw Milk Sales

In Wisconsin, it is legal to sell and distribute pasteurized milk only. Chapter 97, Wis. Statutes is the law governing the production, processing, and sale of pasteurized milk.

It is illegal in Wisconsin to sell or distribute unpasteurized milk (raw milk) or unpasteurized fluid milk products:

- To consumers directly or
- To any person for resale or redistribution to a consumer

The law applies to any sale and distribution across Wisconsin's borders to another state and anywhere within its borders. The term "distribution" is distinguished from the word "sale." The word "distribution" is a broader term and has the general meaning of "giving out or delivering".

Wisconsin law does not prohibit the distribution of unpasteurized milk, produced on a licensed dairy farm to:

- The milk producer licensed to operate that dairy farm. The producer can give herself or himself milk that is not pasteurized.
- An individual who has a bona fide ownership interest in the licensed dairy farm operation if it is a legal entity other than an individual or married couple.
- A family member or nonpaying household guest who consumes the raw milk at the home of an individual farm operator or bona fide owner.

Wisconsin law does not prohibit the sale and distribution of unpasteurized milk, produced on a licensed dairy farm to:

- The employees of that dairy farm

Wisconsin law does not prohibit the 'incidental' sale of unpasteurized milk to:

- A consumer on the farm where the milk is produced, for consumption by the consumer only, the consumer's family only, or the consumer's nonpaying guests.

The legal definition of an 'incidental' sale is a sale that is not made in the regular course of business or is not preceded by any advertising, offer, or solicitation made to the general public through any communications media. 'Incidental sale' does not include 'distribution' beyond the consumer's family or nonpaying guests.

Legislation to Legalize Raw Milk Sales

Spring of 2010

Senate Bill 434 was introduced in the Wisconsin Legislature in December 2009 to allow the sale of raw milk within the borders of the state. The bill passed both houses of the Legislature in March 2010. The bill was vetoed by Governor Jim Doyle in May 2010. In summary, Governor Doyle stated in his veto message:

> "I am vetoing 2009 Wisconsin Senate Bill 434 in its entirety... I cannot ignore the potential harmful health effects of consuming unpasteurized milk that have been raised by many groups... I recognize there are strong feelings on both sides of this matter, but I must side with public health and the safety of the dairy industry... "
>
> "This bill does not contain adequate testing requirements to ensure the safety of the public when consuming unpasteurized milk... Significant questions must be answered and improvement should be made, particularly in strengthening testing requirements of unpasteurized milk, before enacting this type of legislation."
>
> "The dairy industry is the centerpiece of Wisconsin agriculture... An outbreak of disease from consumption of unpasteurized milk could damage the state's reputation for providing good, healthy dairy products...However, significant questions must be answered and improvements made...before enacting this type of legislation."
>
> "In January 2010 the Department of Agriculture, Trade and Consumer Protection created the Raw Milk Policy Working Group comprised of a wide array of stakeholders and experts charged with reviewing the legal and regulatory framework that might allow for the sale of unpasteurized milk to consumers without compromising public health...I believe the Working Group should be allowed to complete its analysis prior to making changes to the legal framework surrounding unpasteurized milk. I believe this veto is the right decision to protect the health and safety of Wisconsin citizens."

The full text of Governor Doyle's veto message on the raw milk bill can be found in Appendix 16.

Raw Milk Policy Working Group

In January 2010, Secretary Rod Nilsestuen of the Wisconsin Department of Agriculture, Trade, and Consumer Protection appointed a 22-member working group representing a broad range of stakeholders in Wisconsin's dairy industry and asked it to:

> Explore and evaluate the legal and regulatory alternatives that would be necessary to protect public health if dairy farmers are to be allowed to sell fluid raw milk on their farms in Wisconsin.

The 22 members appointed to the working group represent a wide array of Wisconsin dairy industry, including eight farmers, several artisan cheese makers, dairy processors, consumers, raw milk advocates, food and dairy scientists, an epidemiologist, veterinarian, and food safety and public health professionals.

The Assignment is Specific to Public Health and Consumers

Much of the controversy surrounding the sale of raw milk to consumers is a debate about whether raw milk is safe to drink. When Governor Doyle vetoed the raw milk bill in May 2010, he stated the legislation that had passed did not "ensure the safety of the public when consuming unpasteurized milk." Governor Doyle reiterated the public health and regulatory charge given to the Raw Milk Policy Working Group – "to explore and examine the legal and regulatory alternatives necessary to protect public health."

The working group was not given the assignment to deliberate and make recommendations on whether the current law prohibiting the sale and distribution of raw milk should be changed or if raw milk sales should be legally allowed in Wisconsin. The group was not asked to endorse or reject the idea of the on-farm sale of raw milk, but to identify the regulatory alternatives that would be necessary to protect the health and safety of the public.

The Assignment is Specific to Raw Milk Produced from Cows

The assignment given to the working group is specific to fluid raw milk produced from cows that will be sold directly to consumers on the farm. The group was not assigned to examine options pertaining to raw milk produced from goats or sheep. This distinction was made purposefully. Although farmers milking cows, goats, or sheep use similar production methods and some standards and regulations may be similar, the standards and regulations required to reduce the health risks associated with raw milk produced from different animals are not always the same. The practical implementation of the standards and regulations on the farm for the different species is also achieved in different ways.

Developing effective, reasonable, and practical food safety regulations and best management practices for raw milk produced from different animals requires sufficiently different science, facts, and expertise. For these reasons, the Raw Milk Policy Working Group was comprised of individuals with expertise and practical experience in food safety science associated with producing and processing cow's milk.

The full text of the assignment given to the Raw Milk Policy Working Group can be found in Appendix 1.

Facilitated Consensus Process

The Raw Milk Policy Working Group used a formal facilitated process at its meetings to build and encourage discussions and deliberations, identify and clarify member and group interests, and generate ideas and alternatives for regulating raw milk sales.

Facilitated meetings can be beneficial in bringing people together who have a common stake in a problem and its resolution, often to tackle highly charged or sensitive issues of a complex nature. Facilitated meetings are chosen for groups making recommendations on public policy or programs or strategic direction where the stakeholders have firmly-held beliefs and strong divergent positions on the expected outcome.

The group's meetings were facilitated to encourage participation and listening by all the group members, to generate ideas, develop a variety of options for mutual gain, and to focus attention on the problems and an array of possible solutions, and away from entrenched stakeholder positions. The process is designed to accentuate the knowledge and experience brought to the table by the stakeholders, knowing they are best suited to the task because they have an ownership in the problem, a stake in the outcome, and the expertise and perspective necessary to bear on the issue.

The Raw Milk Policy Working Group held 11 all-day meetings and one teleconference call meeting between January 2010 and March 2011. The group reached consensus on the pieces of a comprehensive framework to regulate the sale of raw milk, a framework necessary to help prevent some of the risk of foodborne illnesses to consumers drinking raw milk. The comprehensive regulatory framework includes food safety regulations, best management practices, and educational initiatives.

Guiding Principles

The Raw Milk Policy Working Group created four principles to guide its work and decisions, striving to ensure its recommendations:

1. Protect public health, the safety of food, consumers, and the Wisconsin dairy industry
2. Establish fair, useful, and clear regulations
3. Are based on science, facts, and education
4. Reflect stakeholder consensus

Review of Federal and State Dairy and Food Safety Laws

To fulfill its assignment, the working group placed the highest priority on identifying food safety regulations that might be effective in reducing the health risks for consumers drinking raw milk. The working group reviewed the current federal and state laws governing food safety and the production and processing of dairy and other food products, including:

- The food safety authorities of the United States Food and Drug Administration and the scope of the regulations under the federal Pasteurized Milk Ordinance
- The food safety authorities of the U. S. Department of Agriculture
- The mission of the Centers for Disease Control and Prevention
- The food safety authorities of the Wisconsin Department of Agriculture, Trade, and Consumer Protection and the public health authorities of the Wisconsin Department of Health Services
- The food safety roles and responsibilities of Wisconsin's county and local public health departments
- The federal and state laws governing food misbranding and labeling, food advertising and promotion, weights and measures, health and nutrition claims, and standards of identity for milk
- Raw milk laws and regulations in other states where it is legal to sell raw milk

- On-farm regulations and best management practices that may help reduce the health risks to consumers drinking raw milk

- The inherent on-farm risks of producing raw milk for consumers to drink and public health issues associated with drinking raw milk

- Wisconsin dairy industry statistics, comparing Wisconsin to other dairy states where raw milk sales are legal and states where raw milk sales are illegal.

A detailed list of the food safety laws and regulations reviewed by the Raw Milk Policy Working Group are summarized in Appendix 7.

Members of the Raw Milk Policy Working Group

Dr. Richard Barrows, Chair Madison	Professor and Associate Vice Chancellor Emeritus Department of Agricultural and Applied Economics College of Agriculture and Life Sciences University of Wisconsin -- Madison
James Baerwolf Columbus	Dairy Farmer Owner - Operator, Sassy Cow Creamery
Dick Cates Spring Green	Grass-fed Beef Farmer, Cates Family Farm Member, Wisconsin DATCP Board Director of the University of Wisconsin School for Beginning Dairy and Livestock Farmers
Jeffrey P. Davis, MD Madison	Chief Medical Officer and State Epidemiologist for Communicable Diseases & Emergency Response Wisconsin Department of Health Services
Patty Edelburg Scandinavia	Dairy Farmer Board of Directors, Wisconsin Farmer's Union
Ted Galloway Neenah	Dairy Processor Vice President, Galloway Company
Mike Gingrich Dodgeville	Dairy Farmer and Artisan Farmstead Cheese Maker Uplands Cheese Company
Dale Grosskurth Wausau	Director, Marathon County Environmental Health Program
Melissa Hughes La Farge	General Counsel Organic Valley Cooperative
Vince Hundt Coon Valley	Organic Dairy and Beef Farmer St. Brigids Meadows LLC
Kevin Krentz Berlin	Dairy Farmer President, Waushara County Farm Bureau
Brad Legreid Madison	Executive Director Wisconsin Dairy Products Association
Willi Lehner Blue Mounds	Artisan Cheese Maker Bleu Mont Dairy
Shelly Mayer Slinger	Dairy Farmer and Executive Director of the Professional Dairy Producers of Wisconsin

Joe Plasterer Madison	Raw Milk Consumer Starkweather and Associates
Dr. Scott Rankin, Ph.D. Madison	Chair and Associate Professor Department of Food Science University of Wisconsin -- Madison
Dr. Pam Ruegg DVM, MPVM Madison	Professor Department of Dairy Science University of Wisconsin -- Madison
Steve Steinhoff Brookfield	Division Administrator (Retired) Division of Food Safety Wisconsin DATCP
Joe Weis Baraboo	Vice-President Foremost Farms USA
Jeff Wideman Monroe	Master Cheese Maker Maple Leaf Cheese Cooperative
Elizabeth Kohl Madison	Facilitator Executive Policy Advisor, Secretary's Office Wisconsin DATCP

Recognition is given to Amy McCauley, organic dairy farmer from Reedsburg and Mark Zinniker, dairy farmer from Elkhorn, for their participation on the Raw Milk Policy Working Group. The contribution of Amy and Mark to the working group's discussion and recommendations is much appreciated.

Pasteurized and Unpasteurized Milk

The Raw Milk Policy Working Group examined the reasons that drinking unpasteurized or raw milk is a public health concern. Throughout its discussion, it reviewed the history of pasteurization and the basic facts and science about pasteurized and unpasteurized milk, the bacteria that can be found in milk, and foodborne illnesses associated with drinking raw milk.

Raw milk is milk that has not been pasteurized. The two terms – raw milk and unpasteurized milk – have the same meaning. Both terms are used interchangeably throughout this report.

Raw cow's milk is rich in nutrients, high quality protein, essential vitamins, minerals, and calcium. For several thousands of years, raw milk has been processed into dairy products such as cream, butter, yogurt, and cheese. The importance of these dairy products in the human culture is undeniable.

Whereas humans have eaten dairy products produced from milk for several millennium, drinking fluid milk by humans in diverse age groups and in large numbers is a relatively recent occurrence. Pasteurization of milk is the primary reason for this change. Prior to 1940, people drinking fluid milk drank raw milk because pasteurization of fluid milk for human consumption was not routinely and widely done. Most importantly, in the late nineteenth and early twentieth century, as links between micro-organisms, foods, and disease were established, fluid raw milk was identified as a source of infection and illness for people. Approximately 25 percent of all foodborne and waterborne outbreaks of disease in humans before 1938 were associated with drinking unpasteurized or raw milk or eating raw milk products because the raw milk was contaminated by bacteria that can cause disease.

Many different kinds of bacteria may be found in raw milk. Some bacteria have no effect on food or humans. Most bacteria in raw milk are harmless. Some bacteria in raw milk are beneficial in helping produce food products enjoyed by many people such as cheese and yogurt. Some of the bacteria in raw milk are harmful, causing infection and disease or illness in humans. Sometimes these infections and illnesses have severe health consequences for raw milk consumers.

Bacteria are everywhere. Both the beneficial and harmful kinds of bacteria can be found commonly in the environment around us and in the foods we eat. Raw milk may become contaminated by harmful bacteria on the farm from many different sources. The harmful bacteria may be on healthy cows or in the air, soil, dust, water, manure, bedding material, silage, or drains in the environmental where the cow lives. Equipment used to produce the milk may harbor harmful bacteria. Equipment harboring harmful bacteria might include utensils, milking

machines, the bulk milk tank, and the pipe-line systems for transporting the milk from the cow to the bulk tank. The bacteria also may be carried by vectors such as insects or flies. People working in the barn or milk house such as the producer, milkers, or milk handlers may carry harmful bacteria on their bodies and clothing.

There is an inherent risk associated with drinking raw milk because it is not possible to keep bacteria out of raw milk. Bacteria are extremely small. The average size of a single bacterium is 1/25,000 of an inch in length. Placed side by side 25,000 bacteria cells create an inch-long line. Generally, only a very small number of the harmful bacteria are needed to be present in the raw milk to cause some people to become sick.

If raw milk is contaminated by the harmful bacteria from any of the potential sources in the barn, the raw milk provides an excellent, nutrient-rich medium for the harmful bacteria to grow. A small number of the disease-causing bacteria in raw milk can grow rapidly and increase to a very high number particularly if the milk has not been adequately cooled.

During the 1940's and 1950's, diligent efforts were made to improve the safety of milk by improving dairy herd health and reducing brucellosis, tuberculosis and mastitis in cattle and ensuring the bacteria that can cause these diseases were not transmitted to humans. Better sanitation practices on farms and dairy processing plants as well as consistent use of temperature controls to cool the milk helped reduce some of the health risks of raw milk.

The moderate heat treatment of pasteurization was found to be the most effective method designed to kill the harmful bacteria in raw milk to make it safe for people to drink. Prior to pasteurization, there wasn't an effective method to eliminate or control the harmful bacteria that can contaminate raw milk and which resulted in the high percentage of foodborne and waterborne illness outbreaks associated with consuming raw milk.

The pasteurization process most often used for the continuous processing of milk is called "high temperature short time" or HTST. This process involves heating the milk to a temperature of 161.5 ° F. for 15 seconds. Unlike sterilization, pasteurization is not designed to kill all the microorganisms in the raw milk. The pasteurization temperature and time are set specifically to reduce the number of viable harmful bacteria that may be in the raw milk without adversely changing the milk composition, flavor or nutrients.

Pasteurization became the principal process for rendering fluid milk and dairy products safe for human consumption. After 1930 to1940, pasteurization of raw milk became a widely adopted food safety practice throughout the United States and in other countries. Public officials at the federal and state levels established laws requiring raw milk to be pasteurized and made it illegal to sell and distribute.

The interstate sale of raw or unpasteurized milk is illegal. The U. S. Food and Drug Administration is responsible for regulating the laws which prohibit the interstate sale of raw milk. Intrastate sale of raw milk is regulated by individual states. Most states prohibit the sale of raw milk or significantly limit its sale within their borders because of the public health concerns associated with drinking it.

With the prevalent use of pasteurization as a food safety requirement, by 2001, less than 1 percent of all foodborne and waterborne outbreaks of disease were related to drinking or eating pasteurized milk and dairy products.

Inherent On-farm Risks of Producing Raw Milk

The Raw Milk Policy Working Group explored and evaluated the inherent risks of producing raw milk on-farm for sale and the food safety issues that make it unsafe to drink. From the information it gathered, the group developed a comprehensive framework of food safety regulations, best management practices, and educational initiatives to help reduce some of the chances for the raw milk to be contaminated when it is produced on the farm for sale directly to consumers.

The group identified several inherent, significant risks to consumers that are critical to address if dairy farmers are to be allowed to sell raw milk on the farm. These significant risks fall into three general categories:

1. Animal diseases that can be transmitted to humans when drinking raw milk. Tuberculosis and brucellosis are two such animal diseases.

2. Sanitation on the farm, in the barn, and during the milking process

3. Several harmful or disease-causing bacteria that most commonly contaminate raw milk and most frequently infect consumers drinking it. These disease-causing bacteria are present in the general environment where a cow lives and is milked.

Animal Diseases

The diligent efforts made during the 1950's and 1960's to improve dairy herd health and reduce brucellosis, tuberculosis and mastitis in dairy cattle addressed one of the critical on-farm food safety risks associated with consuming raw milk. Laws were passed to ensure animals were tested for infection and disease, and infected animals were quarantined and killed to achieve dairy herds that tested free of tuberculosis and brucellosis. Once Wisconsin attained status as tuberculosis-free and brucellosis-free, tuberculosis and brucellosis testing was either not required or required only in certain situations. These animal health

improvements along with the effectiveness of pasteurization in killing the bacteria that caused tuberculosis, brucellosis, and mastitis ensured milk was free of the bacteria that cause these animal diseases and would not be transmitted to humans.

Sanitation

Sanitation regulations adopted through the Pasteurized Milk Ordinance (PMO) and through state laws as Grade A dairy farm standards have helped improve the sanitation of the barn where dairy cows live and the equipment used to transport and store the milk on the farm from the cow to the bulk tank. The disease-causing or pathogenic bacteria that can contaminate the raw milk are present in the manure, bedding, and general environment where the cow lives. Improving barn and equipment sanitation has helped eliminate some of the places where harmful bacteria can reside. Again, pasteurization of the milk is the primary method essential to ensure the harmful or disease-causing bacteria are killed and the pasteurized milk is safe to drink.

Harmful Bacteria

Today, the likely presence of *Campylobacter, Salmonella, Listeria,* and the Shiga toxin-producing *Escherichia coli* such as *E. coli* O157:H7 in raw milk is the primary reason unpasteurized milk is not safe for consumers to drink.

These four harmful bacteria are the bacteria that most frequently contaminate raw milk today and cause infection and illness in humans. These four are commonly found in the barn environment and in the intestinal tract of healthy dairy cows.

The four common harmful bacteria are pathogenic which means they cause disease or are capable of causing disease. When these bacteria contaminate food and are transmitted from food to a human, they are also referred to as foodborne pathogens. While there are many species of bacteria within these four genera of bacteria, for the purposes of this report they are often referred to in the aggregate as the "four harmful or four disease-causing bacteria."

These four pathogenic or harmful bacteria are not found naturally in raw milk. The four bacteria are extrinsic to the raw milk, meaning they are present in the general environment where the cow is milked and lives. All four of these bacteria may easily get into or contaminate the raw milk as it leaves the cow or after it has left the cow as it travels through the milking equipment and is bottled until it is consumed by the customer.

It is not possible to keep these four bacteria out of the milk prior to pasteurization. *Campylobacter, Salmonella*, and *E. coli* O157:H7 get into the milk from manure, known as fecal contamination of the milk. *Listeria* are generally present in the environment, for example in silage, soil, and manure. Research shows these four harmful bacteria are generally present on the farm in raw milk samples collected from bulk milk tanks as follows:

- *Campylobacter* was present in 2% to 12.3% of the raw milk samples collected.
- *Salmonella* was present in 5% to 8.9% of the raw milk samples collected.
- *Listeria* was present in 2.8% to 5% of the raw milk samples collected.
- *E. coli* O157:H7 was present in 2.4% to 3.8% of the raw milk samples collected.

When any one of these four bacteria are in raw milk and drank by a consumer, the bacteria may cause an infection. In some instances, bacteria can enter a person's body yet no infection occurs. When an infection occurs, some individuals show signs of illness caused by the bacteria. These people have symptomatic illness. Other individuals do not develop signs of illness caused by the bacteria. These people have asymptomatic infections.

Generally, very small numbers of the bacteria can cause infection and illness in people. The infectious dose or the number of bacteria needed to cause an infection varies with the specific bacteria, and with the human population group infected. For example, it takes fewer *E. coli* O157:H7 bacteria to infect a normal healthy person than it does to infect the same person from *Salmonella*. Generally, this means it is easier to spread *E. coli* O157:H7 from one normal person to another than it is to spread *Salmonella* from one normal person to another.

The health of the person infected is an important factor tied to the consequences of the infectious dose. Some individuals and population groups have an increased risk of developing symptomatic illness from these four bacteria. Infants, children, pregnant women, elderly persons, and persons with weakened immune systems are the population groups with the higher risk. Weakened immune systems in humans can be caused by circumstances such as cancer treatments, diabetes, AIDS, or bone marrow and organ transplants.

While opportunities to become infected are similar for all people, individuals in the higher, at-risk populations are more likely to develop symptomatic illness. Compared to the population groups which are not at risk, an even smaller number of bacteria cause infection and illness in these higher at-risk individuals and groups, particularly serious illness and death.

Some people who become infected with one of these four harmful bacteria and become sick can spread or transmit the bacteria to others. The likelihood of spreading the bacteria to others varies depending on the infectious dose of the bacteria, the health of the ill person, and other factors. Some people who become infected with one of these four harmful bacteria and do not show signs or symptoms of illness can transmit the bacteria to others, infecting others and causing others to become sick.

There is an inherent risk associated with drinking raw milk because it is not possible to keep the harmful bacteria out of the raw milk. It takes only a small number of harmful bacteria to infect a person and to cause the person to become sick.

When raw milk is pasteurized, these four harmful bacteria are killed. If on-farm raw milk sale to consumers is legalized, the milk will not be pasteurized and if these four pathogens are present in the raw milk, they will not be killed.

Therefore it is very likely, for at least some farms at some times that are producing raw milk for sale to consumers, one or more of these four harmful bacteria will be present in the raw milk sold. Yet, not everyone exposed to the bacteria will become ill, depending on the concentration of the bacteria, the amount of contaminated raw milk consumed, the individual's age, the person's immune system and other factors.

The working group sought to develop the most stringent food safety regulations and best management practices to attempt to keep these four disease-causing bacteria from contaminating the raw milk as it moves from the cow to the farm's bulk tank and to slow the growth of these four bacteria as the raw milk moves from the milking machine to the bulk tank to a container, and finally, to the consumer.

There are effective testing and control options to identify and eliminate animal diseases such as tuberculosis and brucellosis to help protect consumers drinking raw milk. There are much less effective testing and control options to identify and eliminate the four harmful bacteria from raw milk before a consumer drinks the raw milk.

A brief overview of each of the four disease-causing bacteria which most frequently contaminate raw milk and cause infection and illness in humans is provided below.

Overview of *Campylobacter*

Campylobacter is one of the most common causes of diarrheal illness in the United States. *Campylobacter* are most frequently found in the intestines of healthy cattle and poultry. *Campylobacter* can be shed from animals and contaminate raw milk, causing infections in people that can progress to symptomatic illness which may be severe, including foodborne illness. Some infected people will not show any symptoms of the infection. A very small number of *Campylobacter* (fewer than 500 organisms) can cause illness in humans. Typical *Campylobacter*-related symptoms in people are diarrhea, abdominal cramps, fatigue, fever and nausea. *Campylobacter* can spread from an infected person (either showing symptoms or not) to another person by contact, particularly from an infected person to children and between children.

Infants, children, adolescents and young adults are more at risk than persons in other age groups of becoming infected with *Campylobacter.* The infections cause more severe illness among infants, children, pregnant women, elderly persons, and people with weakened immune systems.

Approximately 1 in 1,000 people with *Campylobacter* infection subsequently develop Guillain-Barré syndrome, a disorder of the nervous system that causes temporary paralysis, may require mechanical ventilation, and may cause death. *Campylobacter* infections in immune-compromised persons occasionally spread to the blood stream and may cause life-threatening infections.

The Centers for Disease Control and Prevention (CDC) estimates campylobacteriosis affects over 2.4 million people annually. Although *Campylobacter* infection is not commonly fatal, it causes approximately 124 reported deaths per year in the United States.

Characteristic foods that may be contaminated with *Campylobacter* are raw and undercooked poultry, raw milk, and untreated water. Results of three research studies demonstrate *Campylobacter* was present in 2% to 12.3 % of the samples of raw milk collected from bulk milk tanks. (Reference Notes 1, 3, 4)

Overview of *Salmonella*

Salmonella live in the intestinal tracts of people and animals. People can become infected with *Salmonella* by eating foods contaminated with animal feces. Raw milk is a food that can be contaminated with bacteria from animal feces. Typical symptoms of *Salmonella* infections in people include nausea, vomiting, diarrhea, abdominal cramps, fever, headaches, and chills. Most people recover from *Salmonella* infection in less than one week and without treatment. Some people develop symptoms that are severe with the infection spreading to the blood stream and then to other body sites where local infections such as meningitis and osteomyelitis (a bone infection) may occur. Shedding of *Salmonella* from the intestinal tract of an infected person may occur for weeks to

months or longer after the person is infected. When there are breaks in personal hygiene, other people may be exposed to the harmful organisms and this can result in the spread of the infection. Severe infections may cause death if they are not treated promptly.

Infants and children, the elderly, and immune compromised persons are more likely to have a severe illness from *Salmonella* infection. Children under the age of five are the most likely to get salmonellosis, and the rate of infection in this age group is higher than the rate in all other persons. People with severe illnesses will need to be hospitalized. Immune compromised persons are vulnerable to sepsis, a bacterial infection causing a severe illness in which the infection invades the bloodstream. Other chronic illness may occur with *Salmonella* infection. For example, a small number of persons with *Salmonella* infection develop Reiter's Syndrome which can lead to long-term chronic arthritis.

CDC estimates 1.4 million cases of *Salmonella* occur annually in the United States, and of these, approximately 40,000 are cultured confirmed cases reported to CDC. CDC estimates 400 people die each year because of acute salmonellosis.

Characteristic foods that may contain *Salmonella* include poultry, eggs, raw meats, and raw milk. The results of three research studies demonstrate *Salmonella* was present in 5% to 8.9% of the bulk tank raw milk samples tested. (Reference Notes 1, 2, 3)

Overview of *Listeria*

Listeria monocytogenes is found in soil and water. Healthy animals, including dairy cows, can be infected with *Listeria monocytogenes* without appearing sick, and can contaminate raw milk and meats.

Listeriosis is primarily caused by a foodborne infection. Healthy persons may consume foods contaminated with *Listeria* without becoming ill from the infection. Healthy children and adults are occasionally infected with *Listeria monocytogenes,* but they rarely become severely ill. However, infected persons may shed *Listeria* for several weeks to months, exposing other people to *Listeria* and spreading the infection. Certain at-risk populations, primarily infants, pregnant women, elderly persons, and immune compromised persons, are more likely to get listeriosis after eating food contaminated with just a very few *L. monocytogenes* organisms. The *Listeria* infections that are diagnosed tend to be severe.

Symptoms of listeriosis in pregnant women are fever, muscle aches, malaise, nausea, vomiting, diarrhea, and back pain. If pregnant women become infected with *L. monocytogenes,* it can cause premature delivery, miscarriage, or stillbirth. Infants infected in the womb during pregnancy can be born with *L.*

monocytogenes infection. Pregnant women are about 20 times more likely than other healthy adults to get listeriosis. Newborns of women who were infected with *Listeria monocytogenes* during pregnancy, rather than the pregnant women, will have the most serious effects of infection. There is a 30 to 50 percent fatality rate among newborns born with *L. monocytogenes* infections. (Silver 1998)

Infection of newborn infants during the first week of life are associated with prematurity, pneumonia and sepsis. In infants older than one week listeriosis is often associated with meningitis. In persons who are older than 50 years or who are immune compromised, the infection can spread to a person's nervous system causing confusion, loss of balance, and convulsions. Listeriosis involving the central nervous system is associated with meningitis, an infection of the brain that can include brain abscess and encephalitis. Listeriosis can also involve infection of the heart valves.

Characteristic foods that may contain *Listeria* are raw milk, soft cheeses, cold cuts and deli meats. Three research studies demonstrate *Listeria* were present in 2.8% and 5% of the bulk tank raw milk samples tested. (Reference Notes 1, 2, 3)

Overview of *Escherichia coli* O157:H7

The broad coliform group of bacteria includes the genus *Escherichia.* Within the *Escherichia* genus is the species of *Escherichia coli* among which there are many different strains. Most strains of *E. coli* are harmless while others cause infection in people, and in some cases, severe illness. Some kinds of *E. coli* cause disease by making a toxin called Shiga toxin and the *E. coli* strains that can produce this toxin are called Shiga toxin-producing *Escherichia coli* or STEC. It is the Shiga toxin produced by these *E. coli* that causes severe illness when they get into the intestinal tract of humans. *E. coli* O157:H7 is the most common of the Shiga toxin-producing *E. coli.*

E. coli is more closely associated with fecal contamination when it's found in food. The *E. coli* O157:H7 can easily contaminate raw milk and the environment where cows live. *E. coli* have several characteristics that make them particularly harmful to people and especially to children. They are hardy organisms that can survive several weeks on surfaces such as counter tops, and up to a year in some materials like compost.

The most well known *E. coli* strain is *E. coli* O157:H7. It is commonly found in the intestinal tract of warm blooded animals, and is typically shed in the feces of dairy cows including healthy cows. Some, such as *E. coli* O157:H7, have a very low infectious dose meaning that only a relatively small number of the bacteria (fewer than 50) are needed "to set-up housekeeping" in a human's intestinal tract and cause infection. Typical signs and symptoms of an *E. coli* O157:H7 infection

include diarrhea, bloody diarrhea, abdominal cramps, fever, headaches, chills, and fatigue.

People of any age can be infected by *E. coli* O157:H7. The population groups most at risk for being infected and becoming ill are infants, children, and elderly persons. These groups are also more likely to develop severe illnesses and complications for the illnesses. Healthy older children and young adults can also become seriously ill. Public health experts estimate about 70,000 *E. coli* O157:H7 infections occur annually in the United States.

Hemolytic uremic syndrome (HUS) can occur subsequent to infection with *E. coli* O157:H7. Hemolytic uremic syndrome is a condition which results from the abnormal, premature destruction of red blood cells and platelets following damage to very small blood vessels. Once this begins, the damaged red blood cells start to clog the filtering systems in the kidneys which may eventually cause kidney failure, permanent kidney damage, and occasionally death.

Most people with HUS recover within a few weeks. Five to ten percent of children infected with *E. coli* O157:H7 develop HUS, and of these, 50 percent require kidney dialysis and five percent die. HUS is most common among children aged less than 5 years old and elderly persons.

Foods most frequently contaminated with *E. coli* O157:H7 include raw milk and raw milk products, uncooked or undercooked ground beef and unpasteurized apple cider. Some foods carry a very high risk of infection from *E. coli* O157:H7, and public health officials recommend people avoid eating these foods. The foods with the highest risk of infecting people with *E. coli* O157:H7 are unpasteurized or raw milk, unpasteurized apple cider, and improperly aged soft cheeses made from raw milk.

Results from two research studies demonstrate *E. coli* O157:H7 were present in 2.4% to 3.8% of the raw milk samples obtained from bulk tanks tested. (Reference Notes 3 and 4)

When raw milk is pasteurized, the *E. coli* O157:H7 in raw milk are killed. However, *E. coli* O157:H7 survive refrigerator and freezer temperatures.

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Public Health and Raw Milk

The spectrum of foodborne diseases in human populations changes over time. A century ago, typhoid fever, tuberculosis and cholera were the most common foodborne diseases that infected people. Improvements in food safety, such as the pasteurization of milk, safe canning, and disinfection of water supplies have assisted in conquering the diseases of a century ago. Today, new or different foodborne infections are of primary concern, having taken the place of the food safety problems of a hundred years ago.

Today, pasteurized milk and dairy products are associated with less than 1 percent of foodborne illnesses traced back to food each year in the United States. The reduction is due primarily to pasteurization; but on-farm programs to improve milk quality and milk cooling, animal disease control, and enhanced sanitation practices have also contributed to the reduction of foodborne illnesses from pasteurized milk and dairy products.

Campylobacter, Salmonella, Listeria and *E. coli* O157:H7 are the four harmful bacteria causing the most common foodborne illnesses associated with drinking raw milk today. These four bacteria have been isolated from on-farm bulk milk tanks at rates ranging from 0.8 percent to 10 percent of total samples collected indicating a measurable probability of encountering these pathogenic bacteria in raw milk. (Ralyea, Brown, Huck, Wiedmann, and Boor, Cornell University). Tuberculosis and brucellosis remain a risk as discussed by the working group in other sections of the report, but there are effective ways to test and control for tuberculosis and brucellosis while there are far less effective ways to test and reduce or eliminate *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7.

The moderate heat treatment of pasteurization is the effective method for eliminating pathogenic or disease-causing bacteria in raw milk. Without the pasteurization step, reducing the health risks for consumers drinking raw milk becomes difficult to achieve. A comprehensive approach of food safety regulations, best management practices, and education will not replace the efficacy of pasteurization, but it is essential to help reduce some of the health risks associated with drinking raw milk.

Infants, small children, pregnant women, elderly persons, and immune compromised persons are those population groups most at risk of becoming infected and ill from drinking raw milk, and at the greatest risk of serious complications from an infection from the bacteria. Of these at-risk groups, infants and children are the population group most vulnerable to the most significant health risks associated with drinking raw milk. Children are more at risk for several reasons. Infants and children who drink raw milk are more likely to become infected and ill because a child's immune system is not fully developed. A higher percentage of children drink milk than the other population groups.

Children may also consume raw milk inadvertently when they are visiting friends or the homes of other people. Because of their age, infants and children are not informed consumers. Some parents believe drinking raw milk is a healthy choice, and make that choice for their children too.

Consumers of raw milk who become infected with foodborne illnesses can shed the bacteria that caused the infection and thereby spread the infection to others, including children. The person-to-person transmission of the bacteria is most likely to occur among young children.

Children are also more at risk than other age groups from foods contaminated with the harmful bacteria, *E. coli* O157:H7. The *E. coli* O157:H7 bacteria are found in undercooked hamburgers and other meats, raw milk, and unpasteurized juices. Children are more likely to become severely ill and develop complications if they eat these foods and the foods are contaminated with *E. coli* O157:H7. The complications for children who become infected include hemolytic uremic syndrome which damages the kidneys.

People will recall that farmers and their families drank raw milk on their farms and question why it is not safe today for consumers to drink raw milk. Farmers and their families do drink raw milk from their farms but there are several reasons why this example is not a accurate public health comparison to advocate for selling raw milk on the farm to consumers. Farmers are drinking the raw milk the same day as it is produced and replacing it with fresh raw milk the following day. The raw milk is generally cooled quickly in small amounts in the refrigerator. Farmers may make choices to limit the risks to themselves and their families. Some may choose to milk specific cows for the raw milk they bring into the kitchen, some may warm the milk for their children, and some may use small countertop pasteurizers in the kitchen. These practices help limit the family's exposure to the health risk, something that can not be practically replicated when raw milk is sold and distributed more widely to consumers who purchase it on the farm and take it home. It is also likely farm family members become sick occasionally from drinking raw milk they consume on their farms.

Today, in the United States, raw milk is consumed by approximately 1 percent of population. Pasteurized and unpasteurized dairy products account for less than 3 percent of single commodity, illness outbreak cases and 71 percent of these dairy illness outbreak cases are attributed to raw milk. (CDC 2009)

An outbreak of foodborne illness occurs when a group of people consume the same contaminated food and two or more of the people become sick from the same infection. An "outbreak" occurs when there are more cases of illness or disease than is normally expected within a specific place or group of people over a given period of time.

Table A summarizes the six raw milk associated illness outbreaks in Wisconsin detected between 1998 and 2009. The percent of patient cases that are children range from 17 percent to 79 percent for an average of 33 percent for the combined six outbreaks, indicating how vulnerable infants and children are to the health risks associated with drinking raw milk.

Table A: Wisconsin Raw Milk-Associated Outbreaks 1998 through 2009*

Year	County	Infectious Agent	Total # of Patient Cases**	# of Total Patient Cases who are Children	# People Hospitalized	Product
1998	Chippewa	*E. coli* 0157:H7	63	Unknown	24	Unpasteurized Cheese Curds
2000	Walworth	*Campylobacter jejuni*	19	15	0	Unpasteurized Milk
2001	Sawyer	*Campylobacter jejuni*	68	32	0	Unpasteurized Milk
2003	Rusk	*Campylobacter jejuni*	2	0	0	Unpasteurized Milk
2006	Ashland	*Campylobacter jejuni*	58	10	2	Unpasteurized Cheese Curds
2009	Multiple Southeast Counties	*Campylobacter jejuni*	52	29	1	Unpasteurized Milk
			Total of 261	Total of 86	Total of 27	

* Source: Unpublished data. Division of Public Health, Wisconsin Department of Health Services (DHS). ** A "patient case" is one person who was sick and who met certain clinical and epidemiologic criteria. Surveillance detected six raw milk-associated outbreaks from 1998 through 2009 during a time when raw milk sales were illegal in Wisconsin. The table shows a total of 261 patient cases (illnesses) of which 86 were children (under the age of 18) and 27 of these people were hospitalized.

Table B summarizes the outbreaks, illnesses, and recalls related to raw milk and pasteurized milk products which occurred during 2010 throughout the United States.

Table B: 2010 Outbreaks, Illnesses, and Recalls in USA Linked to Unpasteurized and Pasteurized Dairy Products

Month	State	Pathogen	# of Illnesses	Product	Notes
January	New York	*Campylobacter*	5	Raw Cow Milk	
February	Washington	STEC	6	Raw Cow Milk	
February	Washington	*Listeria monocytogenes*	5	PM Cheese	
February	Washington	*Listeria monocytogenes*	0	RM Cheese	Recall
March	Washington	*Listeria monocytogenes*	0	RM Cheese	Expanded Recall
March	Michigan, Illinois, Indiana	*Campylobacter* & STEC	12	Raw Cow Milk & RM Cheese	
March	Pennsylvania	*Campylobacter*	10	Raw Cow Milk	1 case Guillain Barre Syndrome
April	Utah	*Salmonella*	10	Raw Cow Milk	
April	Utah	*Campylobacter*	15	Raw Cow Milk	
April	Washington	*Listeria monocytogenes*	0	PM Cheese	Recall
May	Washington	*E. coli* O157:H7	2	Raw Cow Milk	Same Farm Identified in February
May	Minnesota	*E. coli* O157:H7	8	Raw Cow Milk	1 Child with HUS
May	Nevada	*Campylobacter*	1	RM Cheese	
June	Pennsylvania	*Listeria monocytogenes*	0	Raw Cow Milk	Recall
June	Delaware	*Brucella and Listeria monocytogenes*	2	Raw Cow Milk Dairy Products	2 Separate Incidents
June-July	Colorado	*Campylobacter* & *E. coli* O157:H7	30	Raw Goat's Milk	2 Children with Hemolytic Uremic Syndrome
July	New York	*Listeria & Campylobacter*	0	Raw Cow Milk	Recall
July	Pennsylvania	*Staphylococcus aureus*	0	RM Cheese	Recall of 60-day Aged Cheese
July	New York	*Listeria monocytogenes*	0	PM Cheese	Recall

August	Pennsylvania	*Salmonella*	0	Raw Cow Milk	Recall
August	CA,OR,WA	*Salmonella* Braenderup	23	PM and Cheese	Recall Pasteurized Juices too
August	Rhode Island	*Listeria monocytogenes*	0	PM Cheese	Recall
August	Missouri	*Listeria monocytogenes* & *Staphylococcus aureus*	0	Raw Cow Milk Cheese	Recall 60-day Aged Cheese
September	Washington	*Listeria monocytogenes*	0	Raw Cow Milk Cheese	Expanded Recall of 60-day Aged Cheese
October	Washington	*Listeria monocytogenes*	0	Raw Cow Milk Cheeses	Expanded Recall of August Cheese Expanded Recall
October	Minnesota	*Campylobacter* and *Cryptosporidium parvum*	7	Raw Cow Milk Dairy Products	Dairy Products from Same MN Farm as May 2010 Incident
November	AZ, CA, CO, NM, NV	*E. coli* O157:H7 & *Listeria monocytogenes*	38	Raw Cow Milk Cheeses	Illnesses from *E. coli* O157:H7. Expanded Recall
November	Colorado	*E. coli* O157:H7	0	PM Cheese	Import from Italy
November	Washington	*Listeria monocytogenes*	0	PM Cheeses	
December	MN, OR,VT, WA	*E. coli* O157:H7	8	RM Sheep, Cow, & Goat Cheeses	60-day Aged Cheese Produced in Washington

PM = Pasteurized Milk, RM = Raw Milk, STEC = Shiga Toxin-producing *E. coli* (usually identified as non-O157:H7), HUS = Hemolytic Uremic Syndrome

Outbreak is defined as the occurrence of more cases of disease than normally expected within a specific place or group of people over a given period of time. An outbreak of foodborne illness occurs when a group of people consume the same contaminated food and two or more of the people become sick from the same infection.

Foodborne Illness is defined as a disease in one person caused by consuming foods or drinks contaminated with microbes or other harmful substances. Most foodborne diseases are caused by a variety of bacteria, viruses, or parasites.

Recall. A food recall is a request to consumers, a business, or the general market to return a specific food product to the maker when there is reason to believe the food product is causing or may cause the consumer harm. A food product may be recalled prior to any consumer becoming sick.

Raw Milk Laws in Other States

Some individual states have passed laws to allow the sale of raw milk. Although federal law prohibits the interstate sale of raw milk, states have authority to regulate the sale and distribution of raw milk within their borders.

The working group conducted a rigorous review of the raw milk laws in other states. The group evaluated the scope of the state laws and the food safety regulations in the states where raw milk sales are legal.

The group found a variety of similarities and differences between the state laws where it is legal to sell it. Laws allowing the sale of raw milk in other states also vary in definition and scope of sale. Some states allow raw milk to be sold in retail stores and others allow it to be sold on the farm only. States differ on whether they allow the sale of raw milk produced from cows, goats, or sheep, either individually or from all three. Some states allow the sale of fluid raw milk only and other states allow the sale of raw milk dairy products.

The working group learned all states allowing the sale of raw milk also govern the production and sale of raw milk with food safety regulations to help reduce the health risks for consumers drinking it. The working group found no states that allow raw milk sales without food safety regulations.

In summary:

- In 23 states it is illegal to sale raw milk.
- In the 27 states where some form of sale of raw milk is allowed, it is legal in 13 states to sell raw milk in retail stores.
- In the same 27 states there is a large difference in what kind of raw milk product can be sold and where it can be sold. Examples include limiting the sale to fluid goat milk only, limiting the sale to fluid goat milk only with a physician's prescription, limiting the sale of fluid raw milk on the farm from either cows, goats, or sheep or all three, or limiting the sale from a specific number of milking animals on a given farm.
- In the 7 Upper Midwest states (Iowa, Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin) raw milk sale is illegal in 6 of the 7 states. Illinois law allows raw milk to be sold only on the farm where it is produced, but not in retail stores.

There are also similarities between states. The working group reviewed food safety regulations in 12 of the 13 states that allow raw milk to be sold in retail stores. The laws in all 12 states have food safety regulatory requirements governing raw milk production and sale in all of the following categories:

- Raw milk farm licensing requirements
- Raw milk farm standards and inspection frequencies
- Testing for animal diseases
- Testing the farm's well water
- Testing the raw milk for the presence of specific bacteria
- Specifying the kinds of raw milk containers that may be used
- Specifying the ways raw milk containers may be filled
- Processes for filling the containers or bottles
- Temperature requirements for the raw milk
- Setting times within which the raw milk must be sold
- Labeling raw milk containers

The 12 states with these regulations include Arizona, California, Connecticut, Idaho, Maine, Massachusetts, Nevada, New Hampshire, New Mexico, Pennsylvania, South Carolina, Utah, and Washington. The 13th state, Oregon, allows the retail sale of goat and sheep milk and the limited on-farm sale of raw milk produced from either a 3-cow herd or a 9-goat herd, or a 9-sheep herd. The Oregon law limits retail sales quite differently than the other 12 states allowing retail sale, and as a result, the working group chose not to evaluate Oregon's laws further.

At a minimum, these 12 states require raw milk farms to use the sanitary standards in the PMO, Grade A farm standards (designed for milk that will be pasteurized) and most have additional on-farm standards and regulations to address the food safety risks that will be present because the raw milk sold in retail stores will not be pasteurized and to address the new and different on-farm activities necessary to produce raw milk for sale, rather than for pasteurization.

Appendix 2 provides a summary of the raw milk sales laws in all 50 states. Because the scope of the state laws is so varied, it is difficult to place states in simple categories. For Appendix 2, states that prohibit the sale and distribution of raw milk were counted easily as states where the sale and distribution are not legal. For some states where sale is illegal, but there are minor exceptions such as incidental or occasional sales, these states were classified as illegal. If a cow share program was explicitly legal it was counted as being legal regardless of whether it was governed by food safety regulations. (Official cow share programs are financial business arrangements typically without food safety regulations to govern raw milk production and sale.) In some states, cow share programs operate unofficially where there is no law allowing them or prohibiting them, and because there is no accurate count available, these were not included in the count for Appendix 2.

Raw Milk Laws in the Upper Midwestern States

In the Upper Midwest, most states do not allow the sale of raw milk. Wisconsin, Michigan, Minnesota, Ohio, Indiana, and Iowa prohibit raw milk sales and distribution within their states. These six states are also in the top 15 milk producing states in the United States and they have similar dairy farm structures with large dairy industries and with milk production occurring on small farms with average dairy cow herd sizes ranging from 84 to 154 dairy cows per farm. These six states also have large numbers of licensed dairy farms throughout their states. More information on the 15 top milk producing states and their raw milk laws is provided in the next section.

Because most of the Upper Midwestern states prohibit the sale of raw milk, the working group had to look beyond the Upper Midwestern states to get information about state food safety laws and regulations governing raw milk sale and distribution.

Review of Seven Select States

The working group chose to select seven states that allow raw milk sales and thoroughly evaluated their laws and food safety regulations. The seven states are: 1) California, 2) Connecticut, 3) Idaho, 4) New York, 5) Pennsylvania, 6) South Carolina, and 7) Washington.

The group chose to evaluate these seven states for several reasons:

- All seven states allow some form of raw milk sales. Six of the seven states allow both retail sale and on-farm sale and one state (New York) allows on-farm sale only.

- Five of these seven states have large dairy industries, ranking in the top ten milk producing states in the United States.

- Two states -- New York and Pennsylvania -- have dairy farm structures similar to Wisconsin's, with smaller dairy cow herd sizes, on average between 70 and 115 dairy cows/herd.

- Two states -- Connecticut and South Carolina -- have very small dairy industries, ranking in the lower one-third of the milk producing states in the U.S. These two states were chosen because they are quite different than Wisconsin. They have very small dairy industries and allow the sale of raw milk.

- The seven states are geographically dispersed, representing all regions of the United States.

For the seven states selected, the working group specifically evaluated the food safety regulations for water, raw milk, and animal disease testing; raw milk farm licensing, standards, and inspection; raw milk temperature and time controls; labeling; the containers and processes for filling containers that are allowed.

In the recommendations, information comparing the laws and regulations for these seven states is presented. Also, Appendix 13 is a matrix comparing the testing standards and frequencies for each of the seven select states for water, raw milk, and animal disease.

In addition to its evaluation of the laws in these seven states, the Raw Milk Policy Working Group also reviewed the temperature and time controls for raw milk required in Germany. It reviewed best management practices recommended by the Colorado Raw Milk Association, the Raw Milk Production Handbook written by Tim Wightman, and the Safe Handling Consumers' Guide: Preserving the Quality of Fresh, Unprocessed Whole Milk written by Peggy Beals, RN (Michigan). All these resources were helpful to the working group as it conducted its review and framed its recommendations.

Illness Outbreaks in the Seven Select States

Previously in the report, some information on public health, raw milk consumption, and disease outbreaks was discussed. For the seven select states, Table C below presents the number of outbreaks, illnesses, and recalls of unpasteurized and pasteurized dairy products in the seven select states as reported in the United States during 2010. The data is a subset of information from Table B which presents 2010 data on outbreaks, illnesses, and recalls.

Other states, including the seven select states, have sought to achieve the safest possible raw milk by adopting food safety regulations to minimize the risk to consumers drinking raw milk, yet the incidence of reported human illnesses and foodborne illness outbreaks associated with drinking raw milk and eating certain raw milk products continues to occur in states allowing raw milk sale.

According to the Centers for Disease Control and Prevention (CDC), the rate of illness outbreaks associated with consuming raw milk and raw milk products is higher in states that allow legal sale of raw milk compared to states where raw milk sale is illegal. Approximately 80% of illness outbreaks associated with raw milk occurred in states that permit the sale of raw milk. (CDC)

Table C: Seven Select States Where Raw Milk Sales are Legal
Number of Outbreaks, Illnesses, and Recalls Reported in 2010

State	2010: Number of Raw Milk Outbreaks, Illnesses, and Recalls
California	2
Connecticut	0
Idaho	0
New York	2
Pennsylvania	4
South Carolina	0
Washington	11

For 2010 Unpasteurized and Pasteurized Dairy Products
Subset of data from Table B.

Wisconsin's Dairy Industry

National Dairy Industry Comparison by State

Wisconsin's dairy industry has a premier reputation throughout the world. "Dairy" is Wisconsin's signature brand and the largest economic contributor to the state's robust and diverse agricultural sector. The dairy industry has also created a socio-cultural character for Wisconsin rural communities that is cherished by many.

The working group discussed the importance of Wisconsin's diverse $26 billion dairy industry and its impact on state traditions, culture, and the economy. The group acknowledged the dairy industry's long history of food safety regulations implemented to ensure the production and processing of safe dairy products for its worldwide market of consumers.

These facts weighed heavily on the working group as it pursued its assignment and evaluated how regulatory alternatives for raw milk sale might be developed to protect public health. The working group discussed the risk of illness and outbreaks associated with drinking raw milk, the significant public health consequences, and the economic impacts an outbreak could have on the reputation of pasteurized milk as a safe and wholesome dairy product.

The working group discussed the distinctive size of Wisconsin's dairy industry given the relatively small state population and geographical size compared to other states and its importance in the national dairy economy.

The working group reviewed the dairy statistics for Wisconsin compared to the other 49 states, including the dairy statistics on milk production, the number of dairy cows and licensed dairy herds, states' average dairy herd size, milk cash receipts as a percent of a state's total at-farm cash receipts, and the dollar value of cheese production.

In summary, the 2009 National Agriculture Statistics Services (USDA) data on Wisconsin's dairy industry shows:

- The state of Wisconsin ranked first in the country in 2009 in the dollar value of its cheese production.
- In 2010, Wisconsin produced 25.2 million pounds of milk, ranking second to California's milk production of 39.5 million pounds.

- In 2009, Wisconsin ranked second in the nation in milk cash receipts at the farm, with California ranked first. Wisconsin milk cash receipts as a percent of total at-farm cash receipts is 43%. California's is 13%. New York had the highest percent of milk cash receipts at the farm as a total of all cash receipts with 45.9%.

- Wisconsin had 13,170 dairy herds in 2009, ranking first in the nation with the most dairy herds. California had 1820 dairy herds, ranking eighth in the U. S.

- Wisconsin had 1.3 million dairy cows in 2010, ranked second to California's 1.8 million dairy cows.

- Wisconsin's average cow herd size was 95 and California's average cow herd size was 987.

Appendices 3, 4, 5, and 6 provide 2009 dairy statistics by state.

Raw Milk Laws in the Top 15 Dairy Producing States

Facts on the top 15 dairy producing states and their laws related to raw milk sales are presented in this section. Seven of the top 15 dairy states do not allow the sale and distribution of raw milk and the other eight states allow some kinds of raw milk sales. Additional comparisons are summarized here based on dairy facts, dairy structure, and regions of the United States.

Table E: Top 15 Milk Producing States and their Laws on Raw Milk Sales

Rank	State	2009 Milk Production in Million Pounds	Is Retail or On-farm Sale of Raw Milk Legal?
1	California	39,512	Yes, both retail and on-farm
2	**Wisconsin**	25,239	No
3	New York	12,424	Yes, on-farm sale only
4	Idaho	12,150	Yes, retail
5	Pennsylvania	10,551	Yes, both retail and on-farm
6	Minnesota	9,019	No
7	Texas	8,840	Yes, on-farm only
8	Michigan	7,968	No
9	New Mexico	7,904	Yes, both retail and on-farm
10	Washington	5,561	Yes, both retail and on-farm
11	Ohio	5,192	No
12	Iowa	4,379	No
13	Arizona	4,076	Yes, retail
14	Indiana	3,383	No
15	Colorado	2,840	No

Top 15 Milk Producing States and Laws on Raw Milk Sales:

- In 7 of the 15 top milk producing states the sale of raw milk is not legal.
- In 3 of the 15 top milk producing states only the on-farm sale of raw milk is legal.
- 2 of the 15 top milk producing states limit legal raw milk sales to retail only.
- In 4 of the 15 top milk producing states raw milk sales are legal both on-farm and at retail.

Top 15 Dairy States: Raw Milk Laws in States Comparing Average Herd Size:

- Six of 8 states or 75% of states with an average dairy herd size of 74 to 155 dairy cows do not allow sale of raw milk in their states.

- Six of 7 states or 89% of states with an average dairy herd size of 511 to 2168 dairy cows allow raw milk sales on-farm, at retail, or both.

Top 15 Dairy States: Raw Milk Laws in Eight Midwest-Upper Great Lakes States:

- Two of the 8 Midwestern and Upper Great Lakes states allow on-farm or on-farm and retail sales of raw milk.

- Six of the 8 Midwestern and Upper Great Lakes states do not allow raw milk sales.

Top 15 Dairy States: Raw Milk Laws in Seven Southern and Western States:

- Six of the 7 Southern and Western states in the top 15 milk producing states allow raw milk sales on-farm, at retail, or both.

- One of the 7 Southern and Western states does not allow raw milk sales.

Additional information on the top 15 milk producing dairy states and their laws on raw milk sales can be found in Appendix 11.

Cost Analysis of the Regulatory Framework

For Raw Milk Producers and Consumers

The Raw Milk Policy Working Group prepared an analysis of the producer's costs to start a raw milk farm and implement the regulatory framework. The analysis is intended to allow producers who may wish to sell raw milk to assess the start-up and ongoing costs necessary to operate a raw milk farm based on the recommendations made by the working group. These estimated costs are presented in Table F on the spreadsheet entitled, Estimated Costs to Implement the Regulatory Framework for Producers Selling Raw Milk on the Farm.

The analysis estimates the cost to the producer to implement each of the recommended regulations of the comprehensive regulatory framework. For example, costs in the spreadsheet are estimated for each of the recommended animal health tests; the raw milk tests to determine the standard plate count, somatic cell count, and coliform count; and the tests for antibiotic drug residues and tests for the four most common pathogenic bacteria found in raw milk.

The analysis presents the annual cost per regulation per cow based on four different sized herds producing raw milk for sale to consumers. The annual per cow cost is given for a: 1) 3-cow herd, 2) 20-cow herd, 3) 50-cow herd, and 4) 100-cow herd.

In Table F the regulatory cost analysis provides the producer with the estimated cost per gallon that would be added to her or his cost of producing a gallon of raw milk in compliance with the regulations, and again, depending on the size of the producer's herd. The analysis presents the estimates of the percent increase in the cost a consumer would pay per gallon based on the assumption that the producer's start-up and annual, ongoing business costs will be passed onto the consumer.

The analysis also estimates the percent increase in the price of a gallon of raw milk paid by the consumer, based on the herd size of the farm where the consumer is purchasing raw milk. This information is presented in Table G. The analysis compares the current gallon price for raw milk (unregulated) and the percent increase per gallon above the current price, assuming the recommended regulations are implemented in new legislation. The analysis uses two cost scenarios based on estimates that consumers are now paying either $5 per gallon or $7 per gallon for raw milk on Wisconsin farms.

Table G: Cost Analysis of the Regulatory Framework

Estimates of Cost to Consumers per Gallon of Raw Milk Purchased

Herd Size	Estimated Increase in Cost per gallon	Percent Increase if Initial Price was $5 per gallon	Percent Increase if Initial Price was $7 per gallon
3 cows	$ 1.09	21.8 %	15.6 %
20 cows	$ 0.14	2.8%	2.0 %
50 cows	$ 0.05	1.0 %	0.7%
100 cows	$ 0.03	0.6 %	0.4 %

The cost analysis compares costs for producers and consumers based on different herd sizes on the farms producing raw milk for sale. The percent increase per gallon will vary depending on the size of the cow herd where the consumer purchases the raw milk because the milk production per cow varies with the herd size on the farm.

Table H presents additional information on the average number of gallons of milk produced per cow per year in Wisconsin for: 1) a 3-cow herd, 2) a 20-cow herd, 3) a 50 cow herd, and 4) a 100-cow herd.

Table H: Annual Average Milk Production per Cow in Wisconsin

Herd Size	For 1 Cow - Annual Average Milk Production in Pounds	For 1 Cow - Annual Average Milk Production in Gallons
3-Cow Herd	12,869 pounds per year	1,496 gallons per year
20-Cow Herd	12,869 pounds per year	1,496 gallons per year
50-Cow Herd	15,794 pounds per year	1,836 gallons per year
100-Cow Herd	17,972 pounds per year	2,089 gallons per year

National Agricultural Statistics Service, USDA: 2007 Wisconsin Average Production of Milk per Cow. Assumes 8.6 pounds of milk equals 1 gallon in milk.

The working group found the cost analysis gave valuable information as the regulations were discussed and considered, providing a quantifiable cost to the recommendations and an estimated total cost for the comprehensive regulatory framework.

The complete set of assumptions used to estimate the costs of the regulations proposed, the gallon costs to the consumer, and the notes on the cost assumptions, sources, and calculation methods are provided in detail in Appendix 12.

Table F

Estimated Costs to Implement the Regulatory Framework Proposed for Producers Selling Raw Milk

Estimates of costs to consumers per gallon of raw milk purchased are presented in Table A
Notes on the assumptions, sources of data, and calculation methods are available in Appendix 14

All costs are in dollars

Activity or Test	Frequency	Start-Up Cost*	Annual Amortized Cost	On-Going Cost	Annual On-going Cost	Annual Regulation Cost per Cow***				Regulation Cost per Gallon			
						3-Cow Herd	20-Cow Herd	50-Cow Herd	100-Cow Herd	3-Cow Herd	20-Cow Herd	50-Cow Herd	100-Cow Herd
Standard plate count	1/week			4.17	216.84	72.28	10.84	4.34	2.17	0.048	0.006	0.002	0.001
Somatic cell count	1/week			2.90	150.80	50.27	7.54	3.02	1.51	0.034	0.004	0.001	0.001
Coliform (in milk)	1/week			6.50	338.00	112.67	16.90	6.76	3.38	0.075	0.009	0.003	0.002
Well water coliform	1/year				31.95	10.65	1.60	0.64	0.32	0.007	0.001	0.000	0.000
Drug residue	1/ 2-days	200.00	72.96	9.90	1811.70	628.22	94.23	37.69	18.85	0.420	0.051	0.017	0.009
Salmonella	1/month			41.55	498.60	166.20	24.93	9.97	4.99	0.111	0.014	0.004	0.002
Listeria	1/month			37.55	450.60	150.20	22.53	9.01	4.51	0.100	0.012	0.004	0.002
Campylobacter	1/month			51.55	618.60	206.20	30.93	12.37	6.19	0.138	0.017	0.006	0.003
E.Coli 0157:H7	1/month			51.55	618.60	206.20	30.93	12.37	6.19	0.138	0.017	0.006	0.003
Streptococcus ag.	one-time	45.00	16.44			5.48	0.82	0.33	0.16	0.004	0.000	0.000	0.000
Tuberculosis**	1/ 3-years	**				17.16	3.96	2.64	2.40	0.011	0.002	0.001	0.001
Brucellosis**	1/ 3-years	**				11.64	3.60	2.69	2.34	0.008	0.002	0.001	0.001
TOTAL COST						**1637.16**	**248.81**	**101.83**	**52.99**	**1.09**	**0.14**	**0.05**	**0.03**

*Start-up costs are based on the assumption that the drug residue test requires purchase of equipment. See Notes for details.

** Start-up costs recur every 3 years and vary with herd size. See Notes for details.
Start up cost estimates are: $472 for a 3-cow herd; $661 for a 20-cow herd; $976 for a 50-cow herd; $1552 for a 100-cow herd.

***Per cow costs are annual amortized amounts. The producer may sell only part of the milk raw to the consumer. See Notes for details.

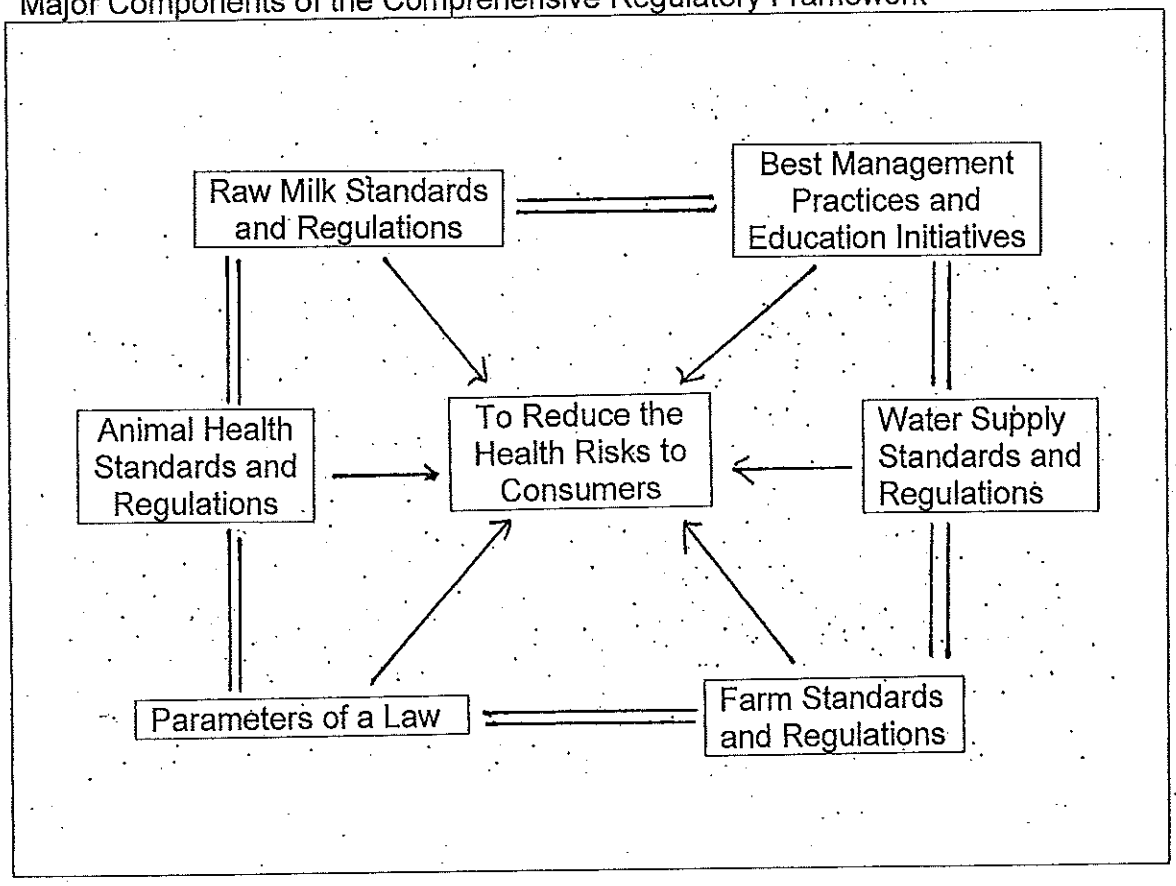
Overview of the Comprehensive Regulatory Framework

Comprehensive Regulatory Framework

The Raw Milk Policy Working Group first explored and evaluated federal and state laws which broadly regulate food safety and protect public health and safety. The group also examined raw milk laws and regulations in states that allow the sale of unpasteurized milk to consumers. Once this was done, the group began to outline a general framework of possible legal and regulatory alternatives that would be necessary to help reduce the health risks to consumers if raw milk sales were to be allowed in Wisconsin.

The final comprehensive regulatory framework developed by the working group includes six major components, designed to help reduce the health risks to consumers drinking unpasteurized milk. The six major components are: 1) parameters of a law, 2) animal health standards and regulations, 3) raw milk standards and regulations, 4) best management practices and education initiatives, 5) on-farm water standards and regulations, and 6) raw milk farm standards and regulations.

Major Components of the Comprehensive Regulatory Framework



Challenges in Designing the Regulatory Framework

As the Raw Milk Policy Working Group deliberated and examined potential regulatory alternatives, it identified both inherent food safety challenges for producing raw milk, information barriers, and practical on-farm limitations that made creating a regulatory framework that would reduce the health risks for consumers a difficult task.

Most of the challenges presented themselves because the working group was treading on new ground. The on-farm sale of raw milk, the new and expanded activities that will occur on a raw milk farm, the new food producing responsibilities of the farmer, and the regulatory alternatives to govern raw milk sale have never been done in Wisconsin previously. Together, these all created challenges to address. In summary, these challenges were:

- **Challenge: Finding a model of existing food safety regulations in other states to use for Wisconsin to help reduce the health risks for consumers**

  The working group thoroughly reviewed the laws and regulations in other states that allow raw milk sales. This information was valuable to the group, and the group used some of the information to create its recommended regulations. The review was also valuable to the group because it learned there is not a package of laws in another state or from a combination of states that has demonstrated the laws substantially protect consumers from the health risks of drinking raw milk.

  Clearly, other states have sought to adopt the strictest food safety regulations possible, yet the incidence of reported illness outbreaks in states allowing raw milk sales, particularly for the population groups most at risk, continues to occur and occur in higher percentages than in states where raw milk sales are illegal.

  The working group was challenged by the limited practical and verifiable information from other states about which regulations were most effective at reducing risk. The group used its extensive dairy farming and processing expertise and food science knowledge to work diligently through the difficulties of this challenge, seeking to create a framework that would reduce the health risks. It is likely the framework proposed will reduce the health risks but will not eliminate them.

- **Challenge: There are imperfect testing options to identify when the most common, harmful bacteria have contaminated raw milk, thus limiting information to consumers about the safety of the product when it is purchased.**

  Generally, the group found effective options for testing cows to identify when the cows are infected with bacteria such as tuberculosis and brucellosis that can be transmitted to humans in raw milk and cause sickness in humans. The group did not find effective options for testing the raw milk for the harmful bacteria from the farm environment that most frequently contaminate raw milk and cause infection and illness in people. For a variety of reasons, testing the raw milk for *Campylobacter, Listeria, Salmonella,* and several important strains of the Shiga toxin-producing *Escherichia coli* is imperfect.

  When the raw milk is sold, and if it tests negative for one of the pathogenic bacteria, there is no guarantee the raw milk is free of that bacteria. The producer will not know if the raw milk is safe to drink. In addition, without knowledge and understanding of this testing issue, producers and consumers may have a false sense of security about the accuracy of the testing and the test results.

  People assume tests can be performed routinely on a myriad of items to identify a product or what is in a product. They may often assume testing is a fail-safe method or gives accurate pass/fail information or results. This is not always true when testing raw milk for any of these four harmful bacteria.

- **Challenge: Effectively reducing the health risks associated with drinking raw milk without the critical step of pasteurization**

  The moderate heat treatment step of pasteurizing raw milk has become the most critical step, often the fail-safe method, to ensure milk sold to consumers is safe to drink. Many of the food safety and sanitary standards required on farms today were established to complement the pasteurization process, assuming the raw milk would be pasteurized prior to sale.

  A key challenge for the working group was determining if raw milk is not pasteurized prior to consumers drinking it, will the current on-farm sanitary requirements and food safety regulations be relevant and effective in helping reduce the health risks? Are there health risks that will arise on the farm that are new and different and will require new standards and regulations to help protect consumers? And, what are the most effective food safety precautions that can be implemented to reduce risk?

The group acknowledged there will be greater health risks because the milk will not be pasteurized and there will be a need for new standards and regulations that take into account the additional risks and the new activities that will occur on raw milk farms. The group was challenged to think practically, scientifically, and creatively about how to address these challenges.

For example, the Grade A dairy farm standards were designed for producing milk on the farm that would be pasteurized. If the milk is not pasteurized, are the Grade A dairy farm standards still useful and effective in reducing or eliminating risks in raw milk, and/or are there new critical food safety risks the Grade A standards are not designed to address?

The group concluded the Grade A standards were not adequate by themselves to address the new and different activities and food safety risks that would occur on farms where the milk would not be pasteurized. In addition, there was less than desired, verifiable and practical experience or information to demonstrate if the ideas being considered by the group would be effective in reducing the health risks to consumers in the absence of pasteurization.

- **Challenge: Farms producing and selling unpasteurized milk to consumers are a new dairy business entity. Raw milk producers have significantly new, expanded, and different on-farm roles and responsibilities compared to the dairy producer selling raw milk to a dairy plant.**

  The challenge to the working group was to identify these new activities and responsibilities and consider how to create on-farm regulations for these activities that will produce the safest milk possible for consumers. The group was also challenged by the fact that these are new on-farm business practices and responsibilities have not been done before on the farm and in a dairy business that has not existed previously.

  The working group identified the new activities and responsibilities of the raw milk producer necessary to produce the product. Some of these new activities include sampling and testing animals, water, and raw milk; bottling and capping the milk; and increased sanitation and expanded temperature and time controls.

  The producer will also take on the new responsibilities of a processor, retailer, and marketer. The working group identified the new knowledge necessary for the producer to acquire expertise in the new activities

and responsibilities. The producer will need to know the regulations and best management practices for activities new to the raw milk farm and those currently required of other food and dairy businesses but not performed on the traditional dairy farm today.

The producer will need to establish new business practices, record keeping, and processes on the farm for these new activities. New business relationships with laboratories and customers will also occur.

The producer will be responsible for the health of her or his customers while producing a food product that has high, inherent risks.

- **Challenge: There may be a fragmented, and perhaps weak, business infrastructure to support the new services needed by the raw milk producers to produce their product.**

  As the working group identified the new activities and responsibilities that would occur on the raw milk farm, it discussed the business support services producers would need, including equipment, technology, testing options and laboratory services, veterinary services, and education and information services. The group discussed whether these services would be available, their location, and the service costs. The working group discussed the possibilities for the producer to undertake some of these tasks on the farm, whether it would be practical and effective as well as how that might be done. The group learned there is an existing infrastructure for some of the services the producer will need and there is a limited infrastructure available for some of the other services.

- **Challenge: Sorting through the myths and misinformation that abound about pasteurized and unpasteurized milk**

  During their discussions, the group methodically sorted through myths and misinformation and developed practical and workable ideas to regulate unpasteurized milk and address the health risks to consumers.

- **Challenge: There is limited practical and academic research on alternative ways to regulate raw milk production to produce a safe product.**

  This is not unexpected. Pasteurization is effective at targeting and killing the specific disease-causing bacteria in raw milk, rendering it safe to drink, and has done so for the past 60 years. Raw milk sales are illegal in many states and across state lines. There has been little reason to conduct research or search for alternatives to pasteurization

to make raw milk safe to drink. The demand and market for raw milk has been relatively small, probably less than one percent of the United States population.

Asked to explore and evaluate regulatory alternatives to protect public health if raw milk sales are allowed, the working group found knowledge gaps in the practical and academic research to assist it, again making its assignment difficult. The group of stakeholders used their extensive dairy farming and dairy processing expertise and food safety and epidemiological knowledge to develop the regulatory framework as it worked through this challenge.

- **Challenge: It is not possible to quantitatively determine the degree to which the comprehensive regulatory framework will reduce the health risks to consumers.**

  It is likely the comprehensive regulatory framework designed by the working group will reduce some of the risk of drinking raw milk for some people. It is not possible to know or predict the quantitative degree to which the risk of drinking raw milk would be reduced if the raw milk is produced in compliance with the comprehensive regulatory framework the working group developed.

Themes of the Regulatory Framework

As the working group began to develop ideas it believed were necessary to address the challenges and develop regulatory alternatives to help protect consumers drinking raw milk, consistent themes emerged from its discussions which began to shape and define the parameters of the comprehensive framework that would emerge. In summary, the themes of the comprehensive framework are:

- **Theme: The highest priority of the working group is designing safeguards to reduce the health risks to consumers drinking raw milk.**

  The working group focused its efforts on how to reduce the health risks to consumers drinking raw milk and sought to design a comprehensive framework that gave the highest priority to consumer's health.

  The working group acknowledged drinking raw milk has high inherent risks and it is not possible to prevent all of the risks of foodborne illness, but food safety regulations can assist in reducing some of them. Some of the food safety regulations recommended in the

comprehensive regulatory framework may create a higher cost or more rigorous on-farm practices for the producer, but the working group gave paramount importance to consumer safety as it developed its recommendations.

- **Theme: The comprehensive regulatory framework should include effective food safety regulations to address the health risks.**

  The working group identified the most serious risks raw milk poses to consumer health, and then recommended food safety regulations to help reduce the risks. The most serious risks are linked to animal diseases that can be transmitted to humans through raw milk, coliform bacteria in on-farm water supplies, raw milk temperatures, unsanitary environments where the cows are kept and the raw milk is produced, antibiotic drug residues, and pathogenic bacteria that can contaminate the raw milk, equipment, and containers.

- **Theme: Testing animals and the raw milk is a central theme of the comprehensive framework.**

  Testing can be used in several ways to help identify and reduce risks. Testing the cows for disease is done to identify the presence of animal diseases in a cow herd to prevent the spread of infection and illness to humans. Some testing of raw milk and the farm's water supply is done to monitor sanitary conditions on the farm. Testing the cows and raw milk prior to receiving is also important to help ensure risks are minimized prior to customers purchasing the raw milk.

- **Theme: Best management practices and education initiatives for raw milk producers and consumers are important tools to add to the comprehensive framework wherever possible.**

  Best management practices and educational tools can significantly strengthen the comprehensive framework, complement the food safety regulations, and assist raw milk producers and consumers in reducing some of the health risks of raw milk.

- **Theme: When evaluating possible regulatory alternatives for raw milk, the group sought to achieve food safety parity with the regulations currently used for other businesses producing and processing dairy and food products.**

  Seeking "parity" or developing functionally equivalent regulatory options for raw milk was a common theme in the group discussions. Seeking regulatory or food safety parity also generated science-based

and time-tested ideas for the working group to consider to increase the potential effectiveness of the regulations being proposed.

- **Theme: Food safety standards for raw milk should meet or exceed what other states use to regulate raw milk.**

  The group sought the strictest food safety regulations to give as much protection to consumers as possible. Other states that allow raw milk sales continue to have illness outbreaks from raw milk and in some cases, more frequently than before raw milk sales were allowed. The group chose to err on the side of consumer protection as it developed the comprehensive framework.

- **Theme: New ideas are needed to regulate food safety on raw milk farms. The same dairy farm regulations for producing unpasteurized milk for processing should not be the same regulations for producing milk that will not be pasteurized.**

  Removing the pasteurization step also removes the most effective step to producing milk that is safe for consumers to drink. The comprehensive framework should focus on the increased risks created when pasteurization will not be done. The group consistently discussed the importance for raw milk producers to be held to a higher set of food safety standards than other dairy producers because of the inherent risks associated with raw milk.

- **Theme: The same food safety regulations should be used for all farms producing raw milk, with no distinction given for different sizes of raw milk farms or different sizes of dairy cow herds producing raw milk.**

  All raw milk farms should be governed by the same regulations regardless of size or any other distinguishing characteristic. Just as one set of laws governs the speed limits for all automobiles, one set of laws should govern dairy cow herds producing raw milk.

  Each healthy cow on each farm has the potential to produce unsafe raw milk. No cow or dairy herd size is inherently healthier or produces safer raw milk than any other cow or different sized dairy herd. In setting public health policy, each cow on each farm should be required to meet the same requirements if it is allowed to produce raw milk for human consumption.

- **Theme: Seek to identify effective food safety regulations that can also be practically applied on the farm.**

  The working group sought to propose and create, wherever possible, efficacious food safety regulations that can be practically implemented on the farm and can be appropriately fitted to on-farm situations.

- **Theme: A new food producing business entity will be created if dairy producers are allowed to sell raw milk on the farm directly to a consumer.**

  This new enterprise is a significantly different business than a dairy farm producing raw milk for sale to a dairy processing plant to be pasteurized before being sold to consumers. In addition, this new dairy enterprise has not been regulated previously and will be producing an inherently high risk food product.

  The working group considered the new activities that would occur on the raw milk farm and asked questions about raw milk safety and regulations that had not been asked and answered previously. The theme of caution was an overarching theme as the group developed the comprehensive regulatory framework for this new food producing business entity.

- **Theme: Ensure food safety regulations are met by the producer prior to the time when the producer is given a permit to sell raw milk to consumers.**

  Consistently, the working group recommended that important food safety regulations be put in place by the producer as pre-requisites to receiving a permit to sell raw milk. The working group wanted the regulations to be implemented to help protect the very first consumers purchasing raw milk on the farm and to assist the producer in selling the safest product possible.

  The group recommended best management practices be implemented by the producer and educational initiatives be instituted by DATCP to create as much opportunity for producers to become knowledgeable about food safety issues prior to producing and selling raw milk. These pre-requisites were considered important precautionary measures.

- **Theme: Parity with other food businesses starting up.**

  The working group recommendations consistently reinforce the idea that raw milk producers are similar to other persons starting any other, new regulated food businesses. The recommendations assume the business entity for a raw milk farm is distinctly different than the entity for a traditional dairy farm. The group assumed the producer starting a raw milk farm will require start up costs, owner investment, a license and inspection to sell the product, new operating practices and procedures, and will pass the costs onto the customers. It will be necessary for raw milk producers to gain new specialized knowledge. The group likened the changes to those necessary for a farmer to begin to produce certified organic products which also means changing operations, markets, production processes, record keeping requirements, testing, and management practices.

Working Group Consensus on the Regulatory Framework

Through the facilitated meeting process, the Raw Milk Policy Working Group reached consensus on a comprehensive regulatory framework that will reduce but not eliminate the health risks to consumers drinking raw milk if dairy producers are to be allowed to sell raw milk on the farm in Wisconsin.

The working group reached consensus on each of the food safety regulations, best management practices, and education initiatives outlined in this report. The group discussions and consensus are summarized in the sections of the report for each of the topics the group explored and evaluated.

The Raw Milk Policy Working Group also reached consensus on these four statements to summarize its work:

1. The group affirmed its assignment to explore and evaluate the regulatory conditions necessary to protect public health if raw milk sales are allowed in Wisconsin.

2. The group affirmed it was not asked to decide whether raw milk sales should be legalized in Wisconsin nor was the group or its individual members endorsing or rejecting raw milk sale by reaching consensus on the recommendations it developed for the comprehensive regulatory framework.

3. The group reached consensus on a comprehensive regulatory framework which includes food safety regulations, best management practices, and education initiatives necessary to help reduce the risks for consumers drinking raw milk if raw milk sales are to be allowed.

4. The group reached consensus on recommending to the Legislature that the comprehensive regulatory framework of food safety regulations, best management practices, and education initiatives develop by the working group should be incorporated into a law, if the Legislature decides on-farm raw milk sales are to be allowed in Wisconsin.

Comprehensive Regulatory Framework

Recommendations

Parameters of a Law

Recommendations

Parameters of a Law

The Raw Milk Policy Working Group received the assignment to explore and evaluate the legal and regulatory alternatives that would be necessary to protect public health if dairy farmers are allowed to sell raw milk on their farms in Wisconsin.

This section outlines the parameters of a law that would be necessary to help reduce the risk of foodborne illness for consumers drinking raw milk. The legal parameters of a law should include:

1. The current Wisconsin law should be repealed and recreated. The recreated law should include all the provisions and requirements outlined in this report.

2. Fluid unpasteurized ("raw") whole cow's milk should be the only unpasteurized dairy product allowed for sale on the farm.

3. The unpasteurized cow's milk should be allowed for sale only on the farm premises by the person who is licensed to operate the farm and delivered to the consumer on the farm where it is licensed and permitted to be sold.

4. The on-farm sale of unpasteurized cow milk should be allowed only in the regular course of business and should be subject to all the requirements and limitations described in this report.

5. The off-farm sale or distribution of raw cow milk, raw sheep milk and raw goat milk to consumers, including distribution under a barter or other arrangement, should be prohibited.

6. The incidental on-farm sale of raw goat milk and raw sheep milk as allowed under current law may continue to be allowed. The incidental on-farm sale of raw goat milk and raw sheep milk as allowed under current law should not be expanded in any way for any purpose. The incidental sale of raw goat milk and raw sheep milk should not be subject to the sale provisions and limitations described in these recommendations.

7. The on-farm sale of raw goat milk and raw sheep milk in the regular course of business should be prohibited.

8. A bona fide farm owner, the farm owner's immediate family, and the farm's employees should be allowed to continue to consume unpasteurized milk produced on the farm owner's farm as allowed under current law. The consumption under this provision should not be considered a sale or distribution subject to a new law.

9. All producers and farms licensed and permitted to sell unpasteurized milk on the farm should be governed by one set of laws and regulations applicable to the on-farm sale of unpasteurized milk. The same set of laws and regulations shall govern all producers and farms where unpasteurized milk is licensed to be sold regardless of the farm size, the number of cows on the farm or any other farm or producer distinction. No part of the regulations and laws created to govern the sale of unpasteurized milk on the farm shall establish tiers of regulations whereby one group of farms is governed by one set or tier of regulations and another group is governed by another tier or different set of regulations.

10. The unpasteurized milk product allowed to be sold on a farm should be fluid unpasteurized whole milk from a female bovine cow without any added ingredients or processing, other than cooling and packaging in a properly labeled container. The new law should not legalize the production, sale or distribution of any other unpasteurized dairy product, including any unpasteurized fluid or non-fluid product such as colostrum, cream, buttermilk, sour cream, yogurt or cheese product whose production, sale or distribution is currently prohibited by state or federal law.

11. A producer permitted to sell unpasteurized milk on the farm should be required to follow the generally-applicable food safety, packaging, labeling, and weights and measures laws, including generally-applicable laws that prohibit the sale of adulterated or misbranded food.

12. A producer selling unpasteurized milk on the farm should not be exempt from any liability for personal injury or damages incurred by a consumer from the consumption of unpasteurized milk. A new law should not constitute a warranty by the State of Wisconsin that unpasteurized milk is safe for human consumption.

13. A new law should not allow any person to engage, without a license, in any activity for which a license is currently required.

    For example, it should not exempt any person from any currently applicable requirement to hold a dairy farm, dairy plant, retail food establishment, buttermaker, cheesemaker, milk weigher and sampler, or milk and cream tester license. (Current license requirements depend on the types of business operations in which a person is engaged.)

14. A new law should authorize the on-farm sale of unpasteurized milk only for delivery to the purchasing consumer on the farm where the milk is produced, and only for that consumer's personal or household consumption. The law should prohibit:

    - The sale or distribution to wholesalers or other third-party distributors.
    - The off-farm delivery to consumers, either by the farm operator or any third party.
    - The resale or redistribution of the unpasteurized milk by the consumer purchasers.
    - Internet or other sales of unpasteurized milk for delivery to consumers at any location other than the farm at which the milk is produced.
    - The sale of unpasteurized milk in interstate commerce.

15. Statutory language for a new law may be written to define a very limited arrangement whereby one customer buying unpasteurized milk on a farm may pick up another customer's unpasteurized milk so the business transaction is not considered a "distribution" or "redistribution." "Distribution" and "redistribution" of raw milk shall be illegal under this law. This very limited transaction shall ensure the sale of the fluid unpasteurized milk is documented to the individual customer who purchased the milk and is verified for purposes of tracing the unpasteurized milk from the individual customer who purchased it back to the farm where it was sold.

    This provision is intended to allow a very limited arrangement whereby the pick-up of the raw milk product will not increase the risk of foodborne illness to a consumer purchasing or drinking the raw milk. The provision must strictly limit the number of total customers in the pick-up arrangement and the geographical range of the business transaction to minimize the foodborne risk of illnesses to the consumers. The arrangement must ensure each of the customer names, addresses, phone numbers, and separate receipts are directly tied to the container and to the customer who purchased the product to

ensure that clear and easy traceability of the product shall be achieved.
Food safety procedures to minimize the foodborne illness risks should be established to accomplish this provision to be done as safely as possible and should be delineated by administrative rule.

Under this provision, no monetary exchange or compensation shall be allowed between the customers cooperating in the pick up of their purchased unpasteurized milk.

16. All producers selling unpasteurized milk on their farm to consumers should be required to:

    a. Be licensed annually as a milk producer (consistent with s. 97.22, WI Stats.) and

    b. Hold an annual Raw Milk Farm Permit

17. To qualify for a Raw Milk Farm Permit, the producer should be required to do the following:

    a. Follow the application process for the Raw Milk Farm Permit as outlined,

    b. Provide documents along with the permit application verifying the producer has met the Raw Milk Farm Permit requirements,

    c. Pass an on-farm inspection by the Department of Agriculture, Trade, and Consumer Protection (DATCP),

    d. Meet the requirements of the Raw Milk Farm Standards established by law and administrative rule.

18. A Raw Milk Farm Permit to sell unpasteurized milk on the farm should not be issued to the producer until the producer meets all the requirements of the Raw Milk Farm Permit and the Raw Milk Farm Standards established by law.

19. A new law should allow a producer to hold both a Grade A dairy farm permit and a Raw Milk Farm Permit if the producer chooses to hold two permits. A producer holding a Raw Milk Farm Permit is not required to hold a Grade A dairy farm permit.

20. The Raw Milk Farm Standards necessary to qualify for a Raw Milk Farm Permit should consist of a combination of:

    a. The existing farm standards equivalent to those applied to a Grade A dairy farm producer as outlined in the current DATCP, Milk Producer Farm Inspection checklist (DATCP Form F-fd-11 (Rev 3/2009)) and in ATCP 60, with one exception. A producer selling unpasteurized milk does not need to be assigned to a Grade A milk marketer unless the producer also produces Grade A milk, and

    b. A set of farm standards created to regulate the new on-farm activities necessary to produce and sell unpasteurized milk legally on a farm. The new standards shall govern new on-farm activities such as filling containers with milk; labeling and refrigerating milk containers; sanitizing and storing containers, and selling milk. The new set of farm standards shall also include requirements for sampling and testing the milk for specific bacteria, organisms and pathogens and testing the cows for disease. These regulations shall govern on-farm activities similar to activities that are regulated in retail food stores and small dairy processing plants as well as activities currently required of milk marketers on behalf of Grade A dairy farm permit holders.

21. The new farm standards established as the Raw Milk Farm Standards should include the requirements outlined in other sections of this report entitled:

    a. Raw Milk Farm Standards

    b. Animal Health and Testing for Diseases

    c. Testing for Standards Plate Count

    d. Testing for Somatic Cell Count

    e. Testing for Coliform Bacteria in Milk

    f. Testing for Antibiotic Drug Residues in Milk

    g. Testing for Pathogens

    h. Testing for Coliform Bacteria in Well Water,

    i. On-farm Sampling Procedures

    j. Milk Temperature Controls

k. Time Controls on Selling Unpasteurized Milk

l. Containers and Processes for Filling Containers

m. Labels for Raw Milk Containers, and

n. On-farm Incident Response Plans

22. The producer selling unpasteurized milk on the farm should be allowed to be his or her own milk marketer.

23. A Raw Milk Farm Permit should not be issued to a producer to sell unpasteurized milk on a farm if any of the cows on that farm are milked by hand.

24. A Raw Milk Farm Permit should not be approved for a farm where the producer uses milk cans to store or transport unpasteurized milk or on a farm where unpasteurized milk is put into a milk can, as defined by administrative rule.

25. DATCP may deny, suspend or revoke a Raw Milk Farm Permit for cause, including failure to meet the Raw Milk Farm Standards established by law.

26. The producer selling fluid unpasteurized milk on the farm should be allowed to advertize the sale of the unpasteurized milk, but only for the purchase and delivery at the farm where the raw milk is produced. Only the producer of the unpasteurized milk should be allowed to advertise the sale of the unpasteurized milk he or she has produced. All advertisement of the sale of unpasteurized milk on the farm must comply with applicable state and federal law and may not contain any false, deceptive or misleading representations.

27. Producers should be required to keep certain records as determined by DATCP through administrative rule, including but not limited to animal testing and herd health, raw milk and water testing, raw milk product sales, and customer sales.

28. DATCP should consult with dairy and food science experts at the University of Wisconsin to prepare a best management practices manual for producers selling fluid unpasteurized milk and a consumer's guide for the safe handling of fluid unpasteurized milk. The manual and guide should identify best management practices and safe handling practices to reduce the foodborne illness risk for consumers drinking raw milk.

The manual and guide must be completed within one year after any new law may go into effect so producers and consumers may take full advantage of these as educational resources.

29. DATCP in consultation with dairy and food science experts at the University of Wisconsin shall develop a competency test for dairy producers who want to apply for a Raw Milk Farm Permit to sell raw milk on the farm. To be eligible to apply for a Raw Milk Farm Permit, a producer must attain a specified score on a one-time competency test administered by DATCP. The DATCP in consultation with the University of Wisconsin should develop key competencies and a course curriculum for dairy producers to prepare for the competency test and acquire the knowledge necessary to gain the competencies to produce and sell raw milk on the farm. The key competencies and core curriculum should include information on the laws, regulations, best farm management practices and knowledge necessary in the production and sale of raw milk on the farm to minimize the risk of foodborne illness to consumers. DATCP should make the relevant information readily accessible and available in a variety of ways for producers to gain knowledge of the core curriculum and competencies.

30. The Governor should appoint a nine-member Raw Milk Oversight Committee to monitor food safety and public health issues associated with a new law that allows the on-farm sale of raw milk. The committee will be responsible for monitoring the public health impacts of the law, including any emerging public health and food safety issues it deems necessary to protect the public health of consumers drinking raw milk. The committee may make recommendations to the Governor and DATCP it deems necessary to protect the public health, safety, and welfare of Wisconsin citizens. Specifically, the committee should: (a) gather information on the availability of commercial tests for raw milk producers to use to detect the presence of any non-0157:H7 Shiga toxin-producing *E. coli* in unpasteurized milk and (b) gather information on any emerging health issues related to Q fever (*Coxiella burnetii)* associated with raw milk consumption and other issues it deems necessary.

    The committee may make recommendations to the Governor and DATCP on issues related to the sale of raw milk at any time. However, no later than four years after any law may take effect allowing the on-farm sale of raw milk, the committee should report to the Governor and the DATCP on the public health and food safety consequences associated with raw milk sales.

31. The nine-member committee appointed by the Governor should include one dairy producer, one state and one local public health official, one consumer, one dairy processor or dairy cooperative processor, one government food safety regulator, one representative of the University of Wisconsin food or dairy science department, and one dairy science veterinarian.

32. For a new law allowing the sale of raw milk on the farm, DATCP should be required to write administrative rules to implement the provisions of the new law to govern the production and sale of raw milk and set raw milk farm permit fees to cover the administrative costs of the new law.

33. A new law that may allow the on-farm sale of unpasteurized milk should not be allowed to take effect until DATCP adopts administrative rules to implement the law.

34. DATCP should be required to write a hearing draft of the administrative rules within twelve months following the enactment of any new law that may occur.

35. For a new law that may allow the on-farm sale of raw milk, DATCP should be required to report regularly to the Board of Agriculture, Trade, and Consumer Protection on the status of the on-farm sale of unpasteurized milk, including statistics on the number of farms licensed, the number of foodborne outbreaks, the financial impact of the law, and other public health and food safety issues as deemed necessary.

Animal Health

Recommended Standards and Regulations

Animal Health and Testing Animals for Disease

Tuberculosis
Brucellosis
Streptococcus agalactiae
Leptospirosis
Q Fever (*Coxiella burnetii)*

Summary: Recommendations for Testing Animals for Disease in Wisconsin

Disease	Test	Disease Standard	Prior to Permit	Routine Testing Protocol	New Animals
Tuberculosis	Insulin	Free	Yes	Once / 3 yrs	When entering herd
Brucellosis	Blood	Free	Yes	Once / 3 yrs	When entering herd
S. agalactiae	Raw Milk	Culture Negative	Yes	When SCC >400,000cells/mL	When entering herd
Leptospirosis	Blood	None set	None	None	None
Q Fever	Raw Milk	None set	None	None	None

Animal Health and Raw Milk Issues

Dairy cows can be infected with bacteria that can cause contagious diseases of both animals and humans and can be transmitted from the cows to people and other warm blooded animals. People can be infected with these bacteria when the animal sheds the bacteria, breathing in air that has been contaminated or by drinking raw milk from infected cows.

When raw milk is pasteurized, the bacteria that can cause infection in humans are killed. The raw milk sold to consumers on the farm to drink will not be pasteurized and harmful bacteria that cause infection may be present in the raw milk that is purchased.

Without pasteurization and because most producers today do not vaccinate or routinely test their animals, it is important that testing be done on raw milk farms to ensure animal diseases that can be transmitted to humans are not present in the herds. Several animal diseases that are contagious to humans include tuberculosis, brucellosis, and Q fever.

Routine testing of dairy cows on a farm is done to monitor the herd health and identify cows with selected diseases. Some dairy producers vaccinate their animals to prevent specific diseases like brucellosis but this is not consistently done throughout the state, is not done by all producers, and does not guarantee herds are disease free. For some diseases such as tuberculosis, vaccinations are not available.

Raw milk producers should ensure their herds test free for tuberculosis and brucellosis and are culture negative for *Streptococcus agalactiae.* It is important to establish certainty regarding the disease status of the animal herd prior to selling any raw milk from the herd and maintain the certainty through testing-based surveillance over time.

The working group reviewed and discussed several animal health diseases associated with raw milk, including tuberculosis, brucellosis, *Streptococcus agalactiae,* leptospirosis, and Q fever (*Coxiella burnetii).*

Tuberculosis

Summary of Working Group Discussion and Consensus

1. Tuberculosis (*Mycobacterium bovis* infection) continues to be sporadically detected in the United States among dairy and beef cattle, commercial deer, and wildlife deer. Cattle from other countries can also have tuberculosis. Tuberculosis infections have been detected among animals in eleven states since October 2008.

2. The bacteria *Mycobacterium bovis* causes tuberculosis in cattle and may infect and cause illness among other warm-blooded animals, including humans. *M. bovis* is a contagious disease that affects the lungs, lymph nodes, and other parts of the body. Symptoms of *M. bovis* include fever, weight loss, and lymph node and gastrointestinal problems. Rarely, if untreated, a person can die. Tuberculosis is treated with antibiotics.

3. People can be infected with the bacteria that cause tuberculosis by drinking raw milk from infected cows. Anyone can become infected with *M. bovis*, but it generally occurs among people who eat or drink unpasteurized milk and milk products. *M. bovis* can spread through the air when an infected person coughs or sneezes. In the United States where few cattle are infected and milk is pasteurized, *M. bovis* causes less than one percent of tuberculosis cases in humans.

4. Today, if tuberculosis is detected on a farm in Wisconsin, DATCP will test and quarantine the herd or positive or suspect animals. "Voluntary" depopulation and removal of animals may also be a course of action. This is done to minimize the spread of tuberculosis and protect the human population and the cattle industry.

5. Twenty seven states require tuberculosis testing of their cattle because of the current prevalence and the persistent nature of the disease regardless of the state's tuberculosis-free status. Twenty three states do not require testing.

With the extensive shipping and movement of domestic and imported cattle within the United States, it is important for farms selling unpasteurized milk to test for tuberculosis.

6. Because Wisconsin is "tuberculosis-free" for purposes of selling cattle to other states, producers in Wisconsin are not required to test their cattle for tuberculosis. For this reason, there is no certainty Wisconsin cattle or other animals do not have tuberculosis.

7. When raw milk is pasteurized, tuberculosis is killed. Because raw milk sold on farms directly to consumers will not be pasteurized, any the bacteria that cause tuberculosis that may be present in the raw milk will not be killed.

8. Dairy cows can be tested to detect tuberculosis. Requiring dairy cows to test free of tuberculosis on farms selling raw milk is one way to reduce the risk to consumers of becoming infected with the bacteria from drinking raw milk.

9. These facts support testing animals for tuberculosis on farms selling unpasteurized milk. Testing should be required prior to selling raw milk, when new cows enter the herd, and routinely over time.

10. There are some animal health requirements that currently exist to regulate tuberculosis. Any testing regulations proposed for raw milk farms should be consistent with the current regulatory framework for animal health requirements.

11. The working group discussed the tuberculosis testing regulations in the seven select states it chose to examine most closely as it reviewed laws where the sale of raw milk is legal. The regulations for testing for tuberculosis in the seven select states are summarized in the table below.

Tuberculosis Testing Regulations in Seven Other States

State	Tuberculosis Testing Requirements
California	Requires annual testing and a disease free herd
Connecticut	Requires annual testing and a disease free herd
Idaho	Requires annual testing and a disease free herd
New York	Test required only when animal is exposed to TB and requires a disease free herd
Pennsylvania	Requires annual testing and a disease free herd
So. Carolina	Requires annual testing and a disease free herd
Washington	Requires annual testing and a disease free herd

Recommended Regulations: Testing for Tuberculosis

The working group believes the following food safety regulations are necessary for testing cows for tuberculosis to help reduce the risk to consumers drinking raw milk.

The goal of animal health testing for tuberculosis is to ensure the cow herd tests free of tuberculosis.

1. The producer should be required to test all the cows in the herd for tuberculosis. The cow herd must test free of tuberculosis as one of the pre-requisites necessary to receive a permit to sell unpasteurized milk on the farm.

2. A producer should be required to test all new cows coming onto the farm (from instate or out-of-state) for tuberculosis. These in-coming cows must test free of tuberculosis.

3. A producer should be required to routinely test all the cows on the farm for tuberculosis at least once every three years or test all the cows on the farm following the protocol for achieving accredited tuberculosis-free status of the cow herd.

   An accredited tuberculosis-free status of the cow herd is achieved by conducting two consecutive tests on the cows that are 24 months and older. The two consecutive testing times are done in nine to fifteen month intervals. If the cow herd tests free of tuberculosis following the testing, the herd achieves an accreditation as having a TB-free status. After the two consecutive tests, the producer must wait two years and the protocol for two consecutive tests is repeated to receive re-accreditation.

4. No raw milk should be allowed to be sold to consumers from a farm where an animal tests positive for tuberculosis. If tuberculosis is detected in any animal on a farm selling raw milk, the producer is required to contact DATCP and follow Wisconsin animal health regulations, including testing animals, quarantine of animals, and voluntary depopulation of animals as determined by DATCP. A producer is not allowed to sell raw milk on the farm until the animals test free of tuberculosis and DATCP approves the sale.

5. Testing the cows for tuberculosis should be required to be done by a Wisconsin licensed veterinarian.

6. The producer should be required to keep careful records to document the tuberculosis testing of the cows on the raw milk farm.

Brucellosis

Summary of Working Group Discussion and Consensus

1. Bacteria of the genus *Brucella* cause brucellosis, primarily a disease of farm animals, although wild animals can also become infected. There is a low likelihood of brucellosis being detected in U.S. cattle, however, brucellosis is detected currently in wildlife animals, particularly west of the Mississippi River. Brucellosis can spread from wild to domestic animals. The bacteria that cause brucellosis can be transmitted to people. Brucellosis is very common in cattle (and humans) in some other countries.

2. People can be infected with *Brucella* that cause brucellosis primarily by drinking raw milk from infected cows and coming into direct contact with infected animal tissue. Everyone is susceptible to brucellosis and may get the disease if infected. Veterinarians and farmers are at greatest risk of being infected. Only rarely is infection transmitted from person to person.

3. *Brucella* infections in people cause flu-like illness. Symptoms of brucellosis include fever, weakness, weight loss, and joint pains. Localized infections may occur in the liver, spleen, bones, and joints. Chronic illness can occur for weeks or months if not treated. Brucellosis can be treated but requires close monitoring by a physician because of the possibilities for recurring infection.

4. Wisconsin currently holds a brucellosis-free status. Cattle in Wisconsin are not required to be tested for brucellosis because of the disease free status. Animals can be vaccinated against the disease. The efficacy of the vaccine is high. Vaccination to prevent brucellosis is not typically done unless buying and selling cattle in the Western United States where brucellosis has been detected among wildlife animals.

5. Wisconsin is brucellosis-free for the purpose of selling cattle to other states. This means little testing is done, and therefore there is no certainty Wisconsin cattle or other animals do not have brucellosis. With the extensive shipping and movement of domestic and imported cattle within the United States it is important for farms selling unpasteurized milk to test for brucellosis.

6. When raw milk is pasteurized, brucellosis is killed. Because raw milk sold on farms directly to consumers will not pasteurized, any the bacteria that cause brucellosis that may be present in the raw milk will not be killed.

7. There is a slightly higher risk of brucellosis in unpasteurized milk today compared to the risk in the past because of the status of brucellosis in wild animals in the Western United States and the prevalence of brucellosis in cattle in other countries.

8. Some dairy producers vaccinate their animals to prevent specific diseases but this is not consistently done throughout the state, is not done by all producers, and does not guarantee herds are disease free. To ensure herds are free of diseases such as brucellosis, testing the animals on raw milk farms should be required.

9. These facts support testing animals for brucellosis on the farms selling unpasteurized milk. Testing should be required prior to selling raw milk, when new cows enter the herd, and routinely over time.

10. There are some animal health requirements that currently exist to regulate brucellosis. Any testing regulations proposed for raw milk farms should be consistent with the current regulatory framework for animal health requirements.

11. The working group reviewed the brucellosis testing requirements in seven select states. The brucellosis testing requirements in these states is summarized in the table below.

Brucellosis Testing Regulations in Seven Other States

State	Brucellosis Testing Requirements
California	Requires annual testing and herd must be disease free
Connecticut	Requires annual testing and herd must be disease free
Idaho	Requires semiannual testing, disease free herd and vaccination of animals between 4 and 12 months of age
New York	Requires annual testing and herd must be disease free
Pennsylvania	Requires annual testing and herd must be disease free
So. Carolina	Requires annual testing and herd must be disease free
Washington	Requires annual testing and herd must be disease free

Recommended Regulations: Testing for Brucellosis

The working group believes the following food safety regulations are necessary for testing cows for brucellosis to help reduce the risk to consumers drinking raw milk:

The goal of this testing requirement is to ensure the cow herd on the farm is tests free of brucellosis.

1. The producer should be required to test all the cows in the herd for brucellosis. The established standard that must be met is that the cow herd tested free of brucellosis as one of the pre-requisites necessary to receive a license to sell unpasteurized milk on the farm.

2. The producer should be required to test any new animals coming onto the farm (from instate or out-of-state) for brucellosis. The new animals entering the herd must test free of brucellosis.

3. A producer should be required to routinely test all the cows on the farm for brucellosis, after the initial herd testing, at least once every three years or test all the cows on the farm following the protocol for achieving a certified brucellosis-free herd status.

   A certified brucellosis-free status of the cow herd is achieved by conducting two consecutive tests on the cows that are 24 months and older. The two consecutive testing times are done in nine to fifteen month intervals. If the cow herd is brucellosis-free following the testing, the herd achieves a certification as having a brucellosis-free status. After the two consecutive tests, the producer must wait two years and then the protocol for two consecutive tests is repeated to receive re-certification.

4. The producer may choose to vaccinate the cow herd but the vaccinations must not replace the testing requirements. Vaccinations do not eliminate the possibility the animals may test positive for brucellosis.

5. No raw milk should be allowed to be sold to consumers from a farm where an animal tests positive for brucellosis. If brucellosis is detected in any animal on a farm selling raw milk, the producer is required to contact DATCP and follow Wisconsin animal health regulations, including testing animals, quarantine of animals, and voluntary depopulation of animals as determined by DATCP. A producer is not allowed to sell raw milk on the farm until the animals test free of brucellosis and DATCP approves the sale.

6. The testing of the cows for brucellosis should be required to be done by a licensed veterinarian.

7. The producer must keep careful records to document the brucellosis testing of the cow herd.

Streptococcus agalactiae

Summary of Working Group Discussion and Consensus

- The public health goal is to ensure the herd is free or clean of *Streptococcus agalactiae* infection (also called Lancefield Group B *Streptococci)*.

- *Streptococcus agalactiae* causes mastitis in cows and the infection is contagious. *S. agalactiae* are found in the cow's respiratory, urinary, intestinal, and reproductive tracts. Infection from *S. agalactiae* is transferred from animal to animal, from animal to milk, from the udder to the hand, and may possibly be transferred from the milk to humans. A dairy cow can acquire *S. agalactiae* infection from raw milk that came from the udder of another infected cow in the herd.

- Scientific research has documented *Streptococci agalactiae* living in cows' udders. There is also a *S. agalactiae* that can infect humans, but research has demonstrated that while human strains of *S. agalactiae* cause mastitis in dairy cows on rare occasions, the common cow strains of *S. agalactiae* have not caused disease in humans. The bovine and human strains of *S. agalactiae* have the same name, yet they are different strains of bacteria. The human *S. agalactiae* strain in cows is very rare and most all *S. agalactiae* problems in cows are caused by other infected cows and poor milking procedures on farms, not from infected humans. (Schulte and Zadoks, 2005)

- Raw milk from cows infected with *S. agalactiae* is not suitable for human consumption. When raw milk is pasteurized, *S. agalactiae* is killed. Because raw milk sold directly to the consumer on the farm will not be pasteurized, there is a risk *S. agalactiae* may be present in the raw milk.

- For raw milk farms, the cleanliness and sanitation of the cows' udders is critical to reduce the presence of *S. agalactiae*. It is important to keep the cows as clean as possible and to eliminate the potential for the bacteria to spread. It is also important to test the raw milk for *S. agalactiae* and treat and control it when it is detected.

- There is no effective vaccine to prevent *S. agalactiae* infection. Antibiotic therapy can effectively eliminate *S. agalactiae* from a cow herd. It is relatively easily controlled.

- Dairy cows with mastitis caused by *S. agalactiae* infection often shed large numbers of the microorganism in raw milk, and these are most commonly associated with subclinical infections in the cow caused by Streptococci, especially *S. agalactiae*. The disease is most prevalent in small dairy cow herds.

- A high somatic cell count (SCC) is an indicator of *S. agalactiae* in a herd. Raw milk with a SCC above 400,000 cells/mL indicates it is likely to be infected with *S. agalactiae.* The weekly raw milk test for SCC can be used to monitor the raw milk for the potential presence of *S. agalactiae* in the cows.

- *S. agalactiae* infection is one of the easiest bovine (cow) diseases to control. The testing, treatment, and control are inexpensive. Raw milk from cows with *S. agalactiae* is contagious to other cows and it is important to isolate the cow if *S. agalactiae* is present to reduce the spread of the infection.

- These facts support testing animals for *S. agalactiae* infection on farms selling unpasteurized milk. Testing should be required prior to applying for a Raw Milk Farm Permit, when new cows enter the herd, and when weekly raw milk samples test above 400,000 cells/mL for SCC.

- The working group reviewed regulations in the seven select states. None of the seven select states examined by the working group require testing for *S. agalactiae*. New York requires quarterly testing for *Staphylococcus aureus*. None of the other six states require testing for *Staphylococcus aureus*.

Recommended Regulations: Testing for *Streptococcus agalactiae*

The working group believes the following regulations are necessary for testing cows for *Streptococcus agalactiae* to help reduce the spread of *S. agalactiae* between cows and to minimize any potential health risk to consumers drinking raw milk.

The goal of this testing requirement for *Streptococcus agalactiae* is to ensure the cow herd is free or clean of *S. agalactiae* infection.

1. The producer should be required to test the cow's milk on the farm for *S. agalactiae*. The producer should be required to send a sample of raw milk from the bulk tank to a certified or accredited laboratory or to the producer's licensed veterinarian to have the raw milk cultured for *S. agalactiae.*

2. The standard for *S. agalactiae* infection should be culture negative (or "clean") for the raw milk from the cow herd.

3. The cow herd's milk should be required to test culture negative for *S. agalactiae* as a pre-requisite necessary to receive a Raw Milk Farm Permit to sell unpasteurized milk on the farm.

4. When any new cow enters into the herd from in-state or from another state, the producer should be required to send a sample of raw milk from that individual cow to a certified or accredited laboratory or to the producer's licensed veterinarian to have the raw milk cultured for *S. agalactiae*. The raw milk must test culture negative (or "clean") for S. *agalactiae* infection from the individual cow(s).

5. The producer should be required to monitor the raw milk in the bulk milk tank for *S. agalactiae* by monitoring the weekly testing for somatic cell count. When the somatic cell count on the raw milk in the bulk milk tank exceeds 400,000 cells/mL, the producer must send a sample of that same raw milk to a certified or accredited laboratory or to the producer's licensed veterinarian to have the sample cultured for *S. agalactiae*.

6. When a test result is culture positive for *S. agalactiae*, the producer should be required to have additional testing done to identify the dairy cow(s) in the herd that are contributing raw milk to the bulk tank that is culture positive. These cows must be removed from milking, treated with antibiotics, and dried out. Once the cow's milk tests culture negative for *S. agalactiae* the cow may be returned to the milking herd.

7. The producer should be required to maintain records associated with testing for *S. agalactiae* in the herd.

Leptospirosis

Summary of Working Group Discussion and Consensus

1. Leptospirosis is caused by a bacteria known as *Leptospira* found in wild and domestic animals. Infected animals shed the bacteria in urine and other fluids. The bacteria can be spread to humans and other animals when the urine from infected animals contaminates water, milk, and the environment. Animals are commonly tested for Leptospirosis on dairy farms. *Leptospira* are killed when raw milk is pasteurized.

2. Because the raw milk sold directly to consumers on the farm will not be pasteurized, the working group discussed the food safety risk of *Leptospira* to consumers drinking raw milk.

3. The working group reviewed and discussed whether the producer should be required to test the cows on a raw milk farm for *Leptospira,* including whether it is necessary for the cows to be free of Leptospirosis as a condition of receiving a Raw Milk Farm Permit and whether testing for *Leptospira* should be done on a routine basis.

4. Leptospirosis is endemic in Wisconsin. It is infrequently diagnosed in humans, but it is serious when it occurs in humans. Leptospirosis is not a disease that is linked only to unpasteurized milk. These facts do not support the testing of animals for leptospirosis on raw milk farms.

5. The working group did not find any of the seven select states requiring testing for leptospirosis on raw milk farms.

Recommended Regulations: Testing for Leptospirosis

The working group recommends there be no animal health testing regulations for Leptospirosis on raw milk farms.

Q Fever or Coxiella burnetii

Summary of Working Group Discussion and Consensus

In summary, the following points reflect both the challenges and the conclusions of the working group's recommendation on Q fever.

- Research has verified that dairy cows are reservoirs of *C. burnetii.*

- Research has documented that humans can become infected with *C. burnetii* from infected dairy cows.

    - Most commonly, humans are infected by inhalation of the *Coxiella burnetii* bacteria from airborne barnyard dust contaminated by dried placental material, birth fluids, and excreta of infected animals. Research has shown people can become sick with serious health complications and die from inhaling air contaminated with *C. burnetii.*

    - People can be infected by eating or drinking unpasteurized milk and dairy products containing *C. burnetii.* However, the ability to assess the public health risk of *C. burnetii* for consumers drinking raw milk is currently limited by insufficient knowledge and understanding about the nature and magnitude of the risk of Q fever in humans who have consumed raw milk.

- Research shows *Coxiella burnetii* in raw milk are killed by pasteurization. Because almost all milk sold to consumers has been pasteurized during the past 50 years, the issue of people becoming infected from *C. burnetii* from drinking raw milk has not been a significant public health concern in the intervening years.

- In the past five years, research has documented a high prevalence of *C. burnetii* in raw milk in bulk tanks and raw milk purchased legally. Researchers have also extrapolated their data from bulk tank raw milk samples to the national dairy cow population and suggested as many as 3 million lactating cows may be shedding *C. burnetii* daily.

- There are limitations on diagnosing *C. burnetii* in animals and humans. Infected animals do not show signs or symptoms of the infection. Fifty percent of infected humans do not show signs or symptoms. When infected humans do show early signs and symptoms, these are similar to other diseases and misdiagnosis is not uncommon.

- There are limitations on prevention and treatment of *C. burnetii* infections in animals and humans. There are no vaccines available for use in the U. S. for either animals or humans. There does not appear to be a practical and effective treatment of *C. burnetii* in animals. Treatment of chronic Q fever in humans can be difficult and may require three years of antibiotic therapy to be effective.

- There are limitations on testing dairy cows and raw milk for *C. burnetii.* The test results using the Complement Fixation (CF) test method on bovine blood samples can yield false negatives, meaning some

animals that are truly infected with *C. burnetii* will have negative test results. The CF test method determines if antibodies to a Q fever antigen are present, but the presence of antibodies cannot differentiate past from current infection.

- The real-time Polymerase Chain Reaction (PCR) test provides accurate information about whether the cow is currently infected with *C. burnetii.* However, PCR testing of raw milk to determine which cows are infected would require the producer to choose one of two options:

  - Use the PCR assay to test the raw milk of each individual cow in the herd. Positive test results showing raw milk produced from cows infected with *C. burnetii* could not be used for direct sale to consumers. The producer would be responsible for segregating the raw milk and deciding whether to have it pasteurized or used for some other purpose. The PCR test cost would be $30 for each raw milk sample from each cow.

  - Use the PCR test to test the bulk tank raw milk. If the bulk tank raw milk tests positive, additional PCR testing of groups of cows or individual cows would need to be done to narrow down and identify individual cows infected with *C. burnetii.* A testing strategy for the cows that did not contribute raw milk to the tank would be needed to identify the infection status of all the cows in the herd. Again, the producer would be responsible for segregating the raw milk produced from infected cows and deciding whether to have it pasteurized or used for some other purpose. The PCR test cost would be $30 for each tank sample, each raw milk sample from a group of cows, or each raw milk sample from an individual cow, depending on the sampling protocol used by the veterinarian.

- Testing services are available for veterinarians wanting to test animal blood samples or raw milk samples for *C. burnetii.*

- The research documents a high prevalence of *C. burnetii* detected in raw milk samples, yet there is no research that documents the magnitude of the human health implications these high percentages pose for consumers drinking raw milk. If testing of animals or raw milk is required in Wisconsin, given the research that has been done, we can assume the tests will likely detect *C. burnetii* in similarly high numbers in the raw milk or in the dairy cows. While it is clear there is a high risk of infection and illness when people breathe in the air and dust contaminated with *C. burnetii,* the ability to assess the public health risk of *C. burnetii* for consumers drinking raw milk is currently limited by insufficient knowledge about the nature and magnitude of

the risk of Q fever in people consuming raw milk. These facts raise questions about what is achieved with a testing requirement.

- Equally significant, the working group concluded it is important for producers and consumers to know that while we do not know how *C. burnetii* establishes an infection and spreads in humans or how *C. burnetii* may produce infectious disease in humans who drink raw milk. There is no research today to suggest it is safe for consumers to drink raw milk produced from dairy cows infected with *C. burnetii.*

Recommended Regulations: Testing for *Coxiella burnetii*

1. At this time, the working group recommends no regulations should be required for producers to test animal blood samples or bulk tank raw milk samples for Q fever or *Coxiella burnetii.*

2. For its report, the working group agreed to document the research and facts on *Coxiella burnetii* related to raw milk that it reviewed, the practical testing limitations it found, and the challenges posed by the lack of information and research about the human infection and illness risks of *Coxiella burnetii* associated with drinking raw milk.

3. The working group recommended additional information should be collected on the research, epidemiology, and the public health risks of *C. burnetii* and raw milk consumption. Particularly, the working group recommends information be collected and examined on the *Coxiella burnetii* infection and illness risks to consumers drinking raw milk. There is research documenting that humans are infected by inhalation of *C. burnetii* but little is known about the extent of human infection from consuming raw milk contaminated with *C. burnetii.*

   The working group recommended the proposed nine-member committee should monitor these issues and make recommendations to DATCP to take further regulatory action to protect public health related to *Coxiella burnetii* based on any new information it gathers if raw milk becomes legal to sell on the farm.

Other Animal Health Disease Issues and Regulations

The working group noted some of the seven select states it chose to examine had additional testing for animal diseases or animal health requirements. These requirements are summarized in the table below.

Additional Animal Health Regulations in Other States

State	Additional Animal Health Regulations
California	None that are known
Connecticut	Herd must be enrolled in state's mastitis program
Idaho	None that are known
New York	Quarterly test for Staphylococcus aureus (<10,000/mL)
Pennsylvania	Requires annual herd health evaluation by veterinarian
So. Carolina	None that are known
Washington	Q fever test of herd prior to license and annually

Recommended Best Management Practices for Animal Health

The Raw Milk Policy Working Group recommended one best management practice for raw milk producers:

- As a best management practice, producers are encouraged to establish an on-going relationship with a veterinarian licensed by the State of Wisconsin and/or establish a Veterinarian-Client-Patient Relationship (VCPR) with a Wisconsin licensed veterinarian for medical care of the animals on the farm.

The working group also recommended:

- DATCP, consulting with the Wisconsin Department of Health Services, should monitor animal health issues that may impact public health in the future, including emerging trends or pathogens that may be important in future years as they relate to raw milk. For example, DATCP may want to monitor the public health issues related to *Coxiella burneii* or Q fever.

Raw Milk

Recommended Standards and Regulations

Weekly Testing of Raw Milk

Standard Plate Count
Somatic Cell Count
Coliform Count

Summary of Working Group Discussion and Consensus

- The working group reviewed and discussed the current milk quality standards used for raw milk that is sold to dairy processors and pasteurized. The milk quality standards have been used in the dairy industry for many years to increase the quality and wholesomeness of the milk and to improve the flavor, consistency, and life of pasteurized dairy products.

- Over time, the standards also provided the framework for regulations to govern milk quality testing and dairy farm and processing plant inspection and setting milk prices based on quality. The dairy industry and dairy science research have continued to define and refine what milk quality, wholesomeness, and milk safety means for consumers as well as processors and producers.

- To produce high quality pasteurized dairy products requires high quality raw milk to be produced on the farm. The quality and safety standards set for raw milk used to make pasteurized dairy products are well established in the dairy industry throughout the world. There are many variables that can influence milk quality and safety. The milk quality standards ensure these variables are controlled to produce high quality pasteurized fluid milk and dairy products.

- In the United States today, milk quality standards are set by the Pasteurized Milk Ordinance (PMO) administered by the Food and Drug Administration. The standards are integrated into the Grade A dairy farm standards and Grade A dairy processing plant standards that are used for fluid milk or dairy products sold for human consumption. Although the PMO sets the standards, states may set their own milk quality standards if the standards they set meet or exceed the national PMO standards. The State of Wisconsin has six standards that define milk quality for raw milk that is produced for sale to dairy processing plants to be pasteurized for fluid milk or other dairy products. These six standards are:

    1. Standard plate count must be ≤ 100,000 cfu/mL
    2. Somatic cell count must ≤ 750,000 cells/mL

3. No antibiotic drug residues may be present in the raw milk
4. The raw milk must be free of pesticides and toxic substances
5. The temperature of the raw milk must ≤ 45° F. when it is received or collected from the dairy farm
6. The milk cannot be visibly adulterated, have any objectionable odor, or be abnormal in appearance or consistency

- Testing raw milk for standard plate count (SPC) and somatic cell count (SCC) is a conventional dairy industry practice and has been used for many years. The PMO and state law sets the standards that must be met to ship pasteurized milk interstate and to ensure the milk quality is suitable for pasteurization.

- SPC is an indicator of the cleanliness and sanitation of the cow udders and the milking equipment, pipe systems, and the bulk milk tank. SCC is an indication of subclinical mastitis infections in dairy cows.

- Testing raw milk for coliform bacteria, although not a milk quality indicator, is an indicator of cleanliness and sanitary conditions or poor hygiene practices in dairy production environments during or after milking. Coliform counts are also routinely done by some dairy processing plants.

- Testing raw milk samples for SPC, SCC, and coliform bacteria is a good tool for the raw milk producer. There are good reasons for requiring these three tests be done routinely on raw milk farms.

- Information on SPC, SCC, and coliform count can be important indicators of the cleanliness of a raw milk farm and can increase the ability to identify raw milk farm sanitation problems.

- It is important to ensure sufficient testing surveillance on raw milk farms to monitor the cows' udder health and sanitation of milking equipment and barn cleanliness to provide good information to help manage the food safety risks associated with raw milk production.

- A numerical test standard for these three tests can provide quantifiable data on existing bacteria or white blood cells in the raw milk, at a point in time, on the herd's udder health and equipment and barn cleanliness and sanitation.

- The numerical results for SPC, SCC, and coliform bacteria from the tests on raw milk samples provide a quantitative gauge for the producer to use to monitor raw milk quality and address problems as they arise. The quantitative gauge allows the producer to learn about the problems sooner and manage them in a timely manner.

- Testing for SPC, SCC, and coliform bacteria is relatively inexpensive and will provide good farm management information to the producer.

- The working group reiterated the SPC, SCC, and coliform count are not predictors or indicators of the possible presence of the foodborne pathogens *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7 in raw milk. The SPC, SCC, and coliform count indicate chronic cleanliness and sanitation problems associated with udder health and milking equipment, pipes, and the bulk milk tank. There are other individual tests used to test raw milk for the specific pathogenic bacteria that cause foodborne illness.

Standard Plate Count for Raw Milk

Summary of Working Group Discussion and Consensus

- Standard Plate Count (SPC) is a measure of the number of the most common types of bacteria in raw milk. The SPC does not measure all the bacterial population. It measures bacteria that grow in the presence of oxygen and at medium range temperatures. The test result is used to evaluate the cleanliness and sanitary conditions of the barn environment and the milking equipment, milking system and the bulk milk tank.

- The SPC does not indicate the presence of pathogenic bacteria which can cause infection in people. A low SPC is not an indicator of a low number of pathogenic bacteria.

- The bacteria detected using a SPC indicate the presence of bacteria in the udder, the teat skin, or in the milking equipment, or as a result of poor temperature controls in the bulk tank. Very high numbers of bacteria will appear in the bulk tank if cooling the raw milk is slow or ineffective.

- Bacteria associated with standard plate count can also originate from contamination external to the cow.

- Generally a lower SPC indicates improved cleanliness and sanitation of equipment.

- Attaining a SPC of ≤ 20,000 cfu/mL for raw milk producers is a reasonable and achievable number. Research in Wisconsin found 85 percent of the standard plate counts in Grade A milk were below 15,000 cfu/mL to 20,000 cfu/mL from 1994 to 2001.

- A test standard for SPC of ≤ 20,000 cfu/mL is consistent with the SPC standard in states allowing the sale of raw milk.

- Setting a test standard of ≤ 20,000 cfu/mL for raw milk is consistent with the SPC standard for ready-to-eat food products sold directly to consumers at retail.

- SPC does not measure pathogenic bacteria that cause foodborne illness nor is it an indicator of the presence of pathogenic bacteria that may cause foodborne illness in humans.

- There are important reasons to require SPC testing of raw milk. The testing results for SPC are a useful tool for the producer to help observe trends in the management of the farm operation and to monitor the cleaning and sanitizing of milking equipment and milk production practices and milk temperature controls.

- The frequency of SPC testing provides a tool for the producer managing raw milk production and farm sanitation. Weekly testing allows a producer to learn quickly of sanitation problems and act to address the problems in a timely manner.

- The working group reviewed the SPC test standards and testing frequency in seven select states that allow raw milk sales. All seven states require SPC testing of raw milk. The standards and the frequency of the testing is summarized in the table below.

Testing in Seven Select States: Standard Plate Count

State	Standard Plate Count
California	TS= ≤ 15,000 cfu/mL and F= 4 times each 6 months
Connecticut	TS= ≤ 30,000 cfu/mL and F= 1 time each month
Idaho	TS= ≤ 15,000 cfu/mL and F= 4 times each 6 months
New York	TS= ≤ 30,000 cfu/mL and F= 1 time each month
Pennsylvania	TS= ≤ 20,000 cfu/mL and F= 2 times each month
So. Carolina	TS= ≤ 10,000 cfu/mL and F= 4 times each 6 months
Washington	TS= ≤ 20,000 cfu/mL and F= 1 time each month

TS = Test Standard; F= Frequency of test

Recommended Regulations: Standard Plate Count

Summary of Regulations Proposed for Standard Plate Count in Wisconsin

Test	Frequency	Standard
Standard Plate Count (SPC)	Once per week	≤ 20,000 cfu/mL

The working group believes the following food safety regulations are necessary for determining standard plate count to assist producers in reducing the risk to consumers drinking raw milk.

1. The producer should be required to collect a sample of unpasteurized milk from the bulk milk tank once each week and send it to a certified laboratory to be tested for standard plate count.

2. The SPC testing standard should be set at ≤ 20,000 cfu/mL for unpasteurized milk sold on the farm to a consumer.

3. The producer should be required to collect a sample of unpasteurized milk and send it to a certified laboratory to be tested for SPC prior to submitting an application for a Raw Milk Farm Permit. The SPC test standard should be set at ≤ 20,000 cfu/mL as a pre-requisite for receiving approval for a Raw Milk Farm Permit.

Testing: Somatic Cell Count for Raw Milk

Summary of Working Group Discussion and Consensus

- Somatic Cell Count (SCC) is a measure of the concentration of white blood cells present in raw milk. White blood cells are made by humans and animals to help fight infection. SCC is almost entirely linked to mastitis which is an inflammation of a cow's udder (mammary gland). Testing for SCC does not measure other animal diseases or infections.

- The SCC test is a good indicator of the udder health of a cow. Traditional testing for SCC is done by the dairy processing plant as an indicator of milk quality.

- Somatic cells originate from udders with mastitis and do not multiply in milk after the milk leaves the udder.

- Generally a lower somatic cell count indicates better udder health.

- Attaining a SCC standard of ≤ 400,000 cells/mL for raw milk is a reasonable and achievable goal for raw milk producers.

- A SCC standard of ≤ 400,000 cells/mL for unpasteurized milk is lower than the current Grade A standard for SCC in Wisconsin. The current SCC is ≤ 750,000 cells/mL for unpasteurized milk which will be sold to be processed and pasteurized. Because the raw milk will not be pasteurized, the SCC standard should be more restrictive.

- A standard of ≤ 400,000 cells/mL is the SCC standard adopted by the European Union and is likely to be the United States Grade A milk standard in the near future. Since the 1980's, the allowable PMO numerical limits for SPC and SCC have been gradually lowered as best management practices and sanitation improvements have helped producers control barn cleanliness and subclinical mastitis.

- Research data demonstrates that most on-farm Wisconsin raw milk currently tests below 400,000 cells/mL for SCC.

- The SCC is not a quantitative measure of pathogens that cause foodborne illness. Also, SCC is not a specific indicator of the presence of pathogens in raw milk that may cause foodborne illness in humans. Tests for SCC are not done to assess a food safety risk for consumers drinking raw milk.

- A SCC testing frequency of once per week is prudent because the testing of the raw milk is a measure or indicator of the udder health of the cows and the producer's animal husbandry.

- The results of a weekly numerical benchmark for the SCC test provides a tool for the producer to facilitate the monitoring and management of the udder health on the farm. Weekly testing gives information to the producer about subclinical mastitis and allows a producer to identify emerging mastitis problems and address them in a timely manner.

- The working group discussed and considered setting a test standard for SCC at ≤ 300,000 cells/mL. The working group decided to set the SCC standard at ≤ 400,000 cells/mL because recommending a standard lower than 400,000 cells/mL was not justified at this time.

- The working group reviewed the SCC requirements set by seven states that allow raw milk sales. All seven states required a SCC test. The test standard and the frequency of the testing required by these seven states is summarized in the table below.

Testing in Seven Select States: Somatic Cell Count

State	Somatic Cell Count
California	TS= ≤ 600,000 cells/mL and F= 4 times each 6 months
Connecticut	TS= ≤ 750,000 cells/mL and F= 4 times each 6 months
Idaho	TS= ≤ 500,000 cells/mL and F= 4 times each 6 months
New York	TS= ≤ 750,000 cells/mL and F= 1 time each month
Pennsylvania*	TS= ≤ 1,000,000 cells/mL and F= 1 time each month
So. Carolina	TS= ≤ 500,000 cells/mL and F= 4 times each 6 months
Washington	TS= ≤ 750,000 cells/mL and F= 1 time each month

TS = Test Standard F= Frequency of test

* The Pennsylvania SCC limit is higher than the PMO because it includes raw milk from goats.

Recommended Regulations: Somatic Cell Count

Summary of Regulations Proposed for Somatic Cell Count in Wisconsin

Test	Frequency	Standard
Somatic Cell Count (SCC)	Once per week	≤ 400,000 cells/mL

The working group believes the following food safety regulations are necessary for determining the somatic cell count to help the producer to reduce the health risk to consumers drinking raw milk.

1. The producer should be required to collect a raw milk sample from the bulk milk tank once each week and send it to a certified laboratory to be tested for somatic cell count.

2. The SCC standard for raw milk intended for on-farm sale to consumers should be set at ≤ 400,000 cells/mL.

3. The producer should be required to sample the unpasteurized milk for somatic cell count and send it to a certified laboratory to be tested prior to applying for a Raw Milk Farm Permit. The SCC standard for this SCC test should be set at ≤ 400,000 cells/mL as a pre-requisite to being granted a permit to sell unpasteurized milk on the farm.

4. The producer should be required to send a SCC test result to DATCP once each month.

Testing: Coliform Bacteria in Raw Milk

Summary of Working Group Discussion and Consensus

- Coliform bacteria are a widespread group of bacteria commonly found in the environment, including soil, surface water, and vegetation and in the feces and intestines of warm-blooded animals, including humans. In some instances, mastitis infections caused by coliform bacteria can shed large numbers of coliform bacteria and can result is increased coliform counts.

- Using coliform counts as an indicator of sanitation has been a common tool in public health protection for many years. The test for coliform bacteria in raw milk is an indicator of cleanliness and sanitary conditions or poor hygiene practices in dairy production environments during or after milk production.

- Poor herd hygiene, contaminated water, unsanitary udders and milking practices, and improperly washed and maintained equipment can all lead to elevated coliform counts in raw milk on a dairy farm. Elevated coliform counts in raw milk occur when there is a failure to detect and divert abnormal milk originating from infected udders. The most common ways for coliform bacteria to enter raw milk occur from milking cows with wet and manure-soiled udders and inadequately cleaned milking equipment. Coliform counts reflect important sanitation practices throughout the milk handling process from milking to bottling.

- Coliform bacteria detected in raw milk is not a definitive indication that disease-causing or pathogenic bacteria are present. Most coliform bacteria are not harmful and do not cause disease in humans. A small percentage of coliform bacteria can cause severe illness in people especially in young children, the elderly, and people with weakened immune systems.

- The coliform bacteria standard required for Grade A pasteurized milk is ≤10 cfu/mL. The coliform bacteria standard for raw milk should be set at the same standard or a more stringent standard than the one set for pasteurized milk because the raw milk sold on a farm to a consumer will not be pasteurized and may be contaminated with pathogenic bacteria that can cause illness in consumers drinking it.

- Pasteurization readily kills coliform bacteria. When raw milk is sold directly to consumers there is no intervening pasteurization and the risk of coliform bacteria contaminating the raw milk is generally present in the environment.

- A test standard of ≤10 cfu/mL for coliform bacteria in raw milk can be routinely achieved by using sound cleaning and sanitation practices. It is a test standard currently achieved by Grade A dairy producers on their farms to sell their raw milk to dairy processing plants to be pasteurized.

- A test standard for coliform bacteria of ≤10/mL is the same standard for ready-to-eat foods at retail. The same test standard for coliform bacteria used in ready-to-eat foods should be used for unpasteurized milk sold on a farm to a consumer.

- Coliform bacteria can be found in any environment. Coliform counts can be particularly high in the bovine (cow) environment and in equipment being used to handle and process unpasteurized milk.

- Several other numerical test standards and testing frequencies for coliform bacteria were reviewed and discussed by the working group including testing daily, using a running average, or setting different numerical standards based on herd size. Consensus on these other alternatives was not reached by the group.

- The group discussed the importance of establishing best management practices for the management of coliform bacteria on the cow and in the farm environment, including effective management practices such as hand washing protocols in the barn and milk house.

- The test standard of ≤ 10 cfu/mL for coliform bacteria is consistent with the standard set in most other states allowing raw milk sales. In four of the six states the working group reviewed, the standard for coliform bacteria is ≤10 cfu/mL. Connecticut has a standard of ≤ 50 cfu/mL and Idaho has a standard of ≤ 25 cfu/mL. The seventh state (New York) tests raw milk for *Escherichia coli* rather than for coliform bacteria as indicated in the table below.

Testing in Seven Select States: Coliform Bacteria in Raw Milk

State	Coliform Bacteria in Raw Milk
California	TS= ≤ 10/mL and F= 4 times each 6 months
Connecticut	TS= ≤ 50/mL and F= 1 time each month
Idaho	TS= ≤ 25/mL and F= 4 times each 6 months
New York	Test for *Escherichia coli* ¼ -ly. No coliform bacteria test
Pennsylvania	TS= ≤ 10/mL and F= 2 times each month
So. Carolina	TS= ≤ 10/mL and F= 4 times each 6 months
Washington	TS= ≤ 10/mL and F= 1 time each month

TS = Test Standard F= Frequency of test

Recommended Regulations: Testing for Coliform Bacteria

Summary of Proposed Testing Regulations for Coliform Bacteria in Wisconsin

Test	Frequency	Standard
Coliform Bacteria in Raw Milk	Once per week	≤ 10 cfu/mL

The working group believes the following food safety regulations are necessary for testing for coliform bacteria in raw milk to help reduce the health risks for consumers drinking raw milk.

1. A producer should be required to collect a sample of unpasteurized milk from the bulk tank once each week and send it to a certified laboratory to be tested for coliform bacteria in the raw milk.

2. The test standard for coliform bacteria should be set at ≤ 10 cfu/mL in unpasteurized milk sold on a farm to a consumer.

3. The producer should be required to collect a raw milk sample from the bulk tank prior to applying for a Raw Milk Farm Permit and send it a certified laboratory to be tested for coliform bacteria. The test result for coliform bacteria should be set at ≤10 cfu/mL as a pre-requisite to being granted a permit to sell unpasteurized milk on the farm.

Testing for Pathogenic Bacteria in Raw Milk

Campylobacter
Listeria monocytogenes
Salmonella species
Escherichia coli O157:H7
Non-O157:H7 Shiga Toxin-producing *Escherichia coli*

Summary of Working Group Discussion and Consensus

- The working group identified the issues and challenges related to testing for the four harmful bacteria found in raw milk that most frequently cause people to become sick. During its discussion about testing raw milk for these four harmful bacteria, the working group learned there are some practical and important challenges associated with testing for the pathogenic bacteria in raw milk. These challenges include:

    - The availability of a commercial infrastructure for the producer to use to test for pathogens in raw milk.

    - Test results for the pathogens may be reported as "negative" but the result may be a false negative, meaning the raw milk may be contaminated with a pathogenic bacteria. This may occur because a relatively small raw milk sample is obtained from a large bulk milk tank and is not representative of all the milk. If pathogenic bacteria are present in the raw milk, they are likely to be unevenly distributed throughout the tank and may not be included in the sample. Only a few pathogenic bacteria can cause infection and illness in people. A negative test result does not guarantee the raw milk is safe to drink.

    - There are no definitive indicator organisms for the four harmful bacteria which most frequently cause illness in people drinking raw milk.

    - Although testing results are not always accurate, testing is an important way to monitor the raw milk over time. The testing limitations create a challenge for both producers and consumers. It is important for producers and consumers to understand the limitations of the tests used for detecting harmful bacteria so producers and consumers do not develop a false sense of security about the testing.

The working group reviewed each of these challenges and discussed how these challenges might be addressed to better protect consumers.

- Commercial Infrastructure Challenges

  - There only a few commercial laboratories that provide testing services for pathogenic bacteria.

  - Pasteurization kills the harmful bacteria that can contaminate raw milk. Because the pasteurization process is effective in killing the pathogenic bacteria, dairy processing plants in Wisconsin or in other states rarely need to test for these four pathogens in milk on a routine basis. Rather than testing the product, milk processors and government inspections focus on preventing food safety problems and ensuring the pasteurization processes in the dairy plants are working correctly. When dairy processing plants do need to test, they may use their own laboratories or contract out the testing services. Government agencies and public health departments will test milk and dairy products for pathogens when an outbreak investigation and tests are needed to verify the cause. For government agencies, these tests are done at government laboratories.

  - The demand for pathogen testing at commercial laboratories is low. Only a few options exist for producers to send raw milk samples to certified private laboratories for testing for pathogens. Unfortunately, there are no programs currently available or in existence to promote, certify, or accredit additional laboratories for pathogen testing that might increase the number of laboratories available for raw milk producers to use. Procedures to certify laboratories for test methods for pathogens are also needed.

  - Results of pathogen testing take a minimum of 48 hours to receive and the raw milk is likely to be sold before the producer receives the test result. If the screening test at the laboratory indicates a "presumed positive," the follow-up confirmatory tests take longer than 48 hours.

- "False-negative" Test Results Create a Problem

  - A raw milk sample that tests "positive" is significant because it indicates to the producer that a pathogenic bacteria is present in raw milk. Positive test results for pathogenic bacteria by a laboratory are likely to be reliable.

- But when a raw milk sample tests "negative" for one of the four harmful bacteria, the result may be a false-negative. A false-negative refers to a test result that indicates a pathogenic bacteria is not present, when in reality, the harmful bacteria is there. A false-negative test result is an error, which means the result is not providing correct information to the producer.

- When screening tests are done for pathogenic bacteria, false-negative test results are not uncommon. A negative test result is not a reliable result, and does not guarantee the raw milk is free of the harmful bacteria.

- If pathogenic bacteria have contaminated the raw milk, they are not usually evenly distributed in the bulk milk tank. Contamination of raw milk can occur when a bulk tank has only a very small number of pathogenic bacteria present because only an extremely small amount of the pathogenic bacteria are needed to cause severe human health problems. The uneven distribution of the bacteria in the raw milk and their presence in low concentrations can make the pathogens difficult to detect with testing. Regardless of the difficulty of detecting such a small number, it is important to do the testing because if the bacteria are detected, the possibility for infection and illness may be avoided.

- The bulk milk tank on a farm typically holds between 200 and 2500 gallons of raw milk. Even if the producer agitates the tank, the producer is collecting a very small sample of milk (less than a pint) to send to the laboratory for testing. Such a small sample is unlikely to be representative of the raw milk in the tank.

- Also, initially, the harmful bacteria may be present in low concentrations in the bulk tank when the sample is taken; however, the bacteria can multiply very quickly during the period between the time the sample is collected and the consumer drinks the raw milk. The pathogens can grow quickly because of the rich medium provided by the raw milk.

- Additionally, these pathogens may be shed only intermittently by infected cows, rendering any testing done weekly or monthly to be a "hit or miss" proposition.

- Significant testing, nearly ongoing testing would be needed to "catch" the harmful bacteria. It is very difficult to determine the pathogen's presence through testing using routine methods.

- A test result received by the producer can be 'Zero" or indicate no pathogen was detected ("None Detected") and yet pathogens can be present in the raw milk. This occurs when the milk sample is taken from a portion of the raw milk that didn't contain any pathogenic bacteria or contained too low of an inoculum to grow. Again, this is a situation when a negative test result may not be accurate.

- Negative test results do not provide accurate information or a guarantee for consumers and producers that no pathogens are present in the raw milk and may provide a false sense of security for producers and consumers.

- These testing limitations create a challenge for both producers and consumers. It is important for producers and consumers to understand the limitations of the tests used for detecting any of these four harmful bacteria. Negative tests results for specific pathogens does not mean -- or guarantee -- these pathogens are not present in the raw milk being produced and consumed.

- Fortunately, positive test results are significant and straightforward, providing accurate information about the presence of the pathogens. When test results denote the presence of pathogens, the information can be used by the producer to act quickly to stop raw milk sales, notify customers, notify public health agencies, and identify and eliminate how and where the pathogen problem is occurring in the milk production process.

• <u>No Definitive Indicator Organisms</u>

- Indicator organisms refer to easily grown, readily and inexpensively detectable bacteria that can be used as a predictor of the presence of disease-causing bacteria. Unfortunately, there are no organisms in raw milk that can be used to predict the likely presence of any one of these four pathogens and that a producer can use to monitor the raw milk. There are no other organisms in the raw milk that can be measured nor is there a correlation between the presence of any other organism or any one of these pathogens to definitively alert the producer that a pathogen is present or likely to be present. Such an indicator organism would be helpful, but none exist.

- For example, somatic cell count is an indicator of *Streptococcus agalactiae.* When the somatic cell count (SCC) in raw milk is above 400,000 cells/mL it indicates the likely presence of *Streptococcus agalactiae* infection in a cow. A producer can use the SCC as a surrogate for the presence of *Streptococcus agalactiae.* But, there

is no specific organism that serves as an indicator of the any of these four pathogens in the raw milk.

- Pathogen Testing, Although Imperfect, is Important

  - There are important reasons to test for the pathogens regardless of the limitations inherent in the testing. Because of the public health risk to consumers, it is important to use all the tools available to reduce as much of the risk of infection as possible from any one of these four pathogens. Each tool available to the producer can contribute to a comprehensive approach to help reduce risk.

  - The working group discussed the importance of testing for these four pathogenic bacteria as a surveillance tool, and believed some testing was important to monitor for the pathogens that can cause infection and illness in consumers.

  - Microbiologic testing serves as an important tool for food safety management. The purpose of sampling food is to collect a representative sample that can provide microbiologic information on the food product. Routine pathogen testing done once per month can give a snapshot of the raw milk for that one testing day each month. That information is important and may be helpful to both the producer and consumer when the testing pattern is examined over time.

  - The most effective regulatory framework necessary to attempt to reduce the presence of pathogens in raw milk must be based on the food and dairy science of food safety and structured as comprehensively as possible to help protect consumers.

- Testing for Non-O157:H7 STEC in Raw Milk

  - The working group discussed whether it should recommend a requirement to test raw milk for non-O157:H7 Shiga Toxin-producing *Escherichia coli* in addition to the testing requirement it is recommending for *Escherichia coli* O157:H7.

  - The non-O157:H7 STEC bacteria may also be found in raw milk. There are more than 100 strains of non-O157:H7 *Escherichia coli* and these strains can cause foodborne illnesses in people drinking raw milk.

  - The working group discussed the important public health issues related to the presence of non-O157:H7 STEC in unpasteurized

milk. The public health concerns are similar to those for *E. coli* O157:H7 organisms.

Again, there is a higher risk of infection for children under the age of five, for children of all ages, and for the elderly. The severity and complications from the infection are also increased for these two groups.

- Additional information on testing for non-O157:H7 STEC was reviewed by the Raw Milk Policy Working Group and is included in the Appendix 8 of this report.

- Pathogen Testing in Other States

  - The working group reviewed the pathogen testing laws of seven of the states that allow the sale of raw milk. Testing regulations in California, Connecticut, Idaho, New York, Pennsylvania, South Carolina, and Washington were reviewed. All these states, except Idaho, require testing for these four harmful pathogens, as summarized in the table below.

Testing for Pathogens: Comparing Seven States that Allow Raw Milk Sales

Does the State Require Testing?
What is the Testing Standard?
What Test Frequency is Required?

State	*Campylobacter*	*Salmonella*	*Listeria*	*E. coli* O157:H7
CA	Test? Yes 0 Detected 4 x / 6 mo.	Test? Yes 0 Detected 4 x / 6 mo.	Test? Yes 0 Detected 4 x / 6 mo.	Test? Yes 0 Detected 4 x / 6 mo.
CN	Test? Yes 0 Detected Quarterly	Test? Yes 0 Detected Quarterly	Test? Yes 0 Detected Quarterly	Test? Yes 0 Detected Quarterly
ID	Test? No	Test? No	Test? No	Test? No
NY	Test? Yes 0 Detected Quarterly	Test? Yes 0 Detected Quarterly	Test? Yes 0 Detected Quarterly	Test? Yes 0 Detected Quarterly
PA	Test? Yes 0 Detected Annually	Test? Yes 0 Detected Annually	Test? Yes 0 Detected Annually	Test? Yes 0 Detected Annually
SC	Test? Yes 0 Detected 4 x / 6 mo.	Test? Yes 0 Detected 4 x / 6 mo.	Test? Yes 0 Detected 4 x / 6 mo.	Test? Yes 0 Detected 4 x / 6 mo.
WA	Test? Yes 0 Detected Monthly	Test? Yes 0 Detected Monthly	Test? Yes 0 Detected Monthly	Test? Yes 0 Detected Monthly

Regulations: Testing for the Four Harmful Bacteria

The working group believes the following food safety regulations for testing for these four select pathogenic bacteria are necessary to help reduce some of the risk to consumers drinking raw milk.

Summary of Recommended Regulations for Testing for Pathogens in Wisconsin

Test	Testing Frequency	Testing Standard
Campylobacter species	Once per month	0 – None can be Detected
Listeria monocytogenes	Once per month	0 – None can be Detected
Salmonella species	Once per month	0 – None can be Detected
Escherichia coli 0157:H7	Once per month	0 – None can be Detected
Non-O157:H7 STEC	No testing required	No testing required

The producer should be required to:

1. Collect a sample of the unpasteurized milk once each month and send it to an ISO accredited laboratory to be tested for:

   a. *Campylobacter*
   b. *Listeria monocytogenes*
   c. *Salmonella*
   d. *E. coli* O157:H7

2. Test the unpasteurized milk for *Campylobacter*, *Listeria monocytogenes, Salmonella,* and *E. coli* O157:H7 at an ISO accredited laboratory prior to applying for a Raw Milk Farm Permit and documenting that each of the test results for the four pathogens have met the testing standard of "0 or none detected" as a pre-requisite to being granted a raw milk permit to sell unpasteurized milk on the farm.

3. Choose a commercial ISO accredited laboratory to hire to test raw milk samples for the four pathogens and establish a business relationship with the laboratory.

4. Immediately, after learning from the laboratory a test result detects the presence of any one of the four pathogens:

   a. Stop sale of unpasteurized milk to consumers.
   b. Divert or dispose of the farm's unpasteurized milk until DATCP authorizes the producer to sell the milk again.

   c. Notify all customers of the test result. This includes all customers who have purchased unpasteurized milk from the farm since the

last negative monthly pathogen test performed on the farm's unpasteurized milk.

d. Notify DATCP and the county local public health department of the test result.

e. Begin to investigate the cause of the problem

f. Follow the On-farm Incident Response Plan.

DATCP should be required to:

5. Provide a list of commercial, ISO accredited laboratories to producers.

6. Approve the testing methods used by ISO accredited laboratories working with raw milk producers and require the laboratory to use certain validated test methods and nationally recognized methods for the pathogen tests for unpasteurized milk.

7. Ensure ISO laboratories use 'approved matrices' (product method) and list all approved food including 'unpasteurized milk' as approved matrices if needed.

8. Create a table of sample sizes for the producer to use to determine the specific sample required to do the test.

9. Require the ISO laboratory to send the raw milk producer's test results for the four pathogens each month to the producer and DATCP.

10. Require the ISO laboratory, when it isolates (or detects) a pathogen from an unpasteurized milk sample sent to it by a producer, to send the bacterial culture from that sample to the Wisconsin State Laboratory of Hygiene to compare the bacterial culture to human isolates so human isolates may be matched to the genetic fingerprints of the pathogens from the raw milk. This requirement will also eliminate questions about who is responsible for storing specimens and who pays the cost.

Recommended Regulations: Testing for Non-O157:H7 STEC

1. The working group acknowledges the significant public health risk of foodborne illness from non-O157:H7 STEC to consumers drinking raw milk.

2. The working group acknowledges viable, rapid screening and confirmatory tests for non-O157:H7 STEC do not exist at commercial laboratories today.

3. The working group recommends no regulations be required for producers to test for non-O157:H7 Shiga toxin-producing *Escherichia coli* (non-O157:H7 STEC) in unpasteurized milk for sale to consumers.

4. The working group recommends the Wisconsin Department of Agriculture, Trade, and Consumer Protection (DATCP) and the proposed nine-member Raw Milk Oversight Committee closely monitor the availability of viable and practical options for testing for non-O157:H7 STEC, including:

    a. The availability of commercial rapid screening tests for non-O157:H7 STEC

    b. The availability of commercial laboratories to test for non-O157:H7 STEC in raw milk

    c. The certification and accreditation of commercial laboratories and their testing methods to test for non-O157:H7 in raw milk and

    d. The cost of screening and confirmatory tests for non-O157:H7 in raw milk.

5. The working group recommended the information collected for its review and discussion of the non-O157:H7 STEC testing be included in Appendix 8 of its report for future reference.

6. To reduce the risk of infection for consumers drinking raw milk, the working group recommends DATCP propose changes to the raw milk administrative rules to require testing of raw milk sold on the farm for non-O157 STEC if the Raw Milk Oversight Committee documents reasonable and practical screening and confirmation tests are available at commercial laboratories to test raw milk for non-O157:H7 STEC.

Recommendations for Education Initiatives

1. DATCP should develop educational materials for consumers to provide information on the pathogens in unpasteurized milk, the accuracy of testing for these pathogens, the meaning of the test standards, the facts about the difficulty of detecting pathogens in raw milk and the

meaning of the pathogen test results, and other information to help consumers make informed choices about drinking unpasteurized milk.

2. DATCP should create educational opportunities for the producer to learn about best management practices to help reduce the risks of foodborne illness related to the production of fluid unpasteurized milk for on-farm sale to consumers.

3. DATCP should gather information and educational materials on the presence of pathogens in unpasteurized milk and the foodborne illness risks associated with these pathogens.

   DATCP should make these materials available to producers who wish to sell fluid unpasteurized milk on their farms. The DATCP is encouraged to ask the University of Wisconsin to assist in this requirement.

Testing for Antibiotic Drug Residues

Background on the Issue

Antibiotic drugs are administered to individual dairy cows for treatment of infections such as mastitis. Residues from these drugs are retained in an animal's body for a certain period of time after antibiotic treatment has stopped, usually a few days later. During and following treatment, residues from the antibiotic drugs can carry through and be found in the raw milk.

Some of the antibiotic drugs used to treat dairy cows such as penicillin, ampicillin, cephapirin, hetacillin 2, and amoxicillin can cause hypersensitivity reactions in some people. Approximately 5 to 10 percent of the human population is hypersensitive to penicillin or other antibiotics. These people may have an allergic reaction (skin rashes, hives, asthma, or anaphylactic shock) when consuming foods containing drug residues at concentrations as low as 1 part per billion of penicillin.

There is also a public health concern that small amounts of certain antimicrobial agents may shift the resistance patterns in the microbial population in the human intestinal tract.

Consumers want to be confident their food products are free of contamination, including contamination from antibiotic drug residues. The presence of antibiotic drug residue in milk is a public health and a food safety concern.

In 1991, the FDA acted to significantly reduce or eliminate antibiotic drug residues in milk because of public health concerns. The Pasteurized Milk Ordinance was modified to require the contents of every bulk milk tanker truck to be tested for antibiotic drug residues prior to entering the food supply for human consumption. A tolerance standard was established to ensure the residual drugs would have no harmful effects on humans if ingested.

Reliable and rapid screening tests were developed and approved by FDA to detect antibiotic drug residues in raw milk. The screening tests can detect residues in milk when present at or above the concentrations corresponding to the test standards established by the Food and Drug Administration to be safe for human consumption.

Pasteurization does not kill, reduce, or eliminate the antibiotic drug residues that may be present in raw milk. To protect consumer health, it is illegal under federal and state law for dairy producers and processors to sell raw milk or pasteurized milk that tests positive for antibiotic drug residues.

Commonly, dairy producers are carefully managing the drug treatment of their animals, keeping records to track the dairy cows being treated and ensuring the milk from any treated cows is kept out of the bulk milk tank so it will not be delivered to the dairy processing plant.

Every bulk milk tanker truck delivering raw milk to the dairy processing plant is tested for antibiotic drug residues. This means all milk sold for human consumption must be tested. If the raw milk in the tanker truck tests positive, the dairy processing plant traces the violation back to the farm where the raw milk was picked up. Federal and state law requires raw milk that tests positive for antibiotic drug residues to be diverted from the human food supply.

Summary of Working Group Discussion and Consensus

- The working group agreed that testing for antibiotic drug residues in raw milk (that will be sold to consumers at the farm) should be based on standards that assure parity or functional equality with existing federal and state drug residue standards for the dairy processing plants.

- Any regulations recommended should seek to achieve assurance that consumers drinking raw milk purchased on the farm are drinking raw milk that meets the same antibiotic drug residue standards set for consumers drinking pasteurized milk.

- To achieve assurance for consumers and regulatory parity with the dairy processing plant requirements:

    - Frequency of testing should correspond to every lot of raw milk sold to a consumer.

    - The test standard should be the same result as required now. The test standard is a "negative result when using a FDA-approved rapid screening test kit."

    - The FDA-approved rapid screening tests are practical and easy to use on the farm by the producer, providing a quick visual read of the test results.

      Simple and reasonably priced test kits are available for the producer to do the testing. An example of such a test kit is the SNAP test which works like a pregnancy test. The FDA approves and validates the test kits which can be purchased by the producers.

It is the responsibility of the producer (serving as his or her own milk marketer) to sample and test the raw milk for antibiotic drug residues. The producer can choose to do the sample and testing or can choose to hire someone to do the sampling and testing.

- Prior to selling any raw milk, the raw milk should be tested for antibiotic drug residues before the producer is issued a Raw Milk Farm Permit. This will help ensure potential contamination risk to consumers is reduced.

- Again, being a licensed Bulk Milk Weigher and Sampler would benefit the producer, providing sampling and testing knowledge to assist the producer in accurate sampling and testing procedures.

- Consistent with the requirements for the dairy processing plants, the producer should be required to keep records to verify the testing results, positive confirmations, animal health drug treatments, and purchase of test kits, at a minimum.

- There are several sampling and testing barriers that need to be addressed:

  - Currently, dairy producers are not responsible for testing their own raw milk for milk quality, pathogens, or residues. For the milk quality test standards and the pathogen test standards being proposed by the working group, the producer will be required to sample the raw milk and send it to a laboratory for testing. Under the scenario being discussed for antibiotic drug residues, the producer will be required to do both the sampling and the testing (screening test). A protocol will need to be developed for the producer to test for antibiotic drug residues.

  - Sampling and testing dairy products on the farm is a new activity for producers. Should the producers need to follow the on-farm sampling procedures being recommended by the working group?

  - Other dairy industry regulations often require third party verification of positive test results. A protocol will need to be developed.

  - Drug residue sampling and testing records are required for other entities in the dairy industry. Again, record requirements will need to be delineated for raw milk producers.

    The working group discussed different ways for the raw milk producers to keep records that would be practical, useful, and provide good documentation of the testing.

The group discussed requiring a printer-reader, a piece of equipment that can "read" and verify the antibiotic drug test results and create a printed record of the results for the producer to use for a record. The printer-reader needs to be linked to an incubator or heater block in order to do the testing. This option is a good way to verify the test result and provide a printed or on-line record, but the printer-reader and incubator / heating block together are expensive one-time purchases (approximately $2,500 to $3,000 in total).

The group discussed the option for the producer to sample the raw milk and send it to a certified laboratory to be tested for antibiotic drug residues. This allowed a laboratory to verify the test results and create a testing record. However, under this option, the test results may not be done prior to the sale of the raw milk.

The working group discussed the possibility of requiring the producer to keep records of the antibiotic drug kit purchases, the testing dates, and the testing results as a way to verify that each lot of raw milk was tested and verify the results of the tests. Keeping records of the antibiotic drug kit purchases, dates, and results could be regulated as a "performance" standard with parameters set to determine how and when the performance standard is met. This option allows the test result to be known prior to the sale of raw milk to consumers and establishes a reasonable and practical way to keep and verify the test results.

This option for a developing a performance standard is similar to the "performance standard" discussed by the working group when it discussed the equipment standards necessary for an on-farm refrigerator to maintain a temperature of less than 40 degrees Fahrenheit.

- Currently, when raw milk is tested and there is a positive antibiotic drug residue test result, the raw milk sample must be sent to a certified laboratory, retested and verified. It is illegal to sell the raw milk until a laboratory retests the sample. If the test result is positive the milk must be diverted from sale to consumers and the human food supply. If the lab test is negative, the milk may be sold. Raw milk producers should be required to follow these regulations consistent with the current requirements for dairy processors.

- The working group reviewed the antibiotic drug residue regulations of the seven states: California, Connecticut, Idaho, New York, Pennsylvania, South Carolina, and Washington. All seven states require testing of raw milk for antibiotic drug residues, using the FDA standard of a "negative result on an FDA-approved test kit." The required frequency of testing the raw milk in these states ranges from testing every bulk milk tanker (CA) to four times every six months.

Recommended Regulations: Antibiotic Drug Residue Testing

The working group reached consensus on the following regulatory conditions necessary to test the raw milk for antibiotic drug residues to help protect consumers drinking raw milk purchased on the farm.

Summary: Recommendations Proposed for Antibiotic Drug Residue Testing in Wisconsin

Test	Testing Frequency	Testing Standard
Antibiotic drug residue	Every lot of milk produced for every day unpasteurized milk goes into a container for sale	Negative result on the FDA approved test

Goal of Testing for Antibiotic Drug Residues in Raw Milk: Unpasteurized milk sold on the farm to consumers is required to meet the same standards as the pasteurized milk standard. All raw milk must be tested prior to packaging and sale to consumers and the test result must be negative.

To achieve this goal, the producer should be required to:

1. Collect and test a representative sample of raw milk from the bulk tank for antibiotic drug residues on every lot of milk produced for every day unpasteurized milk goes into a container for sale to a consumer.

2. Meet the antibiotic drug residue test standard of a "negative result on a FDA-approved test" for all unpasteurized milk sold on the farm.

3. Choose one of three options for testing the raw milk for antibiotic drug residues:

   a. The producer may conduct the test using the FDA-approved rapid screening test on the farm.

   b. The producer may hire a licensed Bulk Milk Weigher and Sampler (BMWS) to conduct the FDA-approved rapid screening test.

c. The producer may contract with a certified laboratory to do the test. The producer must collect the milk sample and then ship or drive the sample to the certified laboratory for testing. If the producer chooses this option, he or she must ensure the test results are known prior to the sale of the raw milk taken from the same lot as the sample, as required of the other options as well.

4. Establish and maintain records, at a minimum, on the purchase receipts of the rapid screening test kits, the dates the tests are taken, and the test results to provide the components for a performance standard to verify the testing results in lieu of third party validation when the producer conducts the rapid screening test.

   The performance standard to verify the on-farm testing will be developed by DATCP through the administrative rule process as a practical, cost effective, and reasonable method to document on-farm testing for antibiotic drug residues in raw milk. The records to document the performance of the raw milk producer must also include a milk disposal record and records of follow-up confirmatory testing done by a certified laboratory to validate the positive test results.

5. Hold the raw milk from sale to consumers when the result of the rapid screening test is positive for antibiotic drug residue. The producer may not sell the raw milk unless a verification test result, done by a certified laboratory, is "negative." (Lab confirmation testing takes only 10 to 30 minutes at a certified laboratory.)

   If the positive test result is verified, the producer is prohibited from selling the raw milk from the production lot from which the raw milk sample was collected and tested.

6. Test the unpasteurized milk for antibiotic drug residue prior to applying for a Raw Milk Farm Permit to sell unpasteurized milk and the raw milk test must meet the testing standard before a raw milk permit is issued.

7. Follow the regulations delineated in the working group recommendations for "On-farm Sampling Procedures."

DATCP should be required to:

1. Develop a performance standard to provide a method for the alternative, verification of the testing and test results done by the producer. The performance standard components should include records of the purchase receipts for the drug residue screening test kits, testing dates, and test results.

2. Develop administrative rules for proper storage of antibiotic drug residue test kits on the farm as necessary to ensure the test kits are working properly.

On-farm Sampling Procedures

Standard Plate Count
Somatic Cell Count
Coliform Bacteria in Raw Milk
Coliform Bacteria in Well Water
Campylobacter, *Salmonella, Listeria,* and *E. coli* O157:H7 in Raw Milk
Antibiotic Drug Residues in Raw Milk

New Responsibilities for Raw Milk Producers

Currently, Grade A and Grade B dairy producers sell and send their unpasteurized milk to a dairy processing plant. The dairy processing plant is responsible for testing the milk or dairy product to ensure it meets the required federal and state standards established for that product. The dairy processing plant acts as the milk marketer for the producer and ensures the testing and processing are done and the product meets the quality standards and any food safety regulations required by law that are necessary to sell a quality food product for human consumption in the marketplace that is as safe as possible.

The dairy producer's roles and responsibilities change greatly if he or she is allowed to legally sell raw milk on the farm to a consumer. The dairy producer becomes a processor, a bottler, a marketer, and a retailer. A new farm business entity is created when a dairy producer chooses to sell raw milk and take on the responsibilities for both the milk and the consumer previously held by the dairy processing plant.

Most importantly, the raw milk producer takes on the responsibility to produce and sell the consumer the safest raw milk possible. To do this, the raw milk producer takes on similar regulatory responsibilities required by law and done previously by her or his dairy processing plant.

Under the new farm business entity, with the dairy producer becoming the milk marketing agent, the producer also takes on new responsibilities for sampling and testing the milk to meet the food safety regulations and milk quality standards set by law.

Summary of Working Group Discussion and Consensus

- In creating this new business entity, the working group discussed practical issues related to how and where raw milk sampling and testing would occur and whether a commercial infrastructure exists to support the sampling and testing needs of a raw milk producer.

- The working group identified several practical challenges that need to be addressed to allow the sampling and testing to be done. The working group discussed the new activities the producer will need to learn to do. The working group discussed whether a commercial laboratory testing infrastructure is in place to test the samples. It found an infrastructure does exist for some of the producer's testing needs, and for other testing needs, the infrastructure either doesn't exist, hasn't existed, or is available, but the infrastructure is fragmented or not as accessible as may be desired.

- The group also found that procedures need to be created to allow the producers to fulfill their new milk marketing and testing responsibilities. The group developed ideas on sampling and testing procedures to ensure the sampling and testing was operationally possible.

- To produce and sell the consumer the safest raw milk possible, it is important for the producer to practically and effectively be able to sample and test the milk. The test results will provide food safety and product quality information about the raw milk that can decrease or increase health risks to the consumer.

- The working group discussed what could be done to help the producer maximize the benefits of sampling and testing the raw milk to reduce the foodborne illness risks to the consumer. The group recommended actions that would benefit the raw milk producer, including:

    - Becoming a licensed Bulk Milk Weigher and Sampler
    - Ensuring the testing laboratory is certified to do the tests
    - Establishing a business relationship with a certified laboratory to do the testing
    - Establishing and maintaining testing and sampling records
    - Ensuring the business relationship with the certified laboratory is in place prior to applying for a raw milk farm permit
    - Asking DATCP to provide producers with names of certified laboratories
    - Asking DATCP to work with laboratories to provide the testing services for producers
    - Asking DATCP, if needed, to work with laboratories to increase the number of certified test methods available

Recommended Regulations: On-farm Sampling Procedures

The working group believes the following food safety regulations are critically necessary for on-farm sampling of well water and raw milk.

The producer should be required to:

1. Collect samples of the well water and bulk tank raw milk and send them to a certified laboratory to be tested for standard plate count, somatic cell count, and coliform bacteria, following the testing frequency established by law.

2. Collect samples of bulk tank raw milk and send them to an International Standards Organization (ISO) accredited laboratory to be tested for *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7, following the testing frequency established by law.

3. Collect samples of bulk tank raw milk and test them for antibiotic drug residues using a FDA-approved rapid screening test kit following the testing frequency established by law.

4. Identify all milk samples collected for testing to their milk production lot code.

5. Collect the raw milk sample from the bulk milk tank at the point where the milk container is manually filled or from the mechanical bottler at the point where the unpasteurized milk container is filled.

6. Be a licensed Bulk Tank Weigher and Sampler (BMWS) as a pre-requisite to receiving a Raw Milk Farm Permit to sell unpasteurized milk on the farm.

7. Follow the certified or ISO accredited laboratory's protocol for sampling and shipping the sample to the laboratory for testing or hire a BMWS to sample the water and milk following the certified or ISO accredited laboratory's sampling protocol. As an option to sending the samples through the mail, the producer may hire or schedule a courier service to pick up the well water or raw milk samples from the farm for delivery to the laboratory.

8. Establish and document a business relationship with a certified laboratory and an ISO accredited laboratory to test the well water or unpasteurized milk prior to applying for a Raw Milk Farm Permit. The documentation should verify the required raw milk samples have been collected on the farm and sent to the laboratory, tests have been done, test results sent to the producer, and business accounts established.

9. Establish and maintain specified sampling and testing records for a specified time period as determined by administrative rule.

DATCP should be required to:

1. Provide the raw milk producers with a list of the certified and ISO accredited laboratories available to test the well water and unpasteurized milk.

2. Establish guidelines for laboratories for testing methods that can be used for raw milk samples as needed.

3. Develop administrative rules related to sampling and testing well water and raw milk that may be necessary to assist the raw milk producer in standardized and effective sampling and testing procedures to increase the accuracy of the sampling and testing results. The rules should identify the laboratory test results that must be sent to DATCP.

Temperature Controls for Raw Milk

Raw Milk is a Rich Medium for Bacterial Growth

Dairy cows are warm-blooded animals and the milk they produce is naturally warm. Bacteria grow quickly in foods with temperatures between 45° F. and 110° F. and in foods that are rich in protein and other nutrients. Warm raw milk provides a nutrient-rich medium for the rapid and progressive growth of bacteria, including the harmful bacteria that can cause infection and illness in people.

Because raw milk is classified as a food that has the potential to encourage the rapid growth of harmful bacteria, both "temperature controls and time controls" are important to use during raw milk production to keep it as safe as possible for human consumption. Other foods that require temperature and time controls are foods such as raw meat and poultry, seafood, and eggs because they too provide a naturally rich medium to support the rapid and progressive growth of bacteria.

When the temperature controls of cooling and cooking are not used or are inadequate, raw meat and poultry, raw milk, seafood, and eggs are some of the riskiest foods for people to eat because they have the greatest potential for encouraging the growth of harmful bacteria such as *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7.

Food safety regulations are critically important for controlling the temperatures at which these risky foods are stored and cooked and the amount of time these foods are kept out of the temperature danger zone (where bacteria grow rapidly). Specific temperature and time controls can help reduce the foodborne pathogens that can cause illnesses in people.

Temperature Controls

A temperature control is set to cool or heat a food product to a specific temperature as an effective way to reduce foodborne pathogens that contaminate food and cause illness in consumers. Refrigeration, pasteurization and cooking are used to achieve temperature control. Improper cooling or heating of foods is a major cause of foodborne illness.

The heating temperature established for pasteurizing milk is specifically designed to kill harmful bacteria such as *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7 that may be present in raw milk. The pasteurization temperature does not kill the beneficial bacteria that are present. The most common pasteurization method in the dairy industry is known as High Temperature/Short Time or HTST whereby the raw or unpasteurized milk is heated to a required minimum temperature of 161.5° F. for 15 seconds.

If the raw milk is not pasteurized, a critical and effective temperature control is eliminated and the harmful bacteria will not be killed. Consumers drinking raw milk are at a significant health risk because these harmful bacteria that can cause disease may be present in the raw milk.

Temperature Controls: Working Group Discussion and Consensus

The working group discussed several different temperature control alternatives that might effectively slow the growth of the harmful bacteria in the raw milk and help reduce the health risks for consumers drinking it. In summary:

- There is no temperature control as effective as pasteurization for killing the harmful bacteria that can cause people to become sick. Establishing a temperature control known to slow the growth of the harmful bacteria in raw milk is critically important.

- Cooling the unpasteurized milk quickly and keeping it cool for as long as possible is important for reducing the growth of the harmful bacteria.

- Keeping raw milk as cool as possible for as long as possible regardless of the location of the raw milk on the farm would be the most effective temperature control for reducing the risk of foodborne pathogens. Establishing one temperature to keep the raw milk cool should be used whether the raw milk is in the bulk tank, a container for sale, a consumer's cooler going home, or a consumer's home refrigerator.

- There may be practical ways to maintain the recommended temperature of the raw milk for as long as possible, if the cooling temperature can be practically applied to the concept of "every particle of raw milk," thereby increasing the effectiveness of the temperature control in slowing the bacterial growth from the beginning of the milking process through to the sale and consumption of the raw milk.

- The working group discussed requiring a cooling temperature for unpasteurized milk sold on the farm that is more stringent than the bulk tank temperature set for raw milk that will be pasteurized as Grade A milk or any ready-to-eat foods in a grocery store. The Conference of Food Protection recommends a retail sale temperature of 41° F. or less for ready-to-eat foods. The U. S. Food and Drug Administration's model food code requires pasteurized milk products to be kept at 41° F. or less when sold at retail stores.

- Very high numbers of bacteria will appear in the raw milk if cooling is slow or ineffective in the bulk tank and the temperature is not maintained until the raw milk is in the container and sold.

- The phrase "Life begins at 40" is commonly used by food scientists as a reminder that temperatures above 40° F. are not effective in preventing the growth of harmful bacteria. Food science research indicates 40° F. or less is the critical temperature required to most effectively reduce the rapid growth of harmful bacteria in foods.

- Temperatures of ≤ 40° F. will not kill the harmful bacteria, but temperatures of ≤ 40° F. will slow the growth of the harmful bacteria such as *Campylobacter, Salmonella, Listeria, and E. coli* O157:H7. The colder the temperature at which raw milk is stored, the longer it will take for the harmful bacteria to grow.

- It is important for slowing the growth of the harmful bacteria to cool the milk as quickly as possible once the raw milk begins to go into the bulk tank after milking begins. If a temperature control is set at ≤ 40° F. for the bulk tank storing the raw milk, it is reasonable and practical to assume the raw milk can be cooled to 40° F. or less within 2 hours after milking begins.

- Establish one temperature for the unpasteurized milk stored in the bulk tank, making the control as simple and clear as possible rather than establishing two or more different temperatures for the raw milk in the bulk tank at different times or in different places on the farm. Establishing one temperature could also be used as the temperature control for "blended" milk, i.e. the raw milk in the bulk tank from the first milking that is combined with the raw milk in the bulk tank from subsequent milkings. This option eliminates the need for a different "blended milk temperature" to be established for raw milk in the bulk tank. The goal would be to maintain one temperature for the raw milk at all times, in all places.

- Recognize that eliminating a "blended milk temperature" in the bulk tank and setting a temperature goal of ≤ 40° F. means the raw milk in the bulk tank is likely to go above 40° F. for short periods of time immediately after a new milking begins as new warmer raw milk is added to the cooled raw milk present in the bulk tank. However, this method is likely to be more effective in keeping the raw milk cool for longer periods of time and slowing the growth of the harmful bacteria until the time of sale as well as being a clear and practical goal for producers to meet.

- It is possible to increase the effectiveness of reducing the growth of the harmful bacteria in the raw milk by controlling temperature and "time" together. Time controls should be recommended for raw milk as well to increase the effectiveness of the regulations to help protect consumers.

- The working group reviewed the temperature controls required for raw milk sold in California, Connecticut, Idaho, New York, Pennsylvania, South Carolina and Washington. Generally, these seven states require a temperature control for raw milk and the controls are similar to those required by the Pasteurized Milk Ordinance for milk in the bulk tank.

Recommended Regulations: Controlling Raw Milk Temperature

Goal: The temperature control for unpasteurized milk is ≤ 40° F. at all times in all locations to minimize the growth of harmful bacteria and reduce the risk to consumers of foodborne pathogens in the raw milk.

The working group believes the following food safety regulations to control the temperature at which raw milk is stored are critical to help reduce of the risk to consumers drinking raw milk.

1. Within two hours after milking begins and the first drop of raw milk enters the bulk tank until the raw milk is sold to a consumer, the temperature of the unpasteurized milk should be required to be maintained ≤ 40° F.

2. The producer should be required to empty, wash, and sanitize the bulk milk tank at least every 48 hours.

3. The bulk milk tank should be required to have a temperature recording thermometer.

4. The bulk milk tank should be required to have a chart recorder if the bulk milk tank is manufactured after the year 2000 as required currently by federal and state law, and under ATCP 60, Wis. Adm. Code for Grade A dairy farm permits.

   A producer selling unpasteurized milk on the farm may have a bulk milk tank without a chart recorder if the bulk milk tank is manufactured prior to the year 2000.

Recommendations: Best Management Practices and Education Initiatives

The working group believes the following best management practices and education initiatives are important for controlling milk temperature to help reduce the health risks to consumers drinking raw milk.

1. As a best management practice, the working group recommends a producer purchase and use a chart recorder if the producer's bulk milk tank is manufactured before the year 2000. This recommendation is being suggested because the chart recorder is an important management tool for managing the temperature at which the raw milk is stored and achieving the goal for maintaining the unpasteurized milk at a temperature of ≤ 40° F. to reduce the growth of harmful bacteria in the raw milk.

   The chart recorder also monitors the wash temperature when the bulk milk tank is being cleaned to indicate the effectiveness of the tank cleaning. Effective cleaning of the bulk milk tank is another practice that will minimize the risk of foodborne pathogens contaminating the raw milk.

   It is estimated the cost of this best management practice, if the producer chooses to purchase a chart recorder, is between $1,000 and $2,000.

2. The working group recommends raw milk producers consider purchasing and installing a plate cooler as a best management practice to accelerate the cooling of the unpasteurized milk in the bulk milk tank. The plate cooler is an effective tool to help cool the raw milk quickly and increase the likelihood of slowing the growth of the harmful bacteria that may be present.

3. The working group recommends DATCP, in consultation with the University of Wisconsin, write best management practices related to temperature control to further assist the raw milk producers in producing raw milk for consumers that is as safe as possible.

4. The working group recommends educational information and tools be written and developed to provide information to producers, consumers, and the public on the importance of maintaining specific temperatures and storage times for unpasteurized milk.

5. The working group recommends guidance be given to consumers to keep the raw milk they purchase as cool as possible once they leave the farm. Keeping the raw milk at or below 40° F. in the cooler in their car on the way home and in their home refrigerator.

"Time Controls" for Producers Selling Raw Milk

and

"Time" Guidelines for Consumers Drinking Raw Milk

"Time" Controls

Controlling a "time," like controlling temperature, can be an effective way to help reduce the potential of foodborne illnesses in a food product. Some food safety regulations require a certain temperature to be attained within a specific amount of time to minimize or manage food safety risks in food for human consumption. An example of a "time" control is cooking a food product for a certain time or cooling a food product for a certain amount of time.

Raw milk is classified as a food that requires both "temperature and time controls" to keep it as safe as possible for human consumption because raw milk is one of the riskiest foods to consume. Raw milk provides a warm, wet, and nutrient-rich medium for the rapid and progressive growth of bacteria, including the harmful bacteria that can cause infection and illness in people.

Using time and temperature controls together can be much more effective in slowing the growth of the harmful bacteria in raw milk than using either a time control alone or a temperature control alone. Raw milk sold on the farm to consumers will not be pasteurized therefore harmful bacteria such as *Campylobacter, Salmonella, Listeria,* or *E. coli* O157:H7 may be present in raw milk. To protect consumers drinking raw milk, the working group sought the most effective ways to slow the growth of the pathogenic bacteria that can contaminate the raw milk to help prevent foodborne illness in those consumers choosing to drink it.

Summary of the Working Group Discussion and Consensus

The working group reviewed and discussed several options for controlling the time within which it would be best for the producer to sell raw milk to minimize the health risks to consumers. In summary:

- The working group wanted to establish a "time" control for selling raw milk that would provide the most effective food safety protection possible for consumers. The group wanted to set a time control to slow growth of the harmful bacteria staring from the time milking begins until the consumer drinks the raw milk.

- There is no time control as effective as pasteurization for killing the harmful bacteria that can cause people to become sick.

- In current regulations governing the production of Grade A milk on the farm, dairy producers must empty and sanitize the bulk milk tank within every 48 hours. Using this 48-hour time control, the working group discussed setting a requirement that raw milk must be sold within 48 hours from the time milking begins and the first particles of milk enter the bulk tank.

- The working group agreed the most effective way to slow the growth of harmful bacteria in raw milk would be to establish a time control for producers and recommend a time control guideline for consumers covering:

    - The time it takes for the producer to cool the raw milk once it enters the bulk tank. The time control is "the raw milk is cooled as quickly as possible in the bulk tank to 40° F., but no longer than two hours after milking begins and the first particles of milk enter the bulk tank."

    - The time the producer holds or stores the raw milk in the container before it is sold. The time control is "the raw milk is sold within 48 hours after milking begins and the first particles of milk enter the bulk tank."

    - The time it is safest for a consumer to drink the raw milk after it is purchased. The guideline or safe handling practice recommends "the raw milk is consumed within 48 hours after it is purchased on the farm."

- The time controls being considered should be linked to the temperature controls to provide the most effective means to slow the growth of the harmful bacteria on the farm and once purchased by the consumer. The temperature and time controls working in tandem would mean:

    - Setting the temperature at ≤ 40° F. for the 48-hour time period the raw milk begins to go into the bulk tank until it is sold, and recommending a guideline for consumers to keep the raw milk as cool as possible (preferably ≤ 40° F.) for the 48-hour time period within which it is recommended the consumer drinks the milk.

- The working group reviewed the time controls required by other states and one European country that allow raw milk sale. The time controls in these laws is summarized in the table below.

Comparing "Time" Controls for Selling Raw Milk in Other States

State	"Time" Regulation for Sale of Raw Milk
California	Raw milk must be sold to the consumer within 30 hours after production.
Connecticut	Raw milk must be put into a container within 48 hours after production and a "last sale date" of 7 days after bottling.
Idaho	No "time" control for raw milk sale.
New York	Recommendation for filling containers is less than 24 hours prior to raw milk sale.
Pennsylvania	Currently, a new "sell by" regulation is pending in the state for a 17-day maximum sell by code placed on the container label.
South Carolina	No "time" control for raw milk sale.
Utah	Require a pull date, expiration date, or best-if-used-by date on the label. Dates cannot exceed 9 days after packaging.
Germany	Requires stamp of expiration date 4 days after the raw milk comes from the cow.

"Time" Guidelines for Consumers Drinking Raw Milk

The working group discussed the fact that temperature and time controls could be established for raw milk that would slow the growth of pathogenic bacteria, but after the raw milk is sold, temperature and time controls become ineffective in slowing bacterial growth because of the natural characteristics of raw milk as a rich medium for growing harmful bacteria and because the raw milk is not controlled by the producer after sale.

The working group discussed whether it should establish a consumer guideline for a time period within which it would recommend the raw milk be consumed after purchase. A guideline could provide valuable health information to consumers.

The working group discussed "consumption" regulations that have been established for food safety reasons for smoked fish and infant formula. These have been established as regulations for processors rather than recommended guidelines or safe handling instructions for consumers. The working group also discussed shelf-life and expiration dates as they apply to ready-to-eat foods sold at retail and the importance for ready-to-eat foods to be consumed within a certain time period after purchase to reduce potential food safety problems.

The idea for recommending a consumer guideline for drinking raw milk within 48 hours after it is purchased is not related to shelf-life issues such as odor, taste, or souring.

The goal is to advise consumers that raw milk becomes significantly more risky to drink a few days after it is produced by the cow because after that time it becomes more difficult to prevent the rapid growth of harmful bacteria in the raw milk, greatly increasing the risk of foodborne illness to the consumer.

Regulations: Time Controls for Producers Selling Raw Milk

The working group believes the following food safety regulations are critically important and necessary for controlling the time within which raw milk is sold to help reduce the foodborne risk to consumers drinking raw milk.

Goal Every particle of milk is sold by the producer and drank by the consumer within the shortest time possible after milking begins to minimize the food safety risks for the consumer.

1. The producer should be to sell the raw milk within 48 hours after milking begins. The 48-hour time period starts when the first particle of milk goes into the bulk tank.

2. The label for containers holding raw milk for sale should include one of the following two statements:

   a. A safe handling instruction stating "Best used within 48 hours of purchase," or

   b. "Drinking raw milk within 48 hours after purchase may help reduce the risk of foodborne illness."

3. The label for containers holding raw milk for sale should include a numerical code that establishes the 48-hour timeframe within which the unpasteurized milk must be sold by documenting the time when the milking began that produced the raw milk in the container.

4. The producer should be required to divert or dispose of any unpasteurized milk that is not sold within the 48-hour time period. The producer should be required to keep records indicating where and when the unpasteurized milk was disposed or diverted.

5. DATCP should write administrative rules establishing requirements for diverting and disposing of the raw milk and other requirements to implement time controls for producing and selling raw milk.

"Time" Guidelines for Consumers Drinking Raw Milk

Recommended Consumer Guidelines

1. The working group recommends consumer guidelines be written to provide educational information for consumers on the safe handling practices associated with purchasing, cooling, transporting, storing, and drinking raw milk.

2. The working group recommends consumers drink raw milk within 48 hours after purchase as a way to reduce the risk of foodborne illness.

Containers and Processes for Filling Containers

Three Options for Raw Milk Producers

Summary of the Working Group Discussion and Consensus

- The working group discussed the important food safety issues associated with containers and the processes for filling containers with unpasteurized milk. The group acknowledged the food safety risks increase as the containers are filled because the raw milk may be exposed to harmful bacteria from the air, barn environment, human hands, equipment surfaces, animals and insects, and the containers and these bacteria may contaminate the raw milk.

- Manual bottling, hand filling containers, and hand capping may expose the raw milk to contamination from harmful bacteria. Containers and lids may not be properly cleaned and sanitized. Without the regulatory safeguards being proposed, the risk of contaminating the raw milk increases.

- The raw milk will travel from the bulk tank where it has been kept cool ≤ 40° F. into the air and into a container, with some risk of having its temperature rise. A rising temperature and exposure to harmful bacteria can create a point of possible risk.

- Currently, there are no known or established food safety models for regulating the process of filling containers with raw milk from the bulk tank. The working group discussed how to design a process for filling the containers that would effectively reduce some of the risks to help protect consumers.

- The requirements used for selling ready-to-eat foods in a retail store are the kinds of requirements that should be considered and used if possible for selling raw milk at the farm directly to consumers. The requirements for ready-to-eat foods are stringent, and the requirements for selling raw milk to consumers should be at least as stringent as ready-to-eat foods.

- To ensure the safest possible food is consumed by the public, all food should be placed in a container that has been sanitized with a sanitizer to reduce the possibility of foodborne pathogens contaminating the food product.

- The risk of foodborne contamination is increased when a container is filled with raw milk from the bulk tank. The process for filling containers with raw milk must be regulated to ensure sufficient sanitation precautions are in place to address the risks associated with the choice of a container and the filling and capping processes.

  Some of the most critical food safety issues that should be considered in the process of filling containers with raw milk include:

  - Choosing containers and lids that have nonporous or impermeable surfaces
  - Proper sanitation of containers and lids
  - Proper storage containers and lids in clean environments
  - Proper sanitation of hands
  - Proper sanitation of the valve or spigot through which the milk goes into the container
  - Proper sanitation of the equipment used in the filling and bottling of the raw milk
  - The sanitation of the environment where the container is filled
  - Identifying and limiting who is designated to fill the container
  - The temperature of the raw milk as it moves from the bulk tank to a container and to the consumer's home
  - Designing a process to fill the container that will limit the contact of the unpasteurized milk to the air, hands, surfaces, and animals
  - The information and education given to the consumer about safe handling of the raw milk

- The working group discussed the importance of developing options and requirements that are clearly delineated for producers and consumers. The working group identified several questions related to containers and the filling process that should be answered for the benefit of the producers and consumers. The questions are:

  a. What kind of containers and lids are allowed?

  b. Can containers and lids be reused?

c. Who is allowed to provide containers to be filled with raw milk?

d. Who is allowed to fill the containers with raw milk?

e. Who is allowed to sanitize the containers and lids?

f. How will containers and lids be sanitized?

g. How will containers be filled and capped?

h. What are the conditions for filling a container from the bulk milk tank?

i. What are the requirements for keeping the filling equipment and environment sanitary?

- The working group wanted to provide some flexibility for producers to choose a process for filling the containers with raw milk. The working group also believed it was critically important to maintain the highest food safety standards possible in designing these options given the inherent contamination risks associated with filling the containers. The working group sought to design several filling processes to give the producer a choice of options while addressing the most critical food safety concerns for the consumer.

  Generally, the working group discussed three possible options:

1. A customer provided container or producer provided container, manually filled by the producer from the bulk milk tank and given to the customer to take home.

2. A producer provided single service container, manually filled by the producer from the bulk milk tank and put into a refrigerator for the customer to purchase later.

3. A producer provided single service container, mechanically filled by the producer and then put into a refrigerator for the customer to purchase later.

Regulations in Other States: Containers and Filling Processes

The working group reviewed the laws in other states on raw milk containers and the processes required for filling raw milk containers. Regulations in the seven select states of California, Connecticut, Idaho, New York, Pennsylvania, South Carolina, and Washington reviewed by the group are summarized in the table below.

Regulations on Containers and Processes for Filling Containers

--Comparing Seven Select States—

State	Requirements for Containers and Filling Processes
California	Prescribes all containers and sanitation. Requires filling to be in compliance with raw milk dairy processing plant standards.
Connecticut	Prescribes containers and lids; regulates sanitation, storage, filling and capping.
Idaho	Requires containers and bottling operations to meet PMO dairy processing plant standards. Regulates sanitation and filling.
New York	Requires sanitation, mechanical filling and capping of containers. Container can be single service or customer provided.
Pennsylvania	Requires single service containers or customer containers; mechanical means of filling and capping; separate bottling room and container storage; sanitation regulations.
South Carolina	Requires NCIMS-approved containers and lids; approved mechanical equipment; regulates sanitation, capping, mechanical equipment, sealing, and container storage.
Washington	Requires sanitary bottling and capping with approved equipment and operations. Regulates containers, lids and container storage.

Recommended Regulations: Processes for Filling Containers

Overview of the Regulations

Producers selling fluid unpasteurized milk on the farm must meet specific requirements for the kind of raw milk containers that may be used for raw milk that will sold to consumers and the processes for filling the containers with raw milk. In summary, these requirements specify:

- The kinds of containers that may be used
- How and where the containers may be filled
- Cleaning and sanitizing the containers and equipment
- Storing the empty containers
- Refrigerating containers filled with unpasteurized milk
- Who may provide the containers to be filled
- Who may fill the containers with raw milk

Regulations on Containers and the Processes for Filling Containers

The working group reached consensus on the following regulatory conditions necessary to fill containers with raw milk on the farm as safely as possible to reduce the risk of foodborne pathogens to consumers drinking raw milk.

1. **Option # 1: Process for Filling Containers**

   - **A customer provided container**
   - **Hand filled by the producer**
   - **Producer hands container to customer to take home**

   This option allows the producer to fill a clean customer-provided container with unpasteurized milk when the customer arrives on the farm. The container must be sanitized and filled by the producer and then given to the customer to take home. The unpasteurized milk shall be sold to the customer within 48 hours of the time the raw milk from the milking first began to enter the bulk milk tank. This option allows the customer to come into the milk house, watch the producer fill the container with raw milk, and leave the farm. This option must meet the following food safety requirements:

   a. The producer may allow customers to bring a clean container to the farm to be filled with unpasteurized milk. The container must be a container made of glass, with a wide mouth, and a lid as specified by administrative rule.

   b. The producer may choose to provide a clean container for his or her customer, and if the producer chooses to provide the container, the container shall meet the Pasteurized Milk Ordinance (PMO) requirements for containers. The containers must be stored in a separate room other than the milk house.

   c. The producer is the only person allowed to fill the container with raw milk from the bulk milk tank. The producer must follow a prescribed process for filling the container in a sanitary manner as specified by administrative rule.

   d. The producer must fill the container with unpasteurized milk at the time of the sale to a customer, in the presence of the customer. Once the container is filled with unpasteurized milk, the container must be given to the consumer directly to take off the farm.

   e. The containers filled with raw milk under this option may not be refrigerated on the farm prior to the sale to the consumer.

The containers and lids required under this option may be reused if they are approved to meet the materials specified in administrative rule. Administrative rules must clarify the difference between "reusable-grade containers" and the "reuse of single use containers."

f. The producer is the only person who may sanitize the clean, consumer-provided container prior to filling it, following sanitizing practices that will be identified by administrative rule.

g. The producer must wash and sanitize the outlet valve or I Tube on the bulk milk tank after each "continuous" filling of containers. Any additional procedures for cleaning and sanitizing the bulk milk tank outlet valve or I Tube may be identified in administrative rule.

h. A label must be attached to each individual container of raw milk that is sold. The requirements for the label are listed in the "Labeling" recommendations under a different section of this report.

i. DATCP must prepare standard operating procedures by administrative rule that will include sanitary requirements for the milk house and equipment; for cleaning the equipment; sanitizing the containers and lids and for filling the containers; storage of containers; and sanitation of the outlet valve.

j. DATCP must collect a regulatory swab periodically of the inside of the empty consumer-supplied containers and producer-supplied and producer sanitized containers that will be used to hold unpasteurized milk.

k. DATCP must collect a regulatory sample periodically of the unpasteurized product and test the sample for standard plate count, somatic cell count, coliform bacteria, antibiotic drug residue, and *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7.

2. Option # 2: Process for Filling Containers

- **A producer provided container**
- **Hand filled by the producer**
- **Place in a refrigerator until sold**

This option allows the producer to manually pre-fill (or pre-package) and cap an approved sanitized "single service containers" with unpasteurized milk from the bulk milk tank and immediately refrigerate the container until the customer comes to the farm to purchase the

milk. Under this option, only the producer may provide the containers to be filled. The raw milk must be sold to the customer within 48 hours of the time the milking began and the first of the raw milk entered the bulk tank. This option must meet the following food safety requirements:

a. The producer must provide a single service container and corresponding lid for use with the options. The lids must be tamper evident lids as defined by the Pasteurized Milk Ordinance.

b. The containers and lids must be stored in a separate room other than the milk house and the container and lid must be stored following Pasteurized Milk Ordinance requirements.

c. The producer is the only person who may fill the container with unpasteurized milk from the bulk milk tank. After filling the container, the producer must immediately and manually cap the container.

d. The producer must follow specified sanitary procedures when filling and capping the container from the bulk milk tank. The sanitary procedures will be specified by administrative rule.

e. Once the producer manually fills and caps the single service container, the producer must immediately place the container into a refrigerator.

f. The producer must maintain the temperature of the raw milk in the containers at ≤ 40° F. until purchased by the consumer and taken off the farm.

g. The temperature of the refrigerator must be at ≤ 40° F. at all times, meeting the refrigerator performance standards established by DATCP in administrative rule.

h. DATCP must develop a specific performance standard for a refrigerator used on a farm to store raw milk in containers. The refrigerator must be easily cleanable. The performance standard must be established to maintain the raw milk in the containers in the refrigerator at a temperature ≤ 40° F. (DATCP regulates retail stores using performance standards and inspection standards to achieve a food safety outcome. Similar food safety concepts can be applied to develop a performance standard for the refrigerator holding raw milk in containers on a farm)

DATCP may set a mechanical standard for a refrigerator used on a farm to store raw milk in containers as a second option for producers to choose to use as an alternative to a refrigerator with a performance standard.

i. Containers filled with raw milk are the only items allowed to be kept in the refrigerator.

j. The refrigerator must be located in a room separate from the bulk milk tank and the milk house. The room must meet the same milk house requirements specified in ATCP 60.07 (2) (a) for construction, (b) walls and ceilings, (c) doors and windows, (d) lighting, and (e) ventilation.

k. The refrigerator room must meet sanitary environmental requirements as established by administrative rule.

l. The producer must wash and sanitize the outlet valve or I Tube on the bulk milk tank after each "continuous" filling of the containers with raw milk. Any additional procedures for cleaning and sanitizing the bulk milk tank outlet valve or I Tube must be identified in administrative rule.

m. A label must be attached to each individual container of raw milk that is sold. The requirements for the label are listed in the "Labeling" recommendations under a different section of this report.

n. DATCP must collect a regulatory swab periodically of the inside of the empty containers that will be used to hold unpasteurized milk.

o. DATCP must collect a regulatory sample periodically of the unpasteurized product and test it for standard plate count, somatic cell count, coliform bacteria, antibiotic drug residue, and *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7.

p. Additional standard operating procedures for this option may be set by administrative rule.

Recommendations for Two Best Management Practices for Option # 2

Two best management practices are recommended for Option # 2 to help minimize the risk of foodborne illness under this option. The best management practices recommended are:

- The producer is encouraged to install an indicating thermometer for the refrigerator to monitor the refrigerator's temperature.

- The producer is encouraged to keep a log to record the refrigerator temperature two times each day.

3. **Option # 3: Process for Filling Container**

   - **A producer provided container**
   - **Mechanical process for filling**
   - **Refrigerated until sold**

   This option allows the producer to pre-fill or pre-package containers with unpasteurized milk and refrigerate the containers until the consumer comes to the farm to buy the milk. With this option, the producer provides the containers. The option requires mechanical filling and capping of the containers. The option is intended to have broad applicability for very small, medium-sized, and larger farms. It allows the possibility for a very small hand operated mechanical bottling machine, filling one container at a time, to larger machine operated bottller, filling many containers in a shorter period of time. This option requires a producer to hold a dairy processing plant license.

   The unpasteurized milk in these pre-filled and refrigerated containers must be sold to the customer within 48 hours of the time milking began and the first raw milk entered the bulk milk tank. This option has the following regulatory requirements:

   a. The producer must mechanically fill the container with unpasteurized milk and cap it. The mechanical bottling device may be a hand operated system. No hand capping of the containers is permitted under this option.

   b. The mechanical filling device must be located in a separate room, and in a room other than the milk house.

   c. Another, separate room, different than the room where the mechanical filling and capping is done and different than the milk

house, must be used as the room to clean, sanitize, and store the containers.

d. The producer must provide the containers and caps and the containers and caps must meet the specifications of the current ATCP 80 administrative rule.

e. The producer must sanitize the containers and caps, as specified by administrative rule. Additional procedures for cleaning and sanitizing the mechanical equipment must be defined by administrative rule.

f. The producer must be the only person who may mechanically fill and cap the containers with raw milk.

g. Once filled and capped, the filled containers must be immediately put into a refrigerator and they must be maintained at ≤ 40° F. until purchased by the consumer and taken off the farm.

h. A label must be attached to each individual container of raw milk that is sold. The requirements for the label are listed in the "Labeling" recommendations under a different section of this report.

i. Additional standard operating procedures may be set by administrative rule in addition to the ATCP 80 requirements to address food safety issues related to the production and sale of raw milk, including but not limited to the sanitary requirements for all equipment and the rooms used to sanitize, fill, and store containers and caps.

j. If the producer chooses this option, the producer must obtain and meet the requirements for a dairy plant license as specified in ATCP 80. The producer is required to be both a raw milk producer holding a Raw Milk Farm Permit and a dairy plant operator holding a dairy plant license.

k. The specifications for the refrigerator and the refrigerator location must meet the requirements specified in ATCP 80. The refrigerator must have an indicating thermometer to ensure the refrigerator is capable of maintaining a temperature of ≤ 40° F.

l. The bottling operation must be inspected under Wisconsin ATCP Chapter 80 dairy plant administrative rules.

m. Prior to obtaining a license to sell unpasteurized milk on the farm, the producer must submit the equipment plan to be used in the

bottling operation to DATCP for review (only) as required by ATCP 80.08(18) Wis. Adm. Code. If the producer is purchasing equipment to bottle the raw milk or for any other purpose, it is recommended the producer share the equipment plans and consult with DATCP about the plans to ensure the production of the raw milk is done as safely as possible.

n. DATCP must collect a regulatory swab periodically of the inside of the empty containers that will be used to hold unpasteurized milk.

o. DATCP must collect a regulatory sample periodically of the unpasteurized product and test it for standard plate count, somatic cell count, coliform bacteria, antibiotic drug residue, and *Campylobacter, Salmonella, Listeria,* and *E. coli* O157:H7.

4. The producer selling unpasteurized milk under any of the three options outlined must require each of their customers who purchases unpasteurized milk to sign a consent form the first time they purchase raw milk on the farm. The producer is required to keep a record of the signed consent forms.

5. DATCP must write administrative rules to help clarify and define the three processes outlined here for filling containers with raw milk. The rules must also identify what information must be included on the customer consent form and any other records kept.

Labels for Raw Milk Containers

Summary of Group Discussion and Consensus

The working group reviewed the labeling laws for food and dairy products and discussed labeling ideas for raw milk. The group discussion and consensus is summarized as follows:

- Current Wisconsin law requires food products sold in containers or packaged to be labeled. The group agreed raw milk containers should be labeled and the consensus of the group affirmed the labeling regulations for raw milk should meet federal and state labeling requirements for food and dairy products.

- Current Wisconsin law requires a food label to meet certain regulations such as product identity, name and address of producer or processor, net quantity of the food contents, and other generally-applicable information about the product. These generally-applicable requirements should be used for raw milk.

- Food labels may include precautionary or warning statements, safe handling instructions, and the producer's or processor's name and logo. A producer or processor is allowed to advertise on the label.

- The working group agreed standardizing some of the label language allows accurate and consistent information to be shared with the consumers.

- The label on a raw milk container offers an opportunity to educate consumers on the food product, provide accurate health information, and other information for the consumer to make an informed choice.

- Language on the label should provide information on safe handling practices and raw milk health risks, including information for the at-risk populations most susceptible to the risks of drinking raw milk.

- The group placed a high priority on labeling the raw milk containers because of the public health risks associated with drinking raw milk.

- The group acknowledged there may be some problems attaching an individual label to each container, particularly when the containers are wet. They discussed how best to attach the labels, possibilities for using card stock with a ring, and attaching the ring to a wire around the container's neck to secure it, similar to a "hangtag" label.

- The group wanted to ensure there were practical options available for labeling the containers that were reasonable and inexpensive.

- The working group endorsed a simple and clear mock-up label that could serve as a workable label.

- The working group reviewed federal and state laws governing food advertising and labeling and raw milk labeling laws from several states, including California, Connecticut, Pennsylvania, South Carolina, and Washington. Briefly, laws in these five states require standard container labels, warnings, and safe handling instructions as shown in the table here.

Summary of Raw Milk Label Requirements in Other State

State	Container Label Required?	Warning Label Required?	Safe Handling Notice Required?
California	Yes	Yes	Yes
Connecticut	Yes	Yes	Yes
Pennsylvania	Yes	Yes	Yes
South Carolina	Yes	Yes	Yes
Washington	Yes	Yes	Yes

Regulations: Labels for Raw Milk

The working group reached consensus on the following regulatory conditions necessary for labeling raw milk containers to provide accurate product and health information to reduce the health risks for consumers drinking raw milk.

1. Individual containers filled with raw milk should be required to be labeled.

2. The producer should be required to submit the container label to DATCP as part of the permit application process. The label should be required to be reviewed and approved by DATCP as a pre-requisite for receiving a Raw Milk Farm Permit to sell unpasteurized milk on the farm.

3. A producer selling unpasteurized milk on the farm should be required to abide by the food labeling practices currently required by Wisconsin law for food products sold in containers or packages. The label should be required to include the following information:

   a. The term "Unpasteurized Cow's Milk" must be on the label to identify the contents of the container.

   b. The phrase "For Sale or Distribution at the __(farm name)__ Only."

   c. The name of the farm where the unpasteurized milk is sold.

   d. The street address and telephone number of the farm where the unpasteurized milk is sold.

   e. A true and accurate measurement of the contents of the container by volume or a true and accurate unit of measurement of the container that is based on an accurate "fill level" of the container, that is clear to the consumer and practical for the producer.

   f. Three instructions for safe handling practices:

      i. "Important to keep refrigerated at ≤ 40° F."
      ii. "Best if consumed within 48 hours of purchase"
      iii. "Boiling unpasteurized milk reduces the risk of foodborne illness for children."

   g. A numerical code to identify the farm, the production lot, and purchase date to allow the milk to be effectively traced back to the farm source.

   h. Two prominently displayed warning statements:

      i. A declaration and reminder of the disease risk of drinking unpasteurized milk

      ii. A declaration and reminder of the populations that are the most at risk if they consume unpasteurized milk

   These two warning statements should be required to be standardized for all raw milk labels and developed by DATCP through administrative rule. The standard terms, warning statements, and precautionary label language proposed by DATCP should be required to be written as clearly as possible to be understood by a wide range of the general public and consumers.

i. A statement recommending the consumer contact a physician or public health department to report when a consumer has symptoms of a foodborne illness after drinking unpasteurized milk.

j. The words on the label should be required to be in letters of a size and kind consistent with the type and size of other labels, but not less than one-sixteenth of an inch in height.

k. The label should be required to be clear, concise, and easily readable.

4. DATCP should be required to write administrative rules for the label components that will be standardized.

5. The producer may add to the label:

   a. A farm or producer logo
   b. The name of the producer
   c. The farm's business website address

   These additions may be done at the discretion of the producer, and if so, the additions must meet the current federal and Wisconsin food advertising and labeling laws.

6. The producer selling unpasteurized milk on the farm should be required to meet all the current federal and Wisconsin state food advertising and labeling laws on: (a) food misbranding, (b) deceptive advertising and promotional statements, (c) misrepresentation of product weight or measure, and (d) deceptive health and nutrition claims as they pertain to the labeling of containers and advertising of the sale of unpasteurized milk.

7. Based on federal law, the term "Grade A" may only apply to pasteurized milk products and the term cannot legally be allowed to be used to identify unpasteurized milk sold on the farm to consumers in Wisconsin.

Recommendations for Information and Education on Labeling

The working group believes the following food safety suggestions for best management practices are important to help reduce the risk to consumers drinking raw milk:

The working group recommends people interested in selling unpasteurized milk on the farm be given educational information on the current state labeling and advertising laws to be able to obtain a working knowledge of these requirements.

On-Farm Water Supply

Recommended Standards and Regulations

Testing: Coliform Bacteria in Well Water

Summary of Working Group Discussion and Consensus

- Coliform bacteria are a widespread group of bacteria commonly found in the environment, including soil, surface water, and vegetation and in the feces and intestines of warm-blooded animals, including humans.

- The presence of coliform bacteria in well water is an indicator of possible water contamination and that pathogenic bacteria may be present. Most harmful bacteria in well water come from the feces of humans or animals. The presence of coliform bacteria in well water makes the water unsafe for humans and animals. Drinking water standards require that no coliform bacteria are present in well water or drinking water supplies.

- Testing for pathogenic bacteria in water is complex, time-consuming, and expensive process. As an alternative, it is relatively inexpensive to test and easy to identify coliform bacteria in well water. Coliform bacteria are used as an indicator of possible water contamination by pathogenic bacteria.

- If coliform bacteria are detected in well water, further testing is done to identify which organisms are present and whether they may be pathogenic. An established protocol and follow up investigation are done to correct a well water contamination problem.

- The purpose of testing for coliform bacteria on raw milk farms is to ensure the well water systems used on the farm will deliver water that is safe for animals and people to drink, can be used to effectively clean the milking equipment and milking systems and is free from contamination.

- Well water on the farm is used to clean the milking equipment, bulk milk tank, and milk containers. Regular testing of the well water for coliform bacteria helps ensure the water used to clean the equipment is not contaminated, and is not contaminating the raw milk when it moves through the equipment that has been cleaned with the well water.

- The coliform bacteria testing frequency in water supplies at retail stores selling ready-to-eat food is once per year. Well water and water systems on raw milk farms should be required to meet the same standard as the standard set for ready-to-eat foods.

- Wisconsin Grade A dairy farm standards require well water to be tested for coliform bacteria once every two years for farms producing raw milk that will be pasteurized. The PMO requires water to be tested for coliform bacteria a minimum of once every three years. The Wisconsin DATCP uses the 2-year state well water code standard rather than the federal PMO well water standard because the state well water code is equal to or stricter than the PMO.

- Testing well water once every two years for raw milk that will be pasteurized is satisfactory for managing public health risk but it is not satisfactory for managing the risk of foodborne pathogens in raw milk purchased on the farm that will be drank by consumers. The frequency of testing well water for coliform bacteria on a raw milk farm should be more frequent than testing well water on farms selling their raw milk to be pasteurized by a dairy processing plant.

- Pasteurization kills coliform bacteria in the raw milk regardless of where the coliform bacteria contamination occurs.

- Because raw milk sold to consumers will not be pasteurized, any coliform bacteria present in the raw milk will not be killed. Therefore, a more stringent monitoring and testing standard for coliform bacteria should be established for farms producing raw milk for consumers to ensure potential contamination sources are identified at more frequent intervals to reduce the risk of foodborne pathogen contamination of the raw milk. The coliform bacteria standard for raw milk farms should be consistent with the coliform bacteria standard for ready-to-eat foods which is tested once each year.

- The standard for coliform bacteria in well water in other states was set depending on whether the state law required farms selling raw milk to be hand-filled, mechanically bottled or to be licensed as a dairy processing plant. State standards also differed depending on the state standard for potable drinking water or if the state used the federal PMO well water standard. The test standard and frequency of testing for coliform bacteria in well water on raw milks in seven states is summarized in the table below.

Comparing Seven States: Testing for Coliform Bacteria in Well Water

State	Coliform Bacteria in Well Water
California*	TS= DWS and F= before license, 1/three yr, after repair
Connecticut	TS= DWS and F= 1 time each year
Idaho	TS= PMO and F= 1 time every 3 years
New York	TS= PMO and F= 1 time every 3 years
Pennsylvania	TS= 'None can be found' and F= 1 time each 6 months
So. Carolina	TS= 'Coliform absent' and F= 1 time every 3 years
Washington	TS= PMO and F= 1 time every 3 years

TS = Test Standard, F= Frequency of test, DWS= Drinking Water Standard,
PMO= Pasteurized Milk Ordinance standard used
* California requires raw milk bottling plants to test each 6 months

Regulations: Coliform Bacteria in Well Water

Summary of Proposed Regulations for Testing Coliform Bacteria in Well Water

Test	Frequency	Standard
Coliform Bacteria in Well Water	Once per year	The Wisconsin Drinking Water Standard for Safe and Potable Water

The working group believes the following food safety regulations for testing coliform bacteria in well water are necessary to help reduce the risk to consumers drinking raw milk.

1. The producer should be required to collect a sample of well water once per year and send it to a certified laboratory to be tested for coliform bacteria.

2. The producer should be required to collect a sample of well water and send it to a certified laboratory to be tested for coliform bacteria prior to applying for a Raw Milk Farm Permit. The test result for the coliform bacteria must meet the "Wisconsin drinking water standard for safe and potable water" as a pre-requisite for the producer to be granted a permit to sell unpasteurized milk on the farm.

3. The standard for coliform bacteria in well water on farms where raw milk is sold to consumers should be the Wisconsin drinking water standard for "safe and potable water."

Raw Milk Farms

Recommended Standards and Regulations

Raw Milk Farm Permit

Summary of Working Group Discussion and Consensus

- Currently all Wisconsin dairy producers are licensed as "milk producers" and, in addition, hold either a Grade A dairy permit or a Grade B dairy permit to sell raw milk to a dairy processor to be pasteurized. These license and permit process requirements are well established in Wisconsin.

- In addition to dairy farms and dairy plants holding licenses and permits, specialized dairy industry occupations such as butter, egg, and cheese graders and bulk milk weigher and samplers are required to attain knowledge competency in their specialized occupation and take tests to hold professional licenses or certifications. In retail stores, certain employees are certified as safe food handlers, having been trained in food safety and sanitation procedures for ready-to-eat foods.

- Licensing is a common regulatory tool in the dairy and food industry to allow persons and businesses to produce, process, distribute, transport, and buy and sell dairy and food products. These tools commonly require the license or permit holder to abide by specific standards for the product, its production and sale, and the production equipment and facility. Specific inspection standards are established for the product quality, safety, testing and labeling. Sanitation standards for the equipment and the facility must also be met.

- To obtain a license or permit, a dairy producer must meet current Grade A dairy farm standards (outlined in ATCP 60, Wis. Adm. Code) and dairy plant processors must meet current plant standards to be licensed (outlined in ATCP 80, Wis. Adm. Code). Generally, dairy licenses in these different categories are annual and can be renewed each year. Licensed dairy farms and plants are inspected at routine intervals throughout the year, as set by law.

- Grade A and Grade B dairy producers seeking licenses and permits for the first time work closely with their dairy plant processor as they proceed through the license application process. The dairy plants also serve as the milk marketer for their dairy producers.

- If raw milk sales are legalized, licensing requirements, farm standards, and an application process will need to be created for the raw milk farms.

- DATCP has administrative licensing processes in place for dairy farms and dairy plants. These administrative processes can be used to license raw milk farms and the current system can be easily modified to accommodate the administration of raw milk farm permits.

- The working group discussed the possibility of requiring raw milk producers to meet certain food safety pre-requisites before they are granted a permit. This concept is currently used for retail grocery stores selling ready-to-eat food products. The risk of foodborne pathogens in ready-to-eat foods is higher than some other foods, just as the risk of foodborne pathogens in raw milk is high. To minimize the potential for food safety risk, retail grocery stores selling ready-to-eat foods are required to meet certain critical food safety conditions before they acquire a permit and before they begin to sell the ready-to-eat products to ensure adequate regulations are in place at the time the food is sold to consumers.

- Retail grocery stores cannot be granted a license and begin to sell food products until they have met all the food safety license pre-requisites. Once the initial food safety inspection is completed and the retail license is granted, a second inspection is done between 30 and 60 days later to monitor the food safety operations again. The same concept should apply to farms seeking permits to sell unpasteurized milk.

- The working group wanted to ensure the first day the producer starts selling raw milk on the farm to consumers, critical food safety protocols and effective regulatory controls are in place to minimize the risks of foodborne illness in the production of raw milk.

- Grade A dairy farms must meet sanitation and milk quality and food safety standards to received a Grade A permit. The farm permit requirements are established for the production of raw milk that will be sold to a dairy processing plant for pasteurization. The permit requirements for raw milk farms will need to be quite different because the raw milk will not pasteurized (and the foodborne pathogens will not be killed). In addition, there will be new activities being done on the raw milk farm such as sampling and testing, filling containers with raw milk, marketing the product, and selling a food product at retail on the farm. Doing these new activities increases the likelihood harmful bacteria will contaminate the raw milk prior to selling it to consumers. Raw milk permit standards are needed to effectively manage these new activities and to maximize the food safety protections that must be in place.

- For the Grade A dairy farm licensing process the dairy processing plant or the farm's milk marketer plays a significant role throughout the permit application process.

  The dairy processor routinely works with the producer to meet the permit requirements and assists the producer through the permitting steps. A raw milk producer will not have the assistance of a milk marketer when she or he starts the application process for a raw milk farm permit. The raw milk producer will serve as her or his own milk marketer and the producer will take on the new responsibilities for the permit application and meeting the permit requirements.

- Prior to receiving a permit to sell unpasteurized milk on the farm, a producer must pursue a basic curriculum demonstrating a defined competency in the practical knowledge and science of producing unpasteurized milk for sale on the farm and meeting the standards necessary to reduce the risk of foodborne illness for consumers.

- A permit process for raw milk producers should be designed using a regulatory framework established to help reduce the risk of foodborne pathogens that can contaminate raw milk and meet the sanitation standards necessary to produce the safest raw milk possible for consumers.

Recommended Regulations: Raw Milk Farm Permit

The working group reached consensus on the following regulatory conditions necessary for producers to acquire a Raw Milk Farm Permit. These conditions focus on ensuring critical food safety protections are in place prior to the time the Raw Milk Farm Permit is granted to help protect the farm's customers beginning the first day raw milk is sold on the farm.

1. The DATCP should create a new legal dairy permit category known as the Raw Milk Farm Permit to govern the production and sale of raw milk on a farm. The permit should be an annual permit that can be renewed each year.

2. A dairy producer who wants to sell raw milk on his or her farm to consumers should be required to:

   a. Hold a milk producer license issued under s. 97.22 WI Stats., and

   b. Hold a Raw Milk Farm Permit

3. The producer holding a Raw Milk Farm Permit should not be required to hold a Grade A dairy farm permit.

4. The producer may hold both a Grade A dairy farm permit and a Raw Milk Farm Permit at the same time.

5. A dairy producer should be required to meet the Raw Milk Farm Permit requirements and the Raw Milk Farm Standards prior to being issued a Raw Milk Farm Permit. The Raw Milk Farm Standards must include the farm standards that comprise the farm standards for Grade A dairy farms and the new farm standards established for raw milk farms, specifically:

    a. The existing Grade A dairy farm standards equivalent to those applied to a Grade A dairy producer and outlined in the current DATCP, Milk Producer Farm Inspection checklist [DATCP Form F-fd-11 (Rev 3/2009)] and in ATCP 60, Wis. Adm. Code, with one exception. The exception should allow the producer selling unpasteurized milk to act as his or her own milk marketer, and the producer should not be required to be assigned to a Grade A milk marketer unless the producer also chose to produce Grade A milk and sell it to a Grade A milk marketer.

    b. A new set of farm standards, the Raw Milk Farm Standards, should be created to regulate the new on-farm activities necessary to produce and sell unpasteurized milk legally on a farm. These regulations shall govern the on-farm activities such as testing the product and filling and labeling containers with milk for sale, retail activities such as selling milk to consumers, and marketing activities such as advertising raw milk sales.

6. A dairy producer should be required to verify that he or she has met specific pre-requisites necessary to apply for a Raw Milk Farm Permit. When the producer submits the application for a Raw Milk Farm Permit, he or she should be required to submit documents to verify that he or she has:

    a. Attained the score on the Raw Milk Farm Permit competency test necessary to apply for a Raw Milk Farm Permit.

    b. Obtained a Bulk Milk Weigher and Sampler license

    c. Raw milk and water supply test results from a certified or ISO accredited laboratory meeting the established test standards for:

        i. Standard plate count
        ii. Somatic cell count

iii. Coliform count
iv. Antibiotic drug residues
v. *Campylobacter, Listeria, Salmonella, and Escherichia coli* O157:H7.

d. Animal health test results from a Wisconsin licensed veterinarian indicating the cow herd tested free for tuberculosis and brucellosis and the raw milk is culture negative for *Streptococcus agalactiae.*

e. Established a working business relationship with one or more certified or ISO accredited laboratories to test the farm's well water and raw milk; and well water and raw milk samples have been collected, the samples sent to the laboratory, tests done and test results reported, and business accounts established.

f. DATCP approval of:

i. Raw milk containers and lids

ii. Raw milk container labels

iii. The written procedure the producer will use to determine the production lot code for the raw milk sold on the farm

iv. The written On-farm Incident Response Plan

v. The inspection report done prior to applying for a Raw Milk Farm Permit

vi. A dairy processing plant license if the producer intends to bottle raw milk using mechanical means on the farm

7. The general application process to acquire a Raw Milk Farm Permit should be:

a. The producer fills out, signs, and submits a milk producer license application and a Raw Milk Farm Permit application and pays the license and permit fee to DATCP prior to receiving a license and permit.

b. The producer sends documents to DATCP to verify the permit pre-requisites have been met.

c. Once the Raw Milk Farm Permit application is submitted, the producer must contact DATCP and schedule the first farm inspection.

d. The producer must meet all the requirements of the Raw Milk Farm Permit inspection, as certified by the DATCP inspector.

e. DATCP must conduct a second inspection of the producer's farm within 30 and 60 days after the producer has been issued a Raw Milk Farm Permit and has begun to sell raw milk on the farm.

8. There shall be no temporary or conditional license or permit granted under any circumstances to a producer wishing to sell unpasteurized milk on a farm.

9. No producer milking cows by hand or pouring unpasteurized milk into a milk can for storage shall be issued a Raw Milk Farm Permit to sell raw milk on the farm.

10. DATCP must be authorized to set a permit fee by administrative rule.

Recommended Best Management Practices and Education Initiatives

DATCP, with the assistance of the University of Wisconsin Extension, should be required to develop best management practices and educational opportunities for producers selling unpasteurized milk on their farms. It is recommended the best management practices be combined into a handbook or manual for producers. The handbook must include information about permit application procedures and information materials for producers to gain knowledge and competency in raw milk production practices.

Raw Milk Farm Standards

Summary of Working Group Discussion and Consensus

- Today's Grade A dairy farm standards are requirements that have been set by law for producing raw milk for processing and pasteurization only. The farm standards include standards for milk quality, sanitation, temperature, and equipment and facilities. Currently, a dairy producer must meet the farm standards to be licensed, to hold a Grade A dairy farm permit, and to sell milk to a dairy processor. DATCP monitors a producer's compliance with the farm standards through routine inspections. The farm standards also serve as the inspection standards used by DATCP.

- No farm standards exist today for dairy farms selling raw milk on the farm directly to consumers.

- Standards for raw milk farms will need to be established. Farm standards for a raw milk farm could be a combination of two sets of farm standards. (1) the Grade A farm standards serving as the basis of the standards and (2) an additional set of farm standards for new activities necessary to sell unpasteurized milk to consumers on the farm.

- When a producer decides to sell raw milk on the farm, the farm responsibilities will be expanded to include: a) sampler and tester, b) bottler, c) labeler, d) retailer, and e) marketer. New and different kinds of farm activities will occur on raw milk farms. The producer will be collecting milk samples and sending the samples to laboratories to be tested, filling containers or bottling containers with raw milk, labeling containers, refrigerating and storing containers filled with raw milk, and selling the raw milk product to consumers on the farm. The producer will be creating and maintaining records of milk sales, animal health and milk testing results. The producer will be responsible for tracing and recalling the raw milk product if problems arise.

- There are many activities that will occur on a farm selling raw milk that do not occur on a Grade A dairy farm today. The product being sold by the producer is a different product because the product will not be pasteurized. The raw milk product is inherently a more risky product to produce and sell because raw milk can become contaminated by harmful bacteria on the farm. There are critical public health requirements that will need to be met to help prevent, minimize, and manage the risks of foodborne illness.

- Raw milk farm standards will be needed because the raw milk will not be pasteurized. Pasteurization is an effective tool used to ensure bacteria that cause tuberculosis, brucellosis, *Streptococcus agalactiae,* and foodborne illnesses are not present in the pasteurized milk purchased by consumers at the grocery store.

- The working group discussed the standards that would be needed on raw milk farms to replace or substitute for pasteurization. There is no tool as effective as pasteurization in killing the harmful bacteria that can contaminate raw milk. The group talked about a comprehensive package of standards, including a package of regulations, education, best management practices, and information that would be necessary to reduce the risk of foodborne pathogens contaminating the raw milk.

- The newly designed farm standards, known as the Raw Milk Farm Standards, will require the producer to meet a higher overall standard than the Grade A dairy farm standards for the production of raw milk because the product will not be pasteurized and new and different on-farm activities will occur beyond the activities occurring on Grade A farms. The Raw Milk Farm Standards should be designed to reduce the risks of foodborne illness associated with producing and selling unpasteurized milk on the farm.

- At a minimum, requiring a raw milk producer to meet the farm standards for a Grade A farm permit is reasonable and attainable. Grade A standards differ from the Grade B standards, primarily related to well water construction. Today, approximately 97% of Wisconsin dairy farms are licensed as Grade A farms and meet the Grade A farm standards.

Recommended Regulations: Raw Milk Farm Standards

The working group reached consensus on the following regulatory conditions necessary to establish raw milk farm standards that are most critical to help producers reduce the risk of foodborne pathogens contaminating the raw milk consumers will be drinking.

1. The Raw Milk Farm Standards should include both:

    a. The existing set of dairy farm standards used for the Grade A dairy farm permit as outlined in the current DATCP, Milk Producer Farm Inspection checklist [DATCP Form F-fd-11 (Rev 3/2009)] and in ATCP 60, with one exception. The exception is that the producer is not required to sell his or her milk to a dairy plant processor.

b. A new set of farm standards used to regulate the new and different activities that will occur on a farm where the raw milk will not be pasteurized and where raw milk will be sold directly to consumers. The new set of farm activities should be similar to activities that are regulated in retail stores and small dairy processing plants as well as for milk marketers. Activities such as filling containers with milk, labeling and storing containers filled with raw milk, and selling raw milk to consumers should be regulated. The new set of farm standards should also include requirements such as testing the farm animals for disease, and testing the well water and raw milk for pathogenic bacteria.

2. The Raw Milk Farm Standards should include the regulations outlined in more detail in other sections of this report. Regulations and standards should include:

   a. Animal health and testing animals for disease
   b. Testing for standard plate count in raw milk
   c. Testing for somatic cell count in raw milk
   d. Testing for coliform bacteria in raw milk
   e. Testing for coliform bacteria in well water
   f. Testing raw milk for antibiotic drug residues
   g. Testing raw milk for pathogenic bacteria
   h. On-farm sampling procedures
   i. Temperature controls for raw milk
   j. Time controls for raw milk
   k. Containers an caps for raw milk and processes for filling containers with raw milk
   l. Labels for raw milk containers
   m. An on-farm incident response plan

3. A producer should be required to meet the Raw Milk Farm Standards prior to obtaining a Raw Milk Farm Permit.

4. The Raw Milk Farm Standards should serve as the basis for the raw milk farm inspection standards used by DATCP to periodically monitor and inspect raw milk farms for compliance with the law.

On-Farm Incident Response Plans

Summary of Working Group Discussion and Consensus

The working group discussed the importance of requiring a set of tools for the producer to use to respond to an incident on the farm that requires immediate action to address a known or imminent food safety or health risk for their customers. The group identified the essential and critical actions a producer should take to effectively manage and minimize a farm customer's exposure to food safety risks when such an event occurs. The key points of the group's discussion include:

- The consumer's health is always the highest priority for the producer. The producer's responsibility for the farm's customer's health and safety goes beyond the point of sale.

- A producer can diligently follow the best management practices and comply with the standards and regulations to reduce the harmful bacteria that can be found in raw milk. Yet, at some point, the producer may learn a test result did not meet the established standard or find a cooling devise that is broken or some other problem that poses an imminent food safety risk for the farm's customers.

- For the producer, it is crucial to act quickly and effectively to manage the problem and the risks it poses. When a problem arises there is usually some time to take action to limit further exposure of the problem to farm customers and the number of people that may become sick. These actions can decrease the likelihood of the problem spreading to others who did not drink the milk but who may be infected, particularly among children, and begin to investigate and fix the problem.

- There are effective steps a producer can take to help contain the problem and protect the farm's customers. Effective actions include immediately stopping the sale of the milk and contacting customers and food safety and public health agencies to alert them to the problem.

- Being prepared in advance with a simple and clear plan will give the producers information to know what to do, identify steps to take, and respond more quickly and effectively to manage the situation. With a thoughtful plan, there is less down time. Acting productively and saving time can help manage the problem and reduce risk to the farm's customers and others.

- Food businesses and other businesses today either choose, or are required to have, emergency plans, rapid response plans, or disaster plans to help cover a variety of situations that may threaten public health and safety or the safety of the customers. More commonly today, food businesses have recall plans that are required by their customers or suppliers, insurance companies, or government entities, particularly when the consequences may threaten consumer safety or public health and safety.

- A few basic pieces of the incident response plan can make a big difference in managing an incident. Pieces of information such as sales and customer contact records; a plan to notify the customers and to tell them what to do, and records on testing, animal health, and raw milk production lots can all help manage the problem.

- The concept of **"one step back and one step forward,"** is a simple, standard food safety protocol to follow when responding to a food safety problem. Knowing where the milk came from (one step back) and where the milk went (one step forward) can greatly help effectively trace the problem and recall the product. This concept can be the basis of a plan for the raw milk producer to use when managing an incident.

- Response plans used by the dairy industry and other businesses can be adapted and used effectively in a small business and on very small farms. The plan should be based on comprehensive thinking, yet it should be clear, simple, and practical so it will be effective and easy to follow. The plan should list the steps that need to be taken by the producer and the essential information and records needed by the producer to implement the response and any recall of the raw milk that may be needed.

- An effective plan will:

    - Serve as an abbreviated instruction book with steps to facilitate a quick and thoughtful response.

    - List the relevant information or records the producer will need to maintain such as customer contact information, milk production and sales information and testing records on animals, well water, and pathogenic bacteria.

    - Guide the producer's communication with his or her customers, providing them with factual and clear information on the problem, what they should do, and what will happen next.

- A completed written On-farm Incident Response Plan should be a pre-requisite for applying for a Raw Milk Farm Permit, and should be approved prior to receiving the permit. The working group has proposed requirements for the Raw Milk Farm Permit that should be met as a pre-requisite to receiving a permit. This recommendation is consistent with the other permit pre-requisites that are being proposed.

  It is important for the raw milk producer to put the food safety protections in place before beginning the production and sale of raw milk because there is an inherent risk associated with producing and drinking raw milk.

Recommendated Regulations: On-farm Incident Response Plans

The working group reached consensus on the following regulatory conditions necessary for a producer to respond to incidents that require immediate action to address a known or imminent risk for customers who have purchased raw milk that may be contaminated. The conditions listed here are critical to reduce the risk to both consumers who drank the milk and other people who may have had contact with them, who may also be at risk of infection, or spreading infection.

1. The producer should be required to write a plan of action that identifies the steps he or she will take to respond to an incident related to the raw milk production on the farm that may threaten the health of the customers who purchase raw milk at that farm. This plan is called the On-farm Incident Response Plan.

2. The components of the On-farm Incident Response Plan must include information or records on:

   a. The testing results of the farm animals, raw milk, and well water
   b. The raw milk production and lot codes
   c. The raw milk sales
   d. The customers who purchased the raw milk from the producer and the dates and lot codes of the purchase

   Some of these records are also required under other working group recommendations in other sections of this report.

3. The components of the On-farm Incident Response Plan must include:

   a. A plan for diverting or disposing of the raw milk
   b. Public health information for customers
   c. Raw milk product information for customers
   d. A recall plan

4. The producer should be required to receive approval from DATCP on his or her On-farm Incident Response Plan as a pre-requisite to apply for a Raw Milk Farm Permit.

5. The producer should be required to act immediately when a public health trigger or a known or imminent food safety or health risk occurs that is associated with the raw milk production on the farm as defined by DATCP. When an identified public health trigger occurs, the producer shall immediately:

   a. Stop selling raw milk to consumers

   b. Dispose of and/or divert the raw milk

   c. Notify his or her customers of the problem

   d. Notify the county or local public health department and DATCP

   e. Begin to investigate the cause of the problem on the farm

   f. Cooperate with public health and agriculture authorities to identify and solve the problem.

6. A producer should be required to develop a clear and simple numbering system known as a milk production lot code. The lot code should be designed to identify the date and volume of the milking and the date the raw milk was sold. The milk production lot code is necessary to ensure all unpasteurized milk produced on the farm can be retrieved from the customer who purchased it and traced back to the date, milk production lot, and farm where it was produced.

7. The producer should be required to receive approval from DATCP on the milk production lot code system that will be used on his or her farm. Approval of the milk production lot code should be required to be a pre-requisite to apply for a Raw Milk Farm Permit to sell unpasteurized milk on the farm.

8. The producer should be required to keep a record of the customers who purchase raw milk each day raw milk is sold on the farm and identify the production lot for all raw milk sold. These records will serve as a booklet of customer receipts. The customer sales recording and filing system identified here should be required to be in place prior to receiving a Raw Milk Farm Permit.

9. DATCP should be required to identify the incidents that will trigger the need for a raw milk producer to immediately stop raw milk sale; divert or dispose of the raw milk; notify customers, the local health department and DATCP; begin to investigate the problem; and take the actions outlined in his or her On-farm Incident Response Plan.

10. DATCP should be required to identify the "public health triggers" that can be documented and are science-based indicators of a known or imminent threat to food safety or public health and safety. A trigger may include coliform bacteria, animal disease, pathogenic bacteria, and antibiotic drug residue testing results that exceed the testing standards established, reports of consumer illnesses related to drinking raw milk; or violations of the Raw Milk Farm Standards that pose an immediate and significant food safety or public health risk; or other triggers relevant to public health and food safety.

11. DATCP should be required to write administrative rules for the On-farm Incident Response Plan to clarify and define more specifically:

    a. The public health triggers
    b. The approved ways to dispose of or divert the raw milk
    c. The conditions that need to be met and the additional animal, raw milk, or water testing that may be necessary for the producer to begin to sell raw milk again after raw milk sales were stopped
    d. The records the producer must maintain for the plan

12. DATCP in consultation with the University of Wisconsin should be required to write best management practices to assist producers to effectively manage the public health risks when an on-farm incident may threaten their customers' health. Best management practices should be written to assist producers with:

    a. Services that can be provided to customers such as:

        - providing customers with information on the animal, water, and raw milk testing that is done on the farm and what the test results mean

        - implementing a consumer complaint form for customers to raise consumer issues with the producer

        - providing each customer with a unique identification number for quick notification when problems may arise

b. Keeping individual animal health and herd health records, including records on medical treatment of cows, lactating periods, and animals contributing to each milking

c. Practical systems for record keeping and forms that can be used

d. Keeping information and records on the animal feed they are purchasing and the source of the feed

e. Developing a practical system for their raw milk production lot code

f. Developing realistic flow charts to document a producer's standard operating practices and routines on the farm so problems and system errors can be identified when problems arise. The standard operating processes may include sanitizing practices for equipment and containers; milking practices; daily routines to monitor temperature, animals, feed, water systems, or equipment; or collecting samples.

   The flow charting can also include the standard routine practices a producer uses to correct a problem, within the norm of daily operations, when a process step is missed or something doesn't work as planned.

Inspection of Raw Milk Farms

-- Performance-Based Farm Inspection --

Summary of Working Group Discussion and Consensus

The working group reviewed the current dairy farm inspection requirements for Grade A and Grade B dairy farms. They discussed creating an inspection program for raw milk farms based on the existing dairy farm inspection concepts and frequency. The working group's discussion is summarized as follows:

- Currently, Grade A dairy farms in Wisconsin are routinely inspected to monitor compliance with established milk and farm standards. DATCP determines the frequency of farm inspections each year by evaluating a farm's performance in relation to a set of performance benchmarks. The current Grade A dairy farm inspection program is called Performance Based Farm Inspection (PBFI).

- Grade A farms consistently meeting the performance based measures are inspected less frequently than those dairy farms meeting fewer of the performance benchmarks. The performance of the dairy farm measured against the standards determines the number of times each year the dairy farm will be inspected. A dairy farm may be inspected either one, two, three, or four times each year depending on the degree to which it meets the performance benchmarks in one of the corresponding four performance categories.

- The Grade A dairy farm performance standards are tied to milk quality testing for milk that will be pasteurized including numerical benchmarks for standard plate count, somatic cell count, and coliform count. In addition, benchmarks related to recorded violations of farm inspection criteria or milk temperature or cooling standards are also used.

- The scope of the inspection requirements for raw milk farms should be similar to inspection requirements for Grade A dairy farms, at a minimum. The working group has sought to recommend requirements consistent with regulations for other food products in general. In addition, because the raw milk sold to consumers will not be pasteurized, requirements may need to be more stringent to protect consumers drinking raw milk.

- Federal, state, and local laws require all food production and processing facilities to be licensed and inspected in Wisconsin. The food safety pre-requisites for the license and the frequency of inspection are commonly tied to the potential food safety risk of the food being produced or processed. Parameters for inspections and frequency of inspection should be applied to raw milk farms consistent with the requirements for other food facilities that are based on risk.

- Routine inspections for raw milk farms can be done using similar performance concepts used for Grade A dairy farms.

- The DATCP Performance Based Farm Inspection program is in place and can be modified slightly to establish the performance standards and measures that could be applied to raw milk farm inspection.

- Most dairy farms in Wisconsin are Grade A farms and the Grade A dairy producers are familiar with the PBFI system. DATCP has used the PBFI system for more than 15 years. There is no need to create a new farm inspection model for raw milk farms.

- Raw milk farms should be inspected based on a frequency tied to performance based measures to determine how often each year a raw milk farm is inspected.

- The performance standards for raw milk farms should be tied to the Raw Milk Farm Standards and the critical food safety indicators reflected in those standards that are necessary to reduce the presence of pathogenic bacteria in the production of raw milk.

- A system using performance-based farm inspection can encourage farmers to manage their raw milk farms to meet the performance standards and reduce the number of inspections on their farm each year.

- Farms selling unpasteurized milk to consumers should have the opportunity to be inspected at the established minimum number of inspections per year if the farm consistently meets the performance standards for the category with the highest level of performance required.

- The working group reviewed the raw milk farm inspection requirements in California, Connecticut, Idaho, New York, Pennsylvania, South Carolina, and Washington. All seven states require raw milk farms to be licensed and inspected on a routine basis each year, meeting specific farm inspection criteria.

Recommended Regulations: Raw Milk Farm Inspection

The working group reached consensus on the following regulatory conditions necessary for raw milk farms to minimize any foodborne pathogen contamination of the raw milk sold on the farm.

1. Farms with Raw Milk Farm Permits should be required to be inspected routinely by the Department of Agriculture, Trade, and Consumer Protection each year.

2. The Raw Milk Farm Standards should be the farm inspection standards used by the DATCP to inspect raw milk farms.

3. DATCP should be required to develop a farm inspection checklist for raw milk farm inspection consistent with the Raw Milk Farm Standards.

4. DATCP should be required to develop performance benchmarks based on the Raw Milk Farm Standards. The performance benchmarks must reflect the most critical food safety standards for the farm that are necessary to reduce the presence of pathogenic bacteria in the production of raw milk.

5. DATCP should be required to develop performance benchmarks that are quantitative, and incorporate the Raw Milk Farm Standards. Other factors may be included as performance measures such as testing results for animal disease, raw milk, and well water; violations of temperature and time controls; violations related to containers, filling containers, and labeling; and other inspection and compliance violations that create an increased food safety or health risk for consumers drinking raw milk.

6. The performance measures should be required to be based on monitoring data and information routinely gathered on the farm to periodically check, verify, and monitor the farm's performance.

7. DATCP shall determine how verification of producer sampling and testing might be used to meet the categories for performance measures and inspection frequency.

8. The annual frequency of raw milk farm inspections should be required to be determined for each individual raw milk farm based on the degree to which the raw milk farm meets the performance benchmarks.

9. DATCP should be required to develop different categories of performance measures for raw milk farms. Each category should be defined by a unique set of performance measures and tied to a set number of routine farm inspections that will done on those farms each year.

10. Moving through time, the frequency of inspection for raw milk farms should be required to change with fewer inspections or more inspections depending on the degree to which each raw milk farm meets the performance benchmarks established by DATCP.

11. To begin the implementation of the performance based farm inspection program for raw milk farms, these steps should be required to be taken:

    a. For the first year that farms in Wisconsin are allowed to sell raw milk and they have received their Raw Milk Farm Permit, all farms should be inspected at the same frequency. The raw milk farms should be evaluated by DATCP using the performance measures to determine the farm inspection frequency category for the second year.

    b. Each year, DATCP will evaluate each raw milk farm in relation to the performance measures that have been developed. Based on the evaluation, DATCP should place each raw milk farm into a performance category, and the category will determine the inspection frequency for that farm for a twelve-month period beginning the second year raw milk farm permits are issued and sales are allowed in Wisconsin.

    c. Farms consistently meeting the raw milk farm performance benchmarks during the first year must have fewer farm inspections during the second year.

    d. Farms not consistently meeting raw milk farm performance benchmarks during the first year must have more farm inspections during the second year.

    e. By the third year, the performance-based farm inspection program for raw milk farms should be in place. In the third year:

        i. raw milk farms consistently meeting the performance benchmarks the previous year must have the opportunity to stay at the established minimum numbers of inspections for that year, and

ii. raw milk farms that have improved performance consistently during the previous year must have the opportunity to be inspected less frequently the following year.

f. The number of annual farm inspections must increase or decrease depending on the consistency of meeting the performance benchmarks during the previous year.

g. A raw milk farm must have the opportunity to be inspected at the established minimum number of inspections per year if it consistently meets the performance benchmarks.

12. DATCP should be required to write administrative rules to establish the performance benchmarks and the raw milk farm inspection checklist, and to implement inspection procedures and the performance based farm inspection program for raw milk farms.

Fees for a Raw Milk Farm Permit

Summary of Working Group Discussion and Consensus

- A state issued license that gives a citizen the opportunity to drive a car, perform professional duties (such as an engineer) or operate a business commonly requires the citizen to pay a fee for the license.

- The working group reviewed the fee schedules DATCP uses to set license fees for dairy farms, dairy plants, bulk milk tankers, dairy receiving and transfer stations, the milk procurement fee, and other dairy licenses. The license fees are annual fees, paid each year the license is renewed.

- DATCP is given statutory authority to set license fees for programs it is responsible for administering. Revenues from license fees help pay for the costs to administer the programs and enforce the laws passed by the legislature.

- DATCP often sets fees for a license category on a sliding scale, based on the sales revenues of a business or the pounds of a product produced annually. Smaller businesses pay a smaller license fee than larger businesses.

- The administration costs for some state programs are paid with a combination of license fee revenues and general tax revenues. Currently, the DATCP dairy inspection program costs are paid from about 60 percent program revenue license fees and about 40 percent from general tax revenues.

- The working group discussed the importance of setting license fees for Raw Milk Farm Permits consistent with other dairy industry license fees. Throughout the working group discussions, it routinely used a concept of parity when considering recommendations that could be applied to raw milk producers to achieve a specific outcome – whether the recommendations were for testing or labeling or other issues. The group strived to create a measure of parity or equality for raw milk producers with the practices required by law for other dairy producers or dairy industry businesses.

- Consistent with all other dairy and food businesses, the business of producing raw milk should be licensed. The producer should pay a fee for a Raw Milk Farm Permit, and the fee amount should be consistent with licenses charged to other small food businesses.

The milk producer's license is $30 per year, although the producer rarely pays the license fee because it is paid by the processing plant (its milk marketer) because competition for the producer's milk is high.

- The working group discussed DATCP Policy # 175 on the review and approval of department fees. The policy provides guidelines for setting fees based on public or private benefit of the service. A copy of Policy # 175 can be found in Appendix 15.

- Setting a fee for the Raw Milk Farm Permit should consider the extent to which food safety program costs should be born by producers or born by the public, and in what proportion. There is a cost to the state and public that should be factored into the level of the fee, and fee amounts could be determined by splitting the program costs between public and private benefit.

- The initial license fee should be treated as a start-up cost. The annual cost of the fee can be passed onto the consumer as the cost of doing business.

- It is important for the fee paid by the raw milk producer to be adequate to support the DATCP cost to administer a new raw milk program that would be created including the program costs for licensing, inspections, sampling and testing, compliance, and enforcement.

- The working group discussed different alternatives for how to set the license fees for raw milk farms, including ideas about using a sliding scale based on the size of the farm, on-farm sales revenues, or raw milk production. And, or the fee could be based on supply and demand: a) supply to the producer because the producer benefits and is willing to provide the product and b) demand by the consumer because the consumer benefits and is willing to pay for the product, including paying for the cost of the producer permit or license.

Recommended Regulations: Fees for a Raw Milk Farm Permit

1. Raw milk producers should pay a fee to obtain a raw milk permit.

2. The DATCP should be given authority by the Legislature to set fees for a Raw Milk Farm Permit.

3. DATCP should set the Raw Milk Farm Permit fees consistent with:

   a. DATCP Policy # 175,
   b. The concepts used by DATCP to set other dairy license fees, and
   c. The concept of using both general tax revenues and license fee revenues to share the program costs.

Best Management Practices and Education Initiatives

Recommendations

Best Management Practices

and

Education Initiatives

For Raw Milk Producers and Consumers

Summary of Working Group Discussion and Consensus

- Education and information outreach for producers and consumers can play a critical role in effectively minimizing and managing the public health risks of selling raw milk.

- If a law is enacted to allow the sale of unpasteurized milk on the farm, a state program to regulate the new food businesses will be put in place and it will have regulations to control critical parts of raw milk production, bottling, and sale to help ensure the raw milk produced is as safe as possible for consumers to drink.

- Education is a broad-reaching and powerful tool available to help the public make informed choices in the marketplace and help businesses comply with regulations to protect consumers.

- Regulations can help reduce the risk of foodborne illness. Just as importantly, on-farm best management practices and increased education about raw milk to producers, consumers, and others in the dairy and food businesses can be effective companions to workable and reasonable regulations.

- There are best management practices and education initiatives for producers and consumers that can work hand in hand to strengthen the regulatory framework proposed for on-farm raw milk production and sales.

- Recommendations to promote raw milk education and information should be a critical part of a comprehensive package to compliment raw milk regulations to reduce the risk of contaminating the raw milk, furthering knowledge and understanding of the importance of the food safety principles, and protecting consumers.

- Producers working to minimize and manage the food safety risks of unpasteurized milk will face serious challenges because there is an inherent risk associated with drinking raw milk. It is not possible to keep the harmful bacteria out of the raw milk.

  It takes only a small number of harmful bacteria to infect a person and to cause the person to become sick. For this reason, information on best management practices and education to the consumers and producers can broaden the scope and usefulness of the tools that are available to keep consumers as safe as possible.

- Ideas for best management practices for the producers and food safety guidelines for consumers have been incorporated throughout the raw milk recommendations wherever possible because the working group believed education and information initiatives could strengthen the proposed regulatory framework.

- There are several handbooks and manuals on best management practices for producers and safe handling guidelines for consumers. The Farm-to-Consumer Foundation *Raw Milk Production* handbook by Tim Wightman (2008) and the *Safe Handling – Consumers' Guide* by Peggy Beals (Michigan Fresh Milk Council, 2009) were reviewed and discussed by the working group. These two handbooks are good examples of education and information outreach resources that can benefit both producers and consumers.

Recommendation for Best Management Practices

The working group believes the following food safety recommendations for education, outreach, best management practices and safe handling guidelines are important resources to help reduce some of the health risks to consumers drinking raw milk. Education and outreach play an important part in the comprehensive regulatory framework necessary to address the public health issues associated with drinking raw milk.

The goal of these recommendations is to provide accurate, consistent and valuable information and education to help create knowledgeable raw milk producers and consumers.

Several recommendations for best management practices for producers and educational initiatives for both producers and consumers are included in different sections of this report. In addition, the working group recommends the following best management practices and educational initiatives be completed to benefit producers and consumers.

1. Write a Best Management Practices Manual for dairy farmers who wish to sell unpasteurized milk to consumers on their farms.

2. Work with the University of Wisconsin and the Wisconsin Department of Health Services in the preparation of the best management practices manual.

3. Complete the writing of the manual no later than when DATCP officially submits the administrative rule hearing draft to the Wisconsin Legislature for review.

Course Curriculum for Producers

1. DATCP and the University of Wisconsin jointly should prepare a course curriculum for producers who want to become licensed to sell fluid unpasteurized milk on the farm.

2. DATCP and the University of Wisconsin should define the key competencies and the course content.

3. DATCP and the University of Wisconsin should design a course curriculum to provide educational opportunities for the producer to achieve a certain competency and pass a standard exam required to be licensed.

4. DATCP should create full access to educational resources for the curriculum to enable producers to gain the knowledge necessary to become competent in food safety principles and raw milk production.

   Education materials and other educational resources for the curriculum should be made widely available for producers, including online access, at public libraries, UW-Extension offices, and technical colleges. On-farm or field demonstrations may be another opportunity for producers to gain knowledge. There are many possibilities on how and where the materials can be developed and delivered.

   DATCP and the University are responsible for defining the core competencies and the course content that will be made available.

   The producer is responsible for accessing the education materials and resources to learn the core competencies. The working group did not envision this requirement to be structured like a "short course."

5. DATCP and the University of Wisconsin should jointly prepare a test to measure the competency of the knowledge and experience of producers who want to apply for a license to sell fluid unpasteurized milk on the farm. The producer must achieve a certain test score as a condition of meeting the licensing requirements.

Bulk Milk Weigher and Sampler Test

1. DATCP should prepare a Bulk Milk Weigher and Sampler (BMWS) test for producers who want to sell fluid unpasteurized milk on the farm. Producers should be required to hold a BMWS license as a condition of receiving a permit to sell fluid unpasteurized milk on the farm.

Consumers' Guide on the Safe Handling of Raw Milk

1. DATCP should write a Consumers' Guide on the Safe Handling of Unpasteurized Milk.

2. DATCP is encouraged to work with the University of Wisconsin and the Wisconsin Department of Health Services in the preparation of the Consumers' Guide.

Appendices

Appendix 1

Assignment for the Raw Milk Policy Working Group

January 2010

Goal for the Working Group

Explore and evaluate legal and regulatory alternatives under Wisconsin law that:

- May allow dairy farmers to sell fluid raw milk to customers on their farms, beyond the exception of incidental sales allowed under current law,
- And if so, what conditions are necessary for this to be done to protect public health

Raw Milk Policy Working Group Assignment / Responsibilities:

- Review generally the statutory food safety mission of the Wisconsin Department of Agriculture, Trade, and Consumer Protection.
- Examine the current laws regulating 1) dairy farms, 2) milk, 3) dairy products, 4) sale of retail food, 5) dairy product labeling, and 6) the prohibitions of selling and distributing raw milk on and off the farm.
- Examine the current Wisconsin laws protecting public health and safety from foodborne illnesses.
- Examine how Wisconsin regulates and enforces dairy licensing, inspection, testing and sampling, monitoring, and compliance.
- Review and evaluate the laws in other states allowing the sale of raw milk.
- Review, analyze, and discuss ways Wisconsin might allow the sale of fluid raw milk on dairy farms with conditions to protect public health.
- Review and evaluate any other information the Chairperson and Working Group may believe essential to developing practical ideas and solutions.
- Make policy, program, and regulatory recommendations to the Secretary of the Department of Agriculture, Trade, and Consumer Protection for the on-farm sale of fluid raw milk and the regulations necessary to protect public health.

Appendix 2: Summary of Raw Milk Sales Laws in 50 States

State	Retail Sale Legal?	Nonretail Sale for Human Consumption Legal?
Alabama	No	No
Alaska	No	No
Arizona	Yes	No (Sale allowed as commercial animal feed only)
Arkansas	No	Yes -- Limited to raw goat milk sold on farm
California	Yes	Yes -- On-farm sales also allowed
Colorado	No	No
Connecticut	Yes	Yes
Delaware	No	No
Florida	No	No
Georgia	No	No
Hawaii	No	No
Idaho	Yes	Yes -- Through regulated cow share program
Illinois	No	Yes -- On-farm sale only allowed
Indiana	No	No
Iowa	No	No
Kansas	No	Yes - Limited on-farm sale with promotions limited
Kentucky	No	Yes - Only raw goat milk w/ physician permission
Louisiana	No	No
Maine	Yes	Yes -- But not at eating establishments
Maryland	No	No
Massachusetts	No	Yes
Michigan	No	No
Minnesota	No	No (Occasional on-farm sale only legal exception)
Mississippi	No	Yes - Incidental sale from 9-herd goat farms
Missouri	No	Yes -- Sale/delivery from farm to final consumer
Montana	No	No
Nebraska	No	Yes -- On-farm sale only allowed
Nevada	Yes	Yes
New Hampshire	Yes	Yes
New Jersey	No	No
New Mexico	Yes	Yes
New York	No	Yes -- On-farm sale only
North Carolina	No	No (Sale as animal feed only)
North Dakota	No	No
Ohio	No	No
Oklahoma	No	Yes -- On-farm sale only & limits on goat milk sale
Oregon	Yes, goat & sheep	Yes Farm w/ less than 3 cows, 9 goats or 9 sheep
Pennsylvania	Yes	Yes
Rhode Island	No	Yes -- Raw goat milk only w/ doctor's prescription
South Carolina	Yes	Yes
South Dakota	No	Yes, On-farm sale & delivery to consumer allowed
Tennessee	No	No
Texas	No	Yes, On-farm sale only
Utah	Yes	Yes, On-farm sale allowed
Vermont	No	Yes On-farm sale or delivery to consumer allowed
Virginia	No	No
Washington	Yes	Yes
West Virginia	No	No
Wisconsin	No	No (Incidental sale on-farm is not prohibited)
Wyoming	No	No

Table on 2009 Milk Production by State

RANK	STATE	MILK PRODUCTION IN POUNDS (MILLION POUNDS)
1	California	39,512
2	**Wisconsin**	**25,239**
3	New York	12,424
4	Idaho	12,150
5	Pennsylvania	10,551
6	Minnesota	9,019
7	Texas	8,840
8	Michigan	7,968
9	New Mexico	7,904
10	Washington	5,561
35	Connecticut*	355
39	South Carolina*	319

Source: "Milk Production," National Agriculture Statistics Service, USDA, February, 2010. *Note: Connecticut and South Carolina are not among the top ten milk producing states; they are included here because they were in the group of 7 states evaluated by the working group.

Table: 2009 State Data Ranked for Total Number of Dairy Cows

Number of Dairy Cows, Licensed Dairy Herds, and Average Herd Size

RANK	STATE	NUMBER OF DAIRY COWS	NUMBER OF LICENSED DAIRY HERDS	AVERAGE HERD SIZE
1	California	1,796,000	1,820	987
2	**Wisconsin**	**1,257,000**	**13,170**	**95**
3	New York	619,000	5,470	113
4	Idaho	550,000	600	917
5	Pennsylvania	545,000	7,400	74
6	Minnesota	469,000	4,700	100
7	Texas	423,000	650	651
8	Michigan	355,000	2,310	154
9	New Mexico	325,000	150	2,167
10	Ohio	277,000	3,310	84
11	Washington	240,000	470	511
36	Connecticut*	19,000	150	127
38	South Carolina*	17,000	95	179

Source: Milk Production, National Agriculture Statistics Service, USDA, February 2010.
*Note: Connecticut and South Carolina are not among the top ten dairy states; they are included in this table because they were in the group of 7 states evaluated by the working group.

Appendix 5 and 6

Table: 2009 Milk Cash Receipts at the Farm

Total Cash Receipts for all Farm Commodities & Milk as a Percent of Total Cash Receipts

Top Ten Milk Producing States
(Dollars in Thousands)

Rank	State	Milk Cash Receipts at Farm	Total at-the-Farm Cash Receipts (All Farm Commodities)	Milk Cash Receipts as Percent of Total Cash Receipts
1	California	$4,537,171	34,840,648	13.0%
2	**Wisconsin**	**3,270,677**	**7,609,624**	**43.0%**
3	New York	1,685,312	3,675,505	45.9%
4	Idaho	1,430,514	5,160,697	27.7%
5	Pennsylvania	1,509,840	4,979,589	30.3%
6	Minnesota	1,194,476	13,325,231	9.0%
7	Michigan	1,063,960	5,579,184	19.1%
8	Texas	1,172,129	16,573,055	7.1%
9	New Mexico	950,213	2,698,525	35.2%
10	Washington	681,912	6,592,649	10.3%

Source: Farm Income, Annual Cash Receipts 2000-2009, Economic Research Service, USDA.
Note: USDA statistics on milk cash receipts are not available for Connecticut and South Carolina.

Value of Cheese

Top Ten Producing States in 2009

RANK	STATE	TOTAL VALUE
1	**Wisconsin**	**$3,444,727,530**
2	California	2,363,880,213
3	Idaho	981,341,100
4	New York	990,705,600
5	Minnesota	870,316,600
6	New Mexico	737,232,430
7	Pennsylvania	579,900,960
8	South Dakota	319,349,940
9	Iowa	290,285,160
10	Ohio	280,757,790

Source: Dairy Products Annual Summary, April 2010.

Appendix 7

Summary

Current Federal and State Laws

Related to
Unpasteurized Milk, Pasteurized Milk and Other Food Products

Federal Laws

Food and Drug Administration (FDA)

- The United States Food and Drug Administration (FDA) regulates all food in interstate commerce (except meat, poultry and eggs, which are primarily regulated by the United States Department of Agriculture).

- FDA rules currently prohibit the sale or distribution, in interstate commerce, of unpasteurized ("raw") milk or fluid milk products for sale to consumers.

- FDA also administers the Interstate Pasteurized Milk Ordinance (PMO), as part of an interstate cooperative agreement among all the states and FDA.

    - The PMO applies to milk and fluid milk products such as cream, yogurt and sour cream.
    - Milk and fluid milk products distributed between states, for sale to consumers, must meet Grade A standards specified in the PMO.
    - All Grade A products must be pasteurized.
    - FDA may "de-list" any state or milk shipper that fails to enforce or comply with PMO including pasteurization requirements.
    - Other states may refuse to accept any shipments of milk or fluid milk products from "de-listed" states or milk shippers.
    - PMO compliance is important to Wisconsin, which exports more than 85% of its milk and dairy products to other states.

- FDA also administers food "standards of identity," including standards of identity for cheese. Cheese *may* be made from raw milk *but only if* it is aged for at least 60 days.

U.S. Department of Agriculture (USDA)

- USDA does all of the following:

- Regulates meat, poultry and eggs.
- Administers federal milk marketing orders.
- Administers dairy product grading programs.

- These USDA programs do not have a significant bearing on the regulation of raw milk.

Centers for Disease Control

The Centers for Disease Control and Prevention (CDC) is not a regulatory agency. CDC collects and analyzes information on foodborne disease outbreaks and provides scientific and technical support on foodborne disease investigations.

Wisconsin State Laws

Department of Agriculture, Trade and Consumer Protection (DATCP)

- DATCP is Wisconsin's primary food agency. DATCP administers state laws related to food safety, advertising, and labeling. DATCP may adopt administrative rules to interpret and implement these laws.

- DATCP licenses all of the following persons, as required by statute. License holders must comply with applicable state laws, including DATCP administrative rules:

  - Dairy farm operators. A Grade A farm must also hold a Grade A permit.
  - Dairy plant operators. Grade A processing plant must also a hold Grade A permit.
  - Bulk milk tanker operators. A Grade A tanker operator must also hold Grade A permit.
  - Milk weighers and samplers.
  - Milk and cream testers.
  - Buttermakers.
  - Cheesemakers.
  - Food processing plant operators.
  - Food warehouse operators.
  - Milk distributors.
  - Retail food establishment operators (grocery stores, etc.)
  - Food laboratory operators.
  - Meat establishment operators.

- DATCP administers s. 97.24(2), Stats., which regulates the sale and distribution of milk in this state and provides in relevant part:

- "No person may sell or distribute any milk or fluid milk products, which are not Grade A milk or grade A milk products to consumers, or to any restaurant, institution or retailer for consumption or resale to consumers. Grade A milk and grade A milk products shall be effectively pasteurized, and shall be produced, processed and distributed in compliance with standards established by the department by rule.... [*Note:* Grade A standards must comply with the PMO, in order for Wisconsin to ship milk in interstate commerce. See also s. 97.24(3).]

- This provision of the law does not prohibit ... "Incidental sales of milk directly to consumers at the dairy farm where the milk is produced."

- Current DATCP rules (ATCP 60.235, Wis. Adm. Code) state, in relevant part, as follows:

> **"ATCP 60.235** ***Raw milk sales prohibited; exemptions.*** No person may sell or distribute unpasteurized milk or fluid milk products to consumers, or to any person for resale or redistribution in unpasteurized form to consumers. This section does not prohibit any of the following:
>
> **(2)** The distribution of unpasteurized milk, produced on a dairy farm, to any of the following:
>
> (a) The milk producer who is licensed under s. ATCP 60.02(1) to operate that dairy farm, and who, as license holder, assumes legal responsibility for the dairy farm operations.
>
> (b) An individual who has a bona fide ownership interest in the milk producer under par. (a), if the milk producer is a legal entity other than an individual or married couple.
>
> (c) A family member or nonpaying household guest who consumes the milk at the home of an individual operator or bona fide owner under par. (a) or (b).
>
> **(3)** The sale or distribution of unpasteurized milk, produced on a dairy farm, to the employees of that dairy farm.
>
> **(4)** The incidental sale of unpasteurized milk to a consumer, for delivery to the consumer at the dairy farm where the milk is produced, for consumption by the consumer, the consumer's family, or the consumer's nonpaying guests. A sale is not incidental if it is made in the regular course of business, or is preceded by any advertising, offer or solicitation made to the general public through any communications media."

Department of Health Services (DHS)

- DHS does all of the following:
  - Works to improve public health.
  - Collects public health information from local health departments and DATCP.
  - Houses the State Epidemiologist.
  - Collects disease statistics, and oversees disease investigations.
  - Provides direction and oversight to local public health departments.
  - Licenses and inspects restaurants, hotels and vending machines.
- DHS regulations prohibit the sale or serving of raw milk in restaurants, hotels or vending machines, and prohibit the use of raw milk in the preparation in meals served by restaurants, hotels or vending machines.

County and Local Public Health Departments

- County and local public health departments often license and inspect retail food establishments, restaurants, hotels and vending machines on behalf of DATCP (retail food establishments) and DHS (restaurants, hotels and vending machines).
- These departments often investigate food-borne outbreaks.

Federal and State Laws on Food Advertising and Labeling

Food Misbranding (General)

- Food may not be "misbranded."
- Food is "misbranded" if it's "labeling" is false or misleading in any particular, or if it violates affirmative labeling requirements. For example, if a food package fails to contain required manufacturer, content, ingredient or nutrition labeling.
- "Labeling" includes the immediate food label and any written, printed or graphic materials accompanying the food. "Labeling" may include, for example, a point-of-sale placard at a retail store. According to FDA, "labeling" may also include website information if, for example:
  - A seller or distributor promotes a food product on its website and allows consumers to purchase the product directly from the website.

- A food product label refers consumers to a website for additional information about the food product.

- FDA enforces federal misbranding laws while USDA is responsible for enforcing federal labeling requirements for meat.

- DATCP enforces state misbranding laws, which are nearly identical to federal laws.

- State law references:

  - Prohibitions: ss. 97.03 and 97.10, Wis. Stats.
  - Penalties: s. 97.72, Wis. Stats.
  - Court injunction: s. 97.73, Wis. Stats.

Food Advertising and Promotion (General)

- The law prohibits deceptive advertising and promotional statements by a food seller or distributor, not just deceptive labeling.

- Applies to all media and forms of communication such as in-person statements, newspaper, mail, telephone, television, internet, printed or graphic statements.

- Applies to statements by employees or agents acting on behalf of a seller or distributor.

- May apply to 3rd party statements if orchestrated, paid for, or used as part of a deceptive advertising or promotional scheme by a seller or distributor.

- A statement is deceptive if it has the tendency or capacity to deceive ordinary consumers. It is not necessary to prove that consumers were deceived in fact.

- The law does not prohibit mere "puffery." An example of mere puffery is "our ice cream tastes great."

- Federal Trade Commission (FTC) enforces federal law, the Federal Trade Commission Act (FTC Act).

- DATCP enforces state laws, including Wisconsin's "Little FTC Act" (which is nearly identical to federal FTC Act).

- State law references:
  - Fraudulent food advertising:
    - Prohibition: s. 100.183, Wis. Stats.
    - Penalty: s. 100.26(1), Wis. Stats.
  - Unfair and deceptive business practices ("Little FTC Act"):
    - General: s. 100.20, Wis. Stats.
    - DATCP may prohibit unfair or deceptive practices by rule or order: ss. 100.20(2) and (3), Wis. Stats.
    - Penalties for violating DATCP rule or order: ss. 100.26(3) and (5), Wis. Stats.
    - Private remedy for violation of DATCP rule or order: s. 100.20(5), Wis. Stats.
    - Court injunction and restitution for violation of DATCP rule or order: s. 100.20(6), Wis. Stats.

Weights and Measures

- Sellers and distributors may not misrepresent product weight or measure (applies to food and other products). Net quantity statements on food package and other packages must be accurate.
- Scales, measuring devices, price scanners, etc., must be accurate.
- DATCP enforces state weights and measures laws, based on technical standards published by the National Institute of Standards and Technology.
- State law references:
  - Weights and measures: ch. 98, Wis. Stats.
  - Deceptive declaration of weight or measure also constitutes "misbranding" or deceptive advertising, or both (see above).

Labeling Packaged Food

- Under federal law, packaged food must be labeled with all of the following in a standard format:
  - The product identity.
  - The name and address of the responsible manufacturer, packager or distributor.

- The net quantity of food contents.
- The food ingredients.

- Under the federal Nutrition Labeling and Education Act (NLEA), packaged processed food must also bear "nutrition labeling" in a standard format. "Nutrition labeling" must include serving size, nutrients per serving, fat content per serving, etc.

- Wisconsin law incorporates federal packaging and labeling requirements. See s. 97.03, Wis. Stats., and ch. ATCP 90, Wis. Adm. Code.

Health and Nutrition Claims

- State and federal law prohibit deceptive health and nutrition claims (see above).

- Sellers must have reasonable scientific substantiation for performance claims, including health or nutrition claims (e.g., "reduces cholesterol"), before they make the claims. Substantiation may not consist solely of personal endorsements or other non-scientific information.

- Under federal law, a food label may not claim that a food reduces the risk of a specific disease or health threat unless the labeler notifies FDA and has reasonable scientific substantiation.

Food Standards of Identity

- FDA has adopted federal "standards of identity" for some foods, such as "milk" and various cheeses. State law incorporates federal "standards of identity" by reference (see s. 97.09, Wis. Stats.)

- Food labeled or sold as a standard food (such as "milk" or "cheddar cheese") must conform to the "standard of identity" for that food. Violation constitutes "misbranding" and deceptive advertising (see above).

- Federal standard of identity for "milk" provides that milk in final package form for beverage use has been pasteurized.

- Cheese standards of identity typically provide that the cheese has been made from pasteurized milk, or has been aged for at least 60 days, and sometimes for a longer time.

Precautionary Labels

- Federal and state law prohibit the sale of "adulterated" food. A seller cannot avoid this prohibition merely by disclosing that the food is adulterated. For the state definition of "adulterated" food, see s. 97.02, Wis. Stats..

- Federal law requires precautionary labels for some potentially-hazardous food products such as raw meat, smoked fish, unpasteurized juices, and raw shellfish. Some of the precautionary labels take the form of "safe handling instructions." For example, a safe handling instruction could be used to inform a consumer if the food is normally cooked prior to consumption.

- Federal law prohibits the sale or distribution, in interstate commerce, of unpasteurized ("raw") milk in consumer packages. Hence, there is no federal warning label for raw milk. A seller cannot escape the sales prohibition by putting a warning label on the illegal product.

- States that allow limited on-farm sales of "raw" milk to consumers often require labels that warn of disease risks in addition to safe handling instructions.

- Federal law requires disclosure of known allergens in food.

- Food sellers often put simple food handling instructions on food packages, in order to minimize food safety and liability risks. "Keep Refrigerated" is an example of a food handling instruction.

- A seller's failure to warn consumers of food product hazards may result in damage liability claims, particularly if warnings are required by law.

- Clear and conspicuous warning labels may protect sellers against some types of liability claims, but not others. Liability claims may be based on strict product liability, negligence, express warranty or implied warranty theories. Warning labels will not protect sellers from liability resulting from the seller's negligence, including law violations or poor sanitation practices.

June 2010

Appendix 8

Testing for Non-O157:H7 STEC in Raw Milk

Background on Non-O157:H7 Shiga Toxin-producing *Escherichia coli*

Escherichia coli inhabit the gastrointestinal tract of humans and other warm blooded mammals. There are hundreds of strains of *E. coli.* Some strains are beneficial, many are harmless, and some are pathogenic and cause infection and illness in humans.

The most well known *E. coli* that are pathogenic are called Shiga toxin-producing *Escherichia coli* (STEC). It is the Shiga toxin produced by these *E. coli* that produce severe illness symptoms when released by the organisms in the intestinal tract of humans. *E. coli* O157:H7 and other STEC have been detected in raw milk and can cause symptoms ranging from abdominal cramping to hemorrhagic colitis or hemolytic uremic syndrome (HUS) which can result in abnormal bleeding, kidney failure, central nervous system damage and death.

E. coli live in the intestines of healthy cows and these bacteria are present in cow feces. *E. coli* from the cow's intestines or fecal material on the cow or in the barn can be spread on cows, surfaces, on humans, on other animals, or in the milk. *E. coli* survive refrigerator and freezer temperatures. *E. coli* are killed when heated, for example when meats are cooked to certain temperatures or raw milk is pasteurized.

Testing for *E. coli* O157:H7 and Non-O157:H7 STEC

The working group recommended producers be required to collect bulk tank raw milk samples and send them to commercial laboratories to be tested for *E-coli* O157:H7. The *E. coli* O157:H7 and the non-O157:H7 bacteria are both Shiga toxin producing bacteria; however, the *E. coli* O157:H7 has unique biochemical characteristics that make testing for it much easier than testing for the other Shiga toxin-producing non-O157:H7 *E-coli* strains. The unique biochemical characteristics of *E. coli* O157:H7 allowed the development of rapid screening and confirmatory tests approximately 20 years ago.

All other non-O157:H7 *Escherichia coli* have very different biochemical characteristics than *E. coli* O157:H7. The many, non-O157:H7 *Escherichia coli*, both harmless and harmful, are biochemically identical. Because they are identical, multiple testing steps are required to determine whether the organisms present are harmful Shiga toxin producing bacteria or not, and then additional testing must be done to determine the bacterial strain. The testing to isolate a

strain of non-O157:H7 *E. coli* is not easily done. The testing steps to make these determinations for non-O157:H7 STEC are time consuming and costly.

The working group discussed the barriers for testing for non-O157:H7 STEC. These same barriers do not exist for testing unpasteurized milk for *E. coli* 0157:H7. The testing differences are important. There are several reasons the working group is not recommending a requirement to test raw milk for non-O157:H7 STEC. The reasons include:

1. Today, few commercial laboratories offer testing for non-O157:H7 STEC in raw milk. There is little or no commercial laboratory infrastructure existing for the producer to use to have their raw milk tested.

2. Commercial laboratories that may offer the screening test are generally not certified or accredited to do non-O157:H7 STEC testing.

3. The laboratories certified and accredited to perform the screening and confirmation tests are typically government laboratories that test samples for regulatory government agencies. Commonly these laboratories do not provide fee-for-service testing to non-government entities, such as dairy producers.

4. If commercial laboratories were available to do the testing, the screening tests and confirmatory tests are time consuming, with test results unlikely to be known until after the milk had been consumed. The testing is also much more costly than the other pathogen testing the working group has recommended.

   The screening test takes several days. The confirmatory test can take a week or several weeks to complete. A cost estimate of the screening test is approximately $85 and the additional cost of a confirmatory test is estimated roughly to be between $500 and $1,000.

Human Illness and Non-O157:H7 STEC

The Centers for Disease Control and Prevention (CDC) has found six non-O157 STEC strains to be particularly harmful to humans. These six strains are identified by the following "O" types: O26, O45, O103, O111, O121, and O145. These six cause an estimated 70 percent of the STEC-related illnesses caused by the non-O157 STEC.

The foodborne illnesses caused by non-O157 STEC are most frequently associated with eating raw or undercooked beef and unpasteurized dairy products and drinking raw milk, unpasteurized apple juice, or contaminated water. The aforementioned six non-O157 STEC strains cause about 30 deaths

per year in the U. S. and infect about 37,000 people per year. (CDC: 1999 and 2006)

USDA Actions and the Availability of Screening Tests for Commercial Use

In 1994, the U. S. Department of Agriculture (USDA) classified *E. coli* O157:H7 as an adulterant in ground beef. This means, in the routine course of meat inspection, when ground beef product is tested and found to be contaminated with *E. coli* O157:H7, the raw meat product is required to be removed from commercial sale for human consumption. Viable and rapid screening tests became readily available shortly after *E. coli* O157:H7 was declared an adulterant. Commercial laboratory testing to screen for *E. coli* O157:H7 also became commonly available and relatively inexpensive.

As of September 2010, no validated, USDA-accepted, rapid analytical test for the non-O157:H7 STEC are commercially available. The USDA is currently reviewing whether to define the six, non-O157:H7 STEC strains (O26, O45, O103, O111, O121, and O145) as adulterants in raw beef. If the USDA declares the six non-O157:H7 STEC to be adulterants, the increased availability of tests is likely because rapid screening tests will be needed to confirm no adulterants are present when the meat products are inspected, prior to processing, and before the meat product may be sold for human consumption. Such changes may also drive the availability for screening tests for non-O157:H7 STEC in raw milk at commercial laboratories.

Appendix 9

Testing Dairy Cows for Q Fever
***Coxiella burnetii* Infection Associated with Drinking Raw Milk**

Overview

Coxiella burnetii is a bacterium that can infect humans and causes Q fever. Dairy cows can be infected with *C. burnetii* although most animals infected with *C. burnetii* do not show signs of the disease. *C. burnetii* can be transmitted from dairy cows to humans.

People can be infected with *C. burnetii* by eating or drinking unpasteurized milk and dairy products. Most commonly however, humans are infected by inhalation from airborne barnyard dust contaminated with *C. burnetii* from dried animal tissue and excreta of infected animals.

The working group collected information on Q fever and the public health risks of drinking raw milk from dairy cows infected with *C. burnetii*. When the working group reviewed the raw milk regulations in other states, it noted that Washington, a state that allows raw milk sales, requires animals to be tested for Q fever. The working group wanted to know why Washington required testing for Q fever, to explore further the public health issues of Q fever and drinking raw milk, and to examine whether a Q fever testing regulation to protect public health should be included in the working group's recommendations for a raw milk regulatory framework.

The working group thoroughly reviewed and discussed the public health issues and research on *C. burnetii* associated with drinking raw milk. Given its assignment to search for ways to reduce the foodborne illness risks for consumers drinking raw milk, the working group found there are important knowledge gaps about the implications of the high prevalence of *C. burnetii* detected in raw milk samples and dairy herds that made it difficult to assess the nature and magnitude of the public health risk of Q fever to the consumer. With insufficient knowledge it is not possible to recommend ways to attempt to reduce the risk, if needed.

Equally significant, the working group concluded it is important for producers and consumers to know that while we do not know how *C. burnetii* establishes an infection and spreads in humans or how *C. burnetii* may produce infectious disease in humans who drink raw milk, there is no research today to suggest it is safe for consumers to drink raw milk produced from dairy cows infected with *C. burnetii*.

Information about Q Fever, *Coxiella burnetii*, and Unpasteurized Milk

- Q fever is a disease caused by *Coxiella burnetii,* bacteria found worldwide.

- *Coxiella burnetii* can be transmitted from cows, goats, sheep, and other animals to humans. Most animals infected with *Coxiella burnetii* do not show signs of the disease.

- Goats, sheep, and cows are the primary reservoirs of *Coxiella burnetii. C. burnetii* are excreted in milk, urine, and feces. During the birthing of animals *Coxiella burnetii* are shed in high numbers in the amniotic fluids and the placenta. The organisms are resistant to heat, drying, and many common disinfectants, allowing the *C. burnetii* to survive for long periods of time in the environment.

- Most commonly, humans are infected by inhalation of the *Coxiella burnetii* from airborne barnyard dust contaminated by dried placental material, birth fluids, and excreta of infected animals. People can be infected by eating or drinking unpasteurized milk and dairy products containing *C. burnetii*, but little is known about the magnitude of infection risks of *C. burnetii* from drinking raw milk.

- *Coxiella burnetii* in raw milk are killed by pasteurization.

- Most animals infected with *Coxiella burnetii* do not show signs of the infection. Many human infections are also not apparent. In addition, diagnosis of Q fever is difficult because the human symptoms are similar to infections caused by other diseases and varies in humans, ranging from influenza-like illness to pneumonia, hepatitis, and endocarditis.

- It requires only a very few *C. burnetii* to cause infection in humans. About 50 percent of all people infected with *C. burnetii* become sick or show signs and symptoms of the infection. Symptoms include high fever, severe headache, sore throat, chest or stomach pain, vomiting, and diarrhea. The fever usually lasts for 1 to 2 weeks. Thirty to 50 percent of the people with symptomatic infection will develop pneumonia. Q fever during a woman's pregnancy is associated with abortion and preterm birth. A large percentage of people getting sick also get more serious lung or liver infections, including hepatitis. Most people with clinical illness will recover within several months. One to 2 percent of people infected and sick with *C.* burnetii die from the disease.

- Rarely, *C. burnetii* infection can persist in humans for more than six months, and may persist for as many as 20 years after the initial

infection. When this occurs, it is a much more serious disease, and may cause inflammation of the heart. Transplant recipients, patients with cancer, and those with chronic kidney disease are also at risk of having the *C. burnetii* infection persist. In these rare situations, as many as 65 percent of persons with persistent symptoms of Q fever may die from the disease.

- According to the Centers for Disease Control (CDC) the incidence of acute Q fever is .04 human cases per 100,000 is the risk of acute Q fever. 120 cases of Q fever were reported in the U. S. in 2008. There is no knowledge about how the 120 cases were acquired.

- Q fever data is limited by the fact that cases of the disease are underreported. Q fever is required to be reported in the United States. Reporting is not required in some countries. Because Q fever is underreported, scientists cannot reliably assess the number of Q fever cases occurring worldwide each year. Data is also limited because Q fever symptoms mirror other diseases, it is undiagnosed, some infected people are asymptomatic and the infection can persist in humans in a chronic stage and remain undetected in the environment. Additionally, national data does not distinguish Q fever acquired by inhalation from that acquired via ingestion of raw milk.-

- A human vaccine for Q fever has been developed and has successfully protected humans in occupational settings in Australia. However, this vaccine is not approved or commercially available in the United States. Q fever occurs more frequently in persons with occupational contact with high-risk species. Occupational contacts include farmers, farm laborers, veterinarians, and meat processing plant workers.

- Eradications programs are not yet available because Q fever spreads so effectively among animals. Research on vaccination programs for animals has not had practical success. A vaccine for *C. burnetii* for use in cows has been developed but it is not approved or commercially available for use in the United States.

- Because vaccines for humans and animals are not approved or commercially available for use in the U. S., prevention efforts focus on minimizing contact with animals that may be shedding *C. burnetii.* It is probably not practical or possible to eliminate the risk for Q fever in the typical farm setting. The risk of transmission can be decreased with proper pasteurization of milk products, proper farm sanitation, and handling and disposal precautions when dealing with pregnant animals before and after they have given birth.

<u>The Washington State Raw Milk Sales Law</u>

- Washington State allows raw milk that is produced from cows, goats, or sheep to be sold in retail and on the farm when the licensing requirements and food safety regulations have been met by producers.

- Washington requires a blood sample from each animal to be tested for antibodies against *C. burnetii* prior to licensing and annually for farms producing raw milk to sell to consumers. If the blood sample is positive, milk from that animal is required to be pasteurized. It is the owner's responsibility in Washington to ensure the raw milk from an animal that tested positive is not sold as raw milk directly to consumers.

- Washington State added the Q fever testing requirement to its raw milk sales law, effective January 1, 2008. Its original law did not contain the *C. burnetii testing* requirement.

- Washington added the testing requirement to address the human foodborne illness risks of *C. burnetii* being present in raw milk that would not be killed by pasteurization.

- Washington also added the *C. burnetii* testing requirement as a public health precaution shortly after a significant public health problem associated with *C. burnetii* infection arose in the Netherlands in 2007.

Research: Presence of *Coxiella burnetii* in Raw Milk in Wisconsin

- In 2005, researcher Dr. Suzanne Gibbons-Burgener (through the UW – Wisconsin Veterinary Diagnostic Laboratory) tested stratified, random samples of bulk tank raw milk using real-time Polymerase Chain Reaction (PCR) from 900 geographically representative dairy herds throughout Wisconsin.

- The research of Dr. Gibbons-Burgener indicated that approximately 76% of the bulk tank raw milk samples on the farms had detectable *C. burnetii* DNA. The prevalence of *C.* burnetii in the bulk tank raw milk samples ranged from 53% to 96% depending on three factors. Dairy farms in the southern Wisconsin, Grade A farms, and dairy farms with larger herds appeared to have a greater risk of having detectable *C. burnetii* in their bulk tank raw milk.

Research: Presence of *Coxiella burnetii* in Raw Milk in the U. S.

The working group reviewed other research on *C. burnetii* and raw milk, including these three studies:

1. "*Coxiella burnetii* in Bulk Tank Milk Samples, United States." By Sung Guk Kim, Eun Hee Kim, Caroline J. Lafferty, and Edward Dubovi. Emerging Infectious Diseases. Volume 11, Number 4, April 2005.

   In summary, this research acknowledged dairy cattle are a primary reservoir of *Coxiella burnetii*, although no recent nationwide studies had assessed the prevalence and risks of Q fever in dairy cattle. *C. burnetii* can be isolated in internal organs of infected animals in the acute phase of the disease and the uterus and mammary glands are primary sites of infection in the chronic phase. Shedding of *C. burnetii* into the environment occurs mainly by birthing products and shedding of *C. burnetii* in raw milk by infected dairy cattle is well documented. However, the prevalence of *C. burnetii* infection in cattle has not been established previously, in part, because of the lack of surveillance.

   The researchers tested 316 bulk tank raw milk samples from dairy herds in the U. S. during a 3-year period from January 2001 to December 2003 using trans-PCR. The overall prevalence of *C. burnetii* in the tested samples was 94.3% with little variation from year to year. Test results from across the U. S. indicated that *C. burnetii* infection in the dairy herds was persistent or steady, with little temporal or regional variations, suggesting that *C. burnetii* infections in dairy herds are common throughout the United States.

   The researchers suggested continual daily and weekly shedding in the raw milk by the infected cattle indicated chronic infection by *C. burnetii* and the chronic infections may be the most important source of human infection based on the research sample data that was found. The researchers extrapolated their data to the dairy cow population nationally, suggesting nearly 3 million lactating cattle were shedding *C. burnetii* daily. They noted that epidemiologic studies indicate that Q fever develops in farmers, veterinarians, and slaughterhouse workers, but the mode and extent of *C. burnetii* transmission from bovine to human has not been determined.

   The researchers recommended the need for further investigations to determine the implications of the high prevalence of *C. burnetii* in dairy herds, to address the potential risk to public health, and to be prepared for outbreaks. Currently, no commercial vaccines are available for cattle and no effective treatment protocol exists for infected animals.

2. "Detection of *Coxiella burnetii* in Commercially Available Raw Milk from the United States" by Amanda d. Loftis, Rachael A. Priestley, and Robert F. Massung. FOODBORNE PATHOGENS AND DISEASE, Volume 7, Number 12, 2010.

   This research sampled and tested raw milk sold legally in the U. S. The research concluded that although consumption of raw milk containing *C. burnetii* posed a public health risk, and the bacterium has been previously identified in bulk tank raw milk samples, no information had been available previously on the presence of *C. burnetii* in raw milk sold to consumers. In this study, raw milk was legally purchased from cow milk dairies and goat milk dairies in 12 states and tested for the presence of *C. burnetii* using PCR. *Coxiella burnetii* was detected in 42.9% of the samples, confirming that some individuals who purchase and drink raw milk in the U. S. are exposed to the pathogen.

   The researchers concluded the ability of *C. burnetii* to establish an infection and spread (infectivity) in humans from drinking raw milk is poorly understood. Also, the ability of the pathogen to produce the infectious disease (pathogenicity) after oral exposure in humans is unknown, limiting the ability to assess the public health risk of *C. burnetii*. Further study is needed to determine the infectivity and pathogenicity of *C. burnetii* after ingestion and aspiration (respiratory exposure) of raw milk. Additionally, most of the published research concerning the pathogenicity of *C. burnetii* predates pasteurization. Further work is also needed to determine if the risk of infection is higher in immune compromised individuals.

3. *Coxiella burnetii* and Milk Pasteurization: An Early Application of the Precautionary Principle by O. Cerf and R. Condron in Epidemiology and Infection (2006), Volume 134: Pages 946-951. Cambridge University Press.

   This paper estimates the efficiency of pasteurization time and temperature combinations as required in regulations for food safety particularly for *Coxiella burnetii* and raises research questions on the relationship between *C. burnetii* in raw milk and the risk of Q fever disease from raw milk consumption.

<u>Q Fever in the Netherlands 2007 to the Present</u>

- In the Netherlands, between 2000 and 2006, there were 5 to 20 human cases of Q fever reported annually. From January 1 through August 2, 2007 there were 63 confirmed and probable cases of Q fever reported to municipal health services.

- Since then, a total of 168 human cases of Q fever were reported in 2007; 1,000 cases in 2008; 2,357 cases including 6 deaths in 2009; and 482 cases including 7 deaths from January 1 through October 6, 2010.

- Today, there is consensus among public health and veterinary professionals that most of the human Q fever cases in the Netherlands between 2007 through 2010 were linked to abortion waves on large dairy goat farms, and to a much lesser extent on dairy sheep farms. Extremely dry weather during 2007 exacerbated the conditions in which *C. burnetii* was spread by the inhalation of contaminated dust through the human population living sufficiently close to the infected farms.

- To reverse the trend of the three-year increase in Q fever, drastic measures were implemented in the Netherlands, including:

    - Mandatory vaccination of small ruminants
    - Large-scale culling of pregnant goats on infected farms
    - A temporary ban on breeding of goats and sheep
    - Mandatory PCR testing of bulk tank raw milk samples
    - Advisories to people to stop drinking and eating raw milk products
    - Implementation of a mandatory nationwide hygiene protocol on dairy goat and dairy sheep farms
    - Additional requirements limiting farm visits, avoiding direct contact with animals, banning manure-spreading, screening of pregnant women for Q fever, and banning blood donations.

The Q Fever Research Agenda Today in the Netherlands

The working group reviewed information from: "Q Fever in the Netherlands: An Update on the Epidemiology and Control Measures" by W. van der Hoek, F. Dijkstra, B. Schimmer, P. M. Schneeberger, P. Vellema, C. Wijkmans, R. ter Schegget, V. Hackert, Y. van Duynhoven. Euro Surveillance. 2010; 15 (12).

In summary, the current Q fever issues which arose in the Netherlands have generated a large interdisciplinary research agenda that will begin to address the major public health problem associated with Q fever and will focus on human and veterinary public health and individual patient care to fill in the many, existing Q fever knowledge gaps. The research agenda includes identifying the source and transmission routes of *C. burnetii*. A new project to sequence the whole genome will be done to distinguish between *Coxiella* bacteria from different sources and to identify and match conclusively the bacteria found in the animals with human and environmental samples.

Testing for *Coxiella burnetii*

The goal of testing is to determine if the animals producing the raw milk are infected with *C. burnetii* or if *C. burnetii* is present in the raw milk. If tests detect *C. burnetii* in the animals or raw milk, efforts could be made to ensure consumers are not drinking the raw milk.

There are several options to test for the presence of *C. burnetii.* These testing options have limitations and make decisions about testing yet more challenging.

Federal and state laws since the 1940's and 1950's have required raw milk to be pasteurized before it is sold to consumers, effectively eliminating the risk to consumers drinking milk. The public health risks were diminished by pasteurization to the point where few if any raw milk health problems needed to be addressed. There was little reason to develop tests to detect pathogens in raw milk or animals producing raw milk because these pathogens were being killed in the pasteurization process. Because raw milk could not be legally sold, most of the foodborne illness risks to consumers were significantly reduced or eliminated, thereby minimizing the importance of raw milk testing methods or additional research.

Testing the Blood Samples from Cows Producing Raw Milk

- A blood sample from an animal producing raw milk can be tested using a Complement Fixation (CF) test. The CF test determines whether antibodies to a Q fever antigen are present in the blood, identifying whether the animal has previously been infected or is currently infected with *C. burnetii.* The test does not distinguish between current and past infection. A positive cow may have been infected previously but is not currently infected or vice versa.

- The CF test of a blood sample is not the preferred testing method because it may yield potential false negative results, meaning the test indicates the animal is negative when the animal may in fact be infected with *C. burnetii.* It is not possible to know if a negative test is truly negative or a false negative.

- Testing blood samples for *C. burnetii* provides information about infected cows regardless of the false negatives that may result. A positive test provides accurate information about the animal's status and this information is valuable.

- The CF test method uses a blood sample. If a blood sample is required for raw milk farms for a brucellosis test, that same specimen can be used to test for both *C. burnetii* and brucellosis, thereby reducing some costs.

Testing the Raw Milk or Animal Tissue

- A real-time Polymerase Chain Reaction (PCR) test can be done to detect the DNA of *C. burnetii* in a sample of raw milk or animal tissue. PCR testing is more sensitive and accurate than other tests available such as the CF test for *C. burnetii* antibodies.

- Raw milk samples from an individual cow or the farm's bulk milk tank can be tested for *C. burnetii* using the PCR test.

- Testing a raw milk sample for *C. burnetii* from the bulk milk tank will provide information about the presence of *C. burnetii* in cows in the herd that contributed raw milk to the tank. If the bulk tank raw milk sample tests positive for *C.* burnetii, additional testing of individual cow's raw milk would be needed to further identify the infected cows and designate their raw milk for pasteurization.

- When a bulk tank raw milk sample is tested, it is likely the test is not a whole herd test because at any given time, not all the cows in the herd are contributing milk to the tank. Some cows may be dry, some may be on medication, and some may be in the last few weeks of pregnancy. The producer would need to keep records of the animals to identify which cows contributed raw milk to the tank and which ones were not contributing.

- Placental tissue from a dairy cow can also be tested for *C. burnetii* using the PCR test. Testing placental tissue is done when a farmer wants to determine the cause of an abortion. Testing animal tissue is not a relevant surveillance testing method for raw milk.

ELISA Test

- Enzyme-linked immunosorbent assay (ELISA) is a biochemical technique used as a diagnostic tool in medicine to detect the presence of an antibody or an antigen in a sample. There is an ELISA test for Q fever, but it is not licensed for use in the USA. The ELISA test is easier to do than the CF test and it gives better and more quantitative information about the cow's health than the CF. This test is not an option available for use in Wisconsin.

Co-mingled Raw Milk and Testing for *Coxiella burnetii*

On farms in other states where raw milk sales are legal, it is reasonable to assume raw milk destined to be sold directly to consumers is co-mingled in the bulk milk tank with raw milk that will be sold for processing and pasteurization.

Raw milk produced from animals that test positive for Q fever in Washington cannot be sold to consumers and must be pasteurized. It also means the raw milk contaminated with *C. burnetii* (that will be pasteurized) cannot be co-mingled with raw milk that will be sold directly to consumers. If Wisconsin decides to allow the sale of on-farm raw milk, it will be important to address the issue of co-mingling raw milk or separating raw milk sold to consumers directly and raw milk sold to processors to be pasteurized.

Lack of Effective Treatment for Animals Testing Positive for Q Fever

- *Coxiella burnetii* persists for long periods in animals and their environment. There doesn't appear to be an effective treatment for *C. burnetii* once cows become infected and because most milk is pasteurized, infected animals remain on the farm and continue to produce raw milk destined for pasteurization. Pasteurization of this milk kills *C. burnetii.*

- For other animal diseases such as tuberculosis and brucellosis, there are good treatment options and animal health programs to certify or accredit a herd as disease-free. The characteristics of Q fever make it challenging to maintain a Q fever disease-free herd.

Treatment for Humans Infected with *C. burnetii*

- Antibiotic treatment for humans is the most effective treatment for acute Q fever when it is initiated within the first days of infection. Fifty percent of people do not show symptoms of infection or symptoms will mirror other disease so diagnosis within the first three days is usually difficult to achieve.

Costs for Sampling and Testing for *Coxiella burnetii*

- A private commercial laboratory can perform the CF blood test submitted by the raw milk producer's veterinarian. The cost of the test is $34.50 for each blood sample (testing each animal).

- There would be no additional sample shipping costs or veterinarian trip costs if the Q fever testing was done at the same time as the brucellosis testing. The same blood sample can be used for both tests.

- The Wisconsin Veterinary Diagnostic Laboratory (WVDL) can test blood samples using the CF test and can test raw milk samples using the PCR test. The producer's veterinarian would submit the samples for testing.

- A CF test done by the WVDL will cost $14.50 per blood sample. The WVDL also charges a $10 submission fee per sample batch.

- A PCR test done by the WVDL will cost $30 per milk sample. The WVDL also charges a $10 submission fee per sample batch.

Appendix 10

Glossary of Terms

At-risk populations – At-risk populations are population groups in our society that have an increased risk of developing symptomatic illness from specific bacteria or viruses that cause infection. In these higher risk individuals and groups, an even smaller number of microorganisms can cause infection and illness, particularly serious illness and illnesses with severe complications. Infants and children, pregnant women, older adults, and people with weakened or compromised immune systems are the populations most at risk of infection from *Campylobacter, Salmonella, Listeria, E. coli* O157:H7 and non-O157:H7 STEC.

Best Management Practice (BMP) – Best management practices are operating techniques, principles, activities, processes, procedures, and tools that are effective in achieving a certain outcome or improving long-term performance. Best management practices may be structural, physical, or managerial in nature and they can be used singly or in combination depending on the situation. Often, BMPs are based on common sense, can be implemented quickly and at a low cost through simple changes made to every day activities.

Bulk milk tank or bulk tank – The bulk milk tank is a large permanent storage tank on the farm used to receive, cool, and store the raw milk from the time the cows have been milked until the raw milk is picked up by the milk hauler to be taken by the milk tanker truck to the dairy processing plant. When a cow is being milked, the raw milk moves from the udder into the milking machine and through a system of pipes to the bulk milk tank. The bulk milk tank is made of stainless steel, comes in different sizes, and may hold between 250 and 2500 gallons of raw milk. The bulk milk tank is located in the "milk house", a separate room, often next to or near the barn.

Bulk milk weigher and sampler – A bulk milk weigher and sampler is a person who weighs and collects samples of milk from the farm bulk milk tank or measures milk in the bulk tank to determine weight, on the farm premises where milk is produced. The person must be licensed by DATCP to engage in these activities.

CDC – The Centers for Disease Control and Prevention, United States Department of Health and Human Services.

cfu – Cfu is the acronym for colony forming units. A cfu is a unit of measurement used in microbiology that indicates the number of microorganisms present. It is normally measured by the number of colony forming units (CFU) present in a milliliter.

Cow Shares – A cow share or cow lease is a financial arrangement whereby a consumer pays money to a dairy farmer to become a part-owner of a farmer's dairy cow. In exchange, the consumer or part-owner receives raw milk for free or for an agreed upon price. Cow share arrangements may be done as a way to receive raw milk and to circumvent state laws prohibiting the direct sale of raw milk by farmers to consumers. Cow share programs are legal in some states and illegal in others. Cow share programs are financial arrangements and typically, they are not subject to food safety rules and regulations. Cow share programs or arrangements are not legal in Wisconsin.

Dairy producer – A dairy producer is a dairy farmer.

Dairy processor – A dairy processor is a person or business that operates a dairy plant or cheese factory. The person buys raw milk from a dairy farmer and pasteurizes the raw milk to sell as fluid milk and makes other dairy products such as butter, cottage cheese, sour cream, and ice cream.

DATCP – Department of Agriculture, Trade, and Consumer Protection

FDA – Food and Drug Administration, part of the U. S. Department of Health and Human Services

'Fresh' Milk – The term 'fresh milk' often refers to unpasteurized or raw milk, meaning milk fresh from the cow which is not pasteurized.

Foodborne Illness – A foodborne illness is a disease caused by consuming foods or drinks contaminated with microbes or other harmful substances. Most foodborne diseases are caused by a variety of bacteria, viruses, or parasites.

Homogenized milk – Homogenized milk is milk that is processed to evenly distribute the fat molecules in the milk and keep the cream from separating from the milk.

HUS – hemolytic uremic syndrome. HUS is a condition which results from the abnormal, premature destruction of red blood cells. Once this begins, the damaged red blood cells start to clog the filtering systems in the kidneys which may eventually cause kidney failure and may cause death.

Immune Compromised Persons – Persons with weakened immune systems or compromised immune systems caused by cancer treatment, diabetes, bone morrow or organ transplants, and AIDS.

Mastitis – Mastitis is an inflammation of a cow's mammary gland or udder.

Milk house – The milk house is an enclosed room on a dairy farm in which raw milk is cooled or stored in the bulk milk tank or milk can. The milk house is separate from the milking barn or parlor.

Milk quality -- Milk quality is defined by standards set by the U. S. Pasteurized Milk Ordinance (PMO). States may define "milk quality" and set their own milk quality standards if the standards they set meet or exceed those in the PMO. There are six milk quality standards in the Wisconsin. These six require: 1) an upper numerical limit on standard plate count, 2) an upper numerical limit on somatic cell count, 3) no presence of antibiotic drug or pesticide residues in raw milk, 4) a numerical cooling temperature to be maintained for raw milk; and 5) no visible adulteration or objectionable odor in raw milk.

National Conference on Interstate Milk Shipments (NCIMS) – An organization of voting representatives from state and local regulatory agencies and non-voting representatives from the U. S. dairy industry and the Food and Drug Administration who recommend the standards and requirements for Grade A milk production and processing that comprise the Pasteurized Milk Ordinance.

Organic Milk – Organic milk is defined by the USDA as milk from cows that have been exclusively fed organic feed, have not been treated with synthetic hormones, are held in pens with adequate space, and are not given certain medications to treat illness in the cows. Organic milk must be produced by a certified organic farming operation. By law, "organic milk" must be pasteurized to be sold in the marketplace. Agricultural products labeled "organic" must be verified by an accredited certification agency as meeting or exceeding USDA standards for organic production. Food products containing 95 to 100 percent certified organic ingredients may use the USDA organic seal, reflecting the National Organic Standards Board recommendations for the allowable or prohibited substances that may be used in the production and processing of a certified organic food product.

Outbreak – An "outbreak" is the occurrence of more cases of disease than normally expected within a specific place or group of people over a given period of time. An outbreak of foodborne illness that occurs when a group of people consume the same contaminated food and two or more of the people become sick from the same infection.

Pasteurization – Pasteurization is a moderate method of heat treatment specifically designed to kill the pathogenic bacteria that may be present in raw milk. The beneficial bacteria in milk are not killed when it is pasteurized. To achieve pasteurization, raw milk is heated to a required minimum temperature of 161.5° F. for 15 seconds. Pasteurization is not the same as sterilization which removes or kills all living organisms in a food product.

Pasteurized Milk Ordinance (PMO) – The PMO means the Grade A pasteurized milk ordinance published by the U. S. Department of Health and Human Services, Food and Drug Administration. The PMO is a written document that outlines the minimum standards and requirements necessary for Grade A milk production and processing.

Pathogenic – an organism that causes disease or is capable of causing disease. Pathogenic bacteria are disease-causing bacteria.

Raw milk – Raw milk is milk that has not been pasteurized.

Raw milk cheese – Raw milk cheese is cheese made from raw milk and aged for a minimum of 60 days. Raw milk cheeses may be sold legally in Wisconsin and other states when they are produced in compliance with the law and regulations of the U. S. Food and Drug Administration.

Recall – A food recall is a request to consumers, business, or the general market to return a specific food product to the maker when there is reason to believe the food product is causing or may cause the consumer harm.

Sanitize – To kill or remove injurious microorganisms. Dairy equipment is commonly sanitized with hot water or chemicals to clean it. Sanitizing is not the same as sterilizing.

"Shedding" or "sheds" – A term used to describe a process that occurs when bacteria or viruses are present and are cast off in animal or human bodily fluids, open wounds, feces, or urine and transmitted to other animals, humans or the environment. Bacteria or viruses can also be sloughed off from infected animals and humans on the skin or from the respiratory or intestinal tract. Shedding can happen regardless of whether the infected animal or person is showing signs or symptoms of the infection.

Shelf life – The time after a food is processed and the time during which the food product remains suitable for human consumption, especially the time a food remains palatable and acceptable to consumers.

Sterilize – A process which removes or kills all living organisms. Sterilization is not the same as pasteurization.

USDA – United States Department of Agriculture

Appendix 11

Top 15 Milk Producing States and their Laws on Raw Milk Sales

Rank by State: 2009 Total Milk Production

Rank	State	2009 Milk Production (Million Lb)	2009 Milk Cash Receipts as a Percent of Total at Farm Cash Receipts	2009 Number of Dairy Cows	2009 Number of Licensed Dairy Herds (State Rank)	2009 Ave. Dairy Herd Size	Is Retail or On Farm Sale of Raw Milk Legal?
1	California	39,512	13 %	1,796,000	1,820 (8)	987	Yes, both retail & on-farm
2	Wisconsin	25,239	43 %	1,257,000	13,170 (1)	95	No
3	New York	12,424	46 %	619,000	5,470 (3)	113	Yes, on-farm sale only
4	Idaho	12,150	28 %	550,000	600 (16)	917	Yes, retail
5	Pennsylvania	10,551	30 %	545,000	7,400 (2)	74	Yes, both retail & on-farm
6	Minnesota	9,019	9 %	469,000	4,700 (4)	100	No
7	Texas	8,840	7 %	423,000	650 (15)	651	Yes, on-farm only
8	Michigan	7,968	19 %	355,000	2,310 (6)	154	No
9	New Mexico	7,904	35 %	325,000	150 (29)	2167	Yes, both retail & on-farm
10	Washington	5,561	10 %	240,000	470 (19)	511	Yes, both retail & on-farm
11	Ohio	5,192	11 %	277,000	3,310 (5)	84	No
12	Iowa	4,379	3 %	215,000	1,890 (7)	114	No
13	Arizona	4,076	17 %	177,000	110 (32)	1609	Yes, retail
14	Indiana	3,383	5 %	168,000	1,680 (10)	100	No
15	Colorado	2,840	6 %	123,000	130 (31)	946	No

Source: Milk Production, National Agricultural Statistics Service, USDA, February 2009

In the top 15 milk producing states, annual milk production by state ranges from 39.5 billion pounds (California) to 2.8 billion pounds (Colorado). Of the 15 states, California has the most dairy cows at 1.8 million and Colorado has the smallest number of dairy cows at 123,000.

Comparing the top 15 milk producing states, there are two distinctly different dairy farm structures represented. One group of eight states has average dairy cow herd sizes that are small, ranging from 74 to 155 dairy cows. The eight states have relatively large numbers of licensed dairy herds in their states, ranging from 1,680 to 13,170 licensed dairy cow herds. These eight states are Wisconsin, New York, Pennsylvania, Minnesota, Michigan, Ohio, Iowa, and Indiana, and they are all located in the Midwest and Upper Great Lakes region of the United States.

In contrast, the other group of seven states has average dairy cow herd sizes that are large, ranging from an average herd size of 511 dairy cows in Washington State to an average herd size of 2168 dairy cows in New Mexico. The seven states have relatively small numbers of licensed dairy herds in their states, ranging from 110 licensed dairy cow herds in Arizona to 1820 licensed dairy cow herds in California. These seven states are California, Idaho, Texas, New Mexico, Washington, Arizona, and Colorado, and are all located in the Western and Southern regions of the United States.

Top 15 Milk Producing States and Laws on Raw Milk Sales:

- In 7 of the 15 top milk producing states the sale of raw milk is not legal.
- In 3 of the 15 top milk producing states only the on-farm sale of raw milk is legal.
- In 2 of the 15 top milk producing states raw milk sales at retail are legal.
- In 4 of the 15 top milk producing states raw milk sales are legal both on-farm and at retail.

Raw Milk Sales in States with Small Dairy Herds or Large Dairy Herds

- Six of 8 states or 75% of states with small or with an average dairy herd size of 74 to 155 dairy cows do not allow sale of raw milk in their states.
- Six of 7 states or 89% of states with large or with an average dairy herd size of 511 to 2168 dairy cows allow raw milk sales on-farm, at retail, or both.

Raw Milk Sales in the Seven Southern and Western States in the Top 15 Milk Producing States:

- Six of the 7 Southern and Western states allow raw milk sales either on-farm or at retail, or both.
- One of the 7 Southern and Western states does not allow raw milk sales.

Raw Milk Sales in the Eight Midwest and Upper Great Lakes States in the Top 15 Milk Producing States:

- Two of the 8 Midwestern and Upper Great Lakes states allow on-farm or on-farm and retail sales of raw milk.
- Six of the 8 Midwestern and Upper Great Lakes states do not allow raw milk sales.

Estimated Costs to Implement the Regulatory Framework Proposed for Producers Selling Raw Milk

Estimates of costs to consumers per gallon of raw milk purchased are presented in Table A
Notes on the assumptions, sources of data, and calculation methods are available in Appendix 14

All costs are in dollars

Activity or Test	Frequency	Start-Up Cost*	Annual Amor-tized Cost	On-Going Cost	Annual On-going Cost	Annual Regulation Cost per Cow***				Regulation Cost per Gallon			
						3-Cow Herd	20-Cow Herd	50-Cow Herd	100-Cow Herd	3-Cow Herd	20-Cow Herd	50-Cow Herd	100-Cow Herd
Standard plate count	1/week			4.17	216.84	72.28	10.84	4.34	2.17	0.048	0.006	0.002	0.001
Somatic cell count	1/week			2.90	150.80	50.27	7.54	3.02	1.51	0.034	0.004	0.001	0.001
Coliform (in milk)	1/week			6.50	338.00	112.67	16.90	6.76	3.38	0.075	0.009	0.003	0.002
Well water coliform	1/year				31.95	10.65	1.60	0.64	0.32	0.007	0.001	0.000	0.000
Drug residue	1/ 2-days	200.00	72.96	9.90	1811.70	628.22	94.23	37.69	18.85	0.420	0.051	0.017	0.009
Salmonella	1/month			41.55	498.60	166.20	24.93	9.97	4.99	0.111	0.014	0.004	0.002
Listeria	1/month			37.55	450.60	150.20	22.53	9.01	4.51	0.100	0.012	0.004	0.002
Campylobacter	1/month			51.55	618.60	206.20	30.93	12.37	6.19	0.138	0.017	0.006	0.003
E.Coli 0157:H7	1/month			51.55	618.60	206.20	30.93	12.37	6.19	0.138	0.017	0.006	0.003
Streptococcus ag.	one-time	45.00	16.44			5.48	0.82	0.33	0.16	0.004	0.000	0.000	0.000
Tuberculosis**	1/ 3-years	**				17.16	3.96	2.64	2.40	0.011	0.002	0.001	0.001
Brucellosis**	1/ 3-years	**				11.64	3.60	2.69	2.34	0.008	0.002	0.001	0.001
TOTAL COST						**1637.16**	**248.81**	**101.83**	**52.99**	**1.09**	**0.14**	**0.05**	**0.03**

*Start-up costs are based on the assumption that the drug residue test requires purchase of equipment. See Notes for details.

** Start-up costs recur every 3 years and vary with herd size. See Notes for details.

Start up cost estimates are: $472 for a 3-cow herd; $661 for a 20-cow herd; $976 for a 50-cow herd; $1552 for a 100-cow herd.

***Per cow costs are annual amortized amounts. The producer may sell only part of the milk raw to the consumer. See Notes for details.

Percent Increase in Consumer Price Due to Regulations Proposed

Estimates of Cost to Consumers per Gallon of Raw Milk Purchased

Herd Size	Estimated Increase in Cost/gallon	Percent Increase if Initial Price was $5/gallon	Percent Increase if Initial Price was $7/gallon
3 cows	$ 1.09	21.8 %	15.6 %
20 cows	$ 0.14	2.8%	2.0 %
50 cows	$ 0.05	1.0 %	0.7%
100 cows	$ 0.03	0.6 %	0.4 %

Assumes the producer passes all regulatory costs to the consumer.

Appendix 12

Notes for Estimated Costs to Implement the Regulatory Framework Proposed

For Producers Selling Raw Milk and Consumers Purchasing Raw Milk

General Notes on Cost Assumptions

1. Fixed Costs. All fixed costs are amortized using 6% as the opportunity cost of capital to the producer, regardless of whether the funds are borrowed. A 3-year life is assumed for the antibiotic residue test equipment.

2. Cost Estimate Assumptions. Cost estimates assume the producer already meets Grade A standards (except the requirement for a processor relationship). If the producer is Grade B, and if the well does not meet code, additional costs would be incurred that are not reflected in the cost estimates.

3. Labor Costs. Producers will incur 'time' costs as well as dollar costs in following the regulations. These costs may vary substantially depending on individual producer situations and decisions. For example, training to become a licensed milk sampler for the pathogen and other tests will require a few hours of study, but the larger time cost, for some, may be the time required to participate in educational outreach activities or training. As another example, collecting a milk sample may require only a few minutes but unless the sample is picked up at the farm by a courier service, the drive to the nearest drop-off point to mail the parcel might vary from a few minutes to perhaps a half-hour, depending on the location. At the same time, mailing the samples might be combined with other business in town or at the drop-off point, so the additional time cost for the regulation might be minimal. For these kinds of reasons it is not possible to estimate the time costs, even though these costs are real and should be counted as a cost of the regulatory framework.

4. Raw Milk Producer Also Selling to a Processor. It is possible a raw milk producer may chose a business model in which raw milk is sold to a dairy processing plant to be pasteurized for Grade A milk and also sell raw milk to consumers on the farm. Under this scenario, the producer will be making a profit on both pasteurized milk and raw milk. For example, a producer with a 100-cow herd may only be selling "20 cow's worth" of raw milk to consumers and the remainder to a processor. In such a situation, the producer would incur roughly the costs of a 20-cow operation (slightly more because of higher expense for tuberculosis and brucellosis testing of the entire cow herd on the farm). The regulatory costs estimated for a raw milk farm could be spread between the two profit channels available to the producer. Enough data are supplied in these notes to allow any producer to calculate the per-cow or per-gallon costs for an operation of any size, with any proportion of the milk being sold directly to the consumer.

5. Costs Not Factored into the Analysis.

   a. Costs for testing cows coming into the herd are not included in the cost analysis. The assumption was made that most farms will replace cows through reproduction from their own herd and the likelihood of cows coming into the herd is small and would only happen occasionally.
   b. Costs for treating the cows such as treatment costs for tuberculosis, brucellosis, and Strep-ag are not factored into the analysis. The assumption was made that it is highly unlikely the producer will incur costs to treat cow herds or animals.

6. The Sources of the Cost Estimates. Cost estimates for tests come from laboratories certified to conduct such tests. Data for standard plate count, somatic cell count and coliform bacteria in raw milk are were received from three Wisconsin private commercial laboratories. Test kit costs and equipment costs for testing for drug residues came from two dairy equipment supply companies, one in Wisconsin and one in Maine. Data for pathogen tests were received from three laboratories (two private commercial labs and one state government lab). The estimated animal health testing costs were received from one private commercial veterinarian clinic and three Wisconsin licensed veterinarians. Laboratory fee structures differ because some laboratories charge an "overhead" fee, and the costs for specific tests also vary. In each case the cost range is provided, and the cost used in the analysis will be the average total cost for each specific test. Detailed information on these cost estimates is available by contacting the Wisconsin Department of Agriculture, Trade, and Consumer Protection.

7. Start-up Costs. Start-up costs will vary by herd size. All producers would incur the costs of the antibiotic drug residue equipment ($200). All producers incur the cost for *Streptococcus-agalactiae* testing ($45). Total start-up costs for tuberculosis and brucellosis are: a) $141+$96 or a total of $237 for a 3-cow, b) $216+$200 or a total of $416 for a 20-cow herd, c) $366+$365 or a total of $731 for a 50-cow herd, and d) $666+$641 of a total of $1307 for a 100-cow herd. Thus, total start-up costs are: $472 for a 3-cow herd; $661 for a 20-cow herd; $976 for a 50-cow herd; and $1552 for a 100-cow herd.

8. Other Business Decision Costs Not Factored into the Analysis. Producers may incur other costs, depending on the business decisions they make. For example, if a producer decides to bottle and refrigerate the milk prior to sale, additional costs will be incurred for equipment and supplies. These costs are not factored into the cost analysis.

Specific Notes on Cost Estimates

1. Standard plate count. A single raw milk sample can be used for both standard plate count and coliform count, and a single shipment can include this raw milk sample as well as the sample for somatic cell count. The cost of a sample vial is about $.30 or $.15 each for standard plate count and coliform count. Samples for standard plate count, coliform count and somatic cell count can be shipped together for $4-$5, or approximately $1.50 for each test. The total costs (vial, shipping, and testing) for each of the three laboratories contacted were: $4.00, $4.15 and $4.35. The total average cost is $4.17 for standard plate count.

2. Somatic Cell Count. The vial cost is $.30. Shipping cost is shared with standard plate count and coliform count, and is $1.50 per test (see standard plate count note above). The total cost (vial, shipping, and testing) for each of the three laboratories contacted were: $2.75, $2.80 and $3.25 The total average cost was $2.90 for somatic cell count.

3. Coliform Count in Raw Milk: The test for coliform count (coliform bacteria) can be done on the same raw milk sample as standard plate count, so vial costs are shared and are $.15 for each test. Shipping costs are shared (see note for standard plate count above) and are $1.50 for each test. Testing costs estimates are available from only one laboratory and total cost was $6.50.

4. Coliform Bacteria in Well Water. State Laboratory of Hygiene (SLH) costs are $27 using a kit mailed by SLH, and return mailing costs are $4.95. However, other laboratories will likely do the tests for regular customers, and the cost estimate from one laboratory was less expense at $10.20. Although many producers are likely to be able to get the lower rate from the laboratory they use for other tests, the higher cost for the SLH was used in the cost analysis.

5. Antibiotic Drug Residue: The assumption is that the SNAP screening test will be used (Approved by FDA). A SNAP test kit costs $66 for 20 tests, or $3.30 per test. The tests must be performed every day raw milk is sold, assumed to be every other day in this example. Three tests must be performed each day raw milk is sold, one negative control, one positive control and one sample to show the test kit works properly, for a total of $9.90 every other day. Total cost for the year is $9.90 times 183 (every other day testing) or $1811.70 per year. The test also requires an equipment purchase of an incubator or heater block for roughly $200. (Some producers may already have this equipment.) Amortized annual equipment cost over three years at 6% interest is $72.96. A positive test would need to be confirmed at a laboratory at a cost of $6, a cost not included in the analysis because of the difficulty of estimating the number of times a test will need to be confirmed.

6. *Salmonella*. Raw milk samples for *Salmonella, Listeria, Campylobacter*, and *E. coli* O157:H7 can be shipped together for about $5 or an average of $1.25 for each test. The vial cost is $.30 and testing costs are estimated at $40 for a total of $41.55 for Salmonella.

7. *Listeria*. Raw milk samples for *Salmonella*, *Listeria*, *Campylobacter*, and *E. coli* O157:H7 can be shipped together for about $5 or an average of $1.25 for each test. The vial cost is $.30 and testing costs are estimated at $36 for a total of $37.55 for *Listeria*.

8. *Campylobacter*. The raw milk samples for *Salmonella, Listeria, Campylobacter*, and *E. coli* O157:H7 can be shipped together for about $5 or an average of $1.25 for each test. The vial cost is $.30 and testing costs are estimated at $50 for a total of $51.55 for *Campylobacter.*

9. *E. coli* O157:H7. The raw milk samples for *Salmonella, Listeria, Campylobacter*, and *E. coli* O157:H7 can be shipped together for about $5 or an average of $1.25 for each test. The vial cost is $.30 and testing costs are estimated at $50 for a total of $51.55 for *E. coli* O157:H7.

10. *Streptococcus agalactiae*. The *Streptococcus agalactiae* (strep-ag) test is a one-time test. The herd must be tested prior to issuance of a raw milk permit. In addition, animals added to the herd required a new test. The producer can collect the raw milk sample from the bulk milk tank and ship it to the laboratory for about $10. The laboratory will charge a $10 accession (administrative) fee, and $25 for the test. Total cost is $45 and does not depend on herd size. Raw milk produced from new animals coming into the herd must be tested and the cost is about $8, but this cost was not factored into the cost analysis because it is unlikely new animals will be coming into the herd.

11. Tuberculosis. The cow herd must test tree of tuberculosis prior to issuance of a raw milk permit. In addition the herd must be tested routinely either every three years or the producer can use the testing protocol for obtaining tuberculosis-free herd status which requires testing two years out of every four years. Also, new animals entering the herd must test tuberculosis-free. In this analysis it is assumed that the producer chooses the cheaper three-year option for the ongoing testing required. (Choosing to use the tuberculosis-free herd status option will increase tuberculosis test costs by about 50% but will have very little impact on the total regulatory cost per gallon of raw milk sold). It is also assumed that no new animals join the herd during the three year period (the cost of testing one additional cow would be about $141). The costs of the TB test are treated as a start-up cost amortized over three years. The tuberculosis test is an injection administered by a veterinarian, and there is no cost for the injection per se. Veterinary hourly costs vary from $120 to $200 per hour, and for this analysis $150 per hour was used and billed by the quarter, half, or full hour. Trip charges vary from $25-$40 per trip, and for this analysis $33 per trip was used as the per-trip-charge.

The veterinarian can inject (test) 40 to 60 cows per hour. The veterinarian will read the test results on a return trip, assumed to require the same or less time to read the reactor cows vs. injection. Reactor animals are by USDA at no charge. In this analysis it is assumed 50 cows are tested per hour.

i. Per-cow start-up costs for a 3-cow herd are: time cost $25 (quarter-hour charge of $37.50 times 2 trips divided by 3) and trip costs of $22 ($33 times 2 trips divided by 3) for a total per-cow cost of $47.00. Amortized over 3 years at 6% interest yields an annual per-cow cost of $17.16.

ii. Similarly, the cost for a 20-cow herd is $150 for testing and $66 for the trip for a total of $216 or $10.80 per cow. Amortized annual cost is $3.96 per cow.

iii. The cost for a 50-cow herd is $300 for testing and $66 for the trip for a total of $366 or $7.32 per cow. Amortized annual cost per cow is $2.64.

iv. For a 100-cow herd the total costs are $600 for testing and $66 for the trip for a total of $666 or $6.66 per cow. Amortized annual cost is $2.40 per cow.

12. Brucellosis. The cow herd must test free of brucellosis prior to issuance of a raw milk permit. In addition the herd must be tested routinely either every three years or the producer may use the testing protocol for obtaining a brucellosis-free herd status which requires testing two years out of every four years. New animals entering the herd must test brucellosis-free. In this analysis it is assumed that the producer chooses the cheaper three-year option for the routine testing. If the producer seeks brucellosis-free herd status the brucellosis test costs will increase by roughly 50% but will have very little impact on the total regulatory cost per gallon of raw milk. It is also assumed that no new animals will join the herd during the three year period (the cost of testing a single new cow would be about $92). The costs of the brucellosis test are treated as a start-up cost amortized over three years. The brucellosis test is based on a blood sample drawn by a veterinarian. Veterinary hourly costs vary from $120 to $200 per hour, and for this analysis $150 per hour was used and billed on the quarter, half or hour. Trip charges vary from $25-$40 per trip, and for this analysis $33 per trip was used. The veterinarian can draw blood from 30 to 45 cows, and 38 cows per hour was used as the estimate here. Shipping costs are about $10. Laboratory costs are a flat administrative (accession) fee of $10 and a testing fee of $1.75 per sample (per cow).

i. Per-cow brucellosis start-up costs for a 3-cow herd are include a vet time cost of $12.50 per cow (quarter-hour charge of $37.50 divided by 3), trip cost per cow of $11 ($33 total cost divided by 3), shipping cost per cow of $3.33 ($10 divided by 3), accession fee of $3.33 per cow ($10 divided by 3) and a testing costs of

$1.75 per cow, for a total per-cow cost of $31.91. Amortized over 3 years at 6% interest yields an annual per-cow BR cost of cost of $11.64.

ii. Similarly, the per-cow cost in a 20-cow herd is the vet time cost of $5.62 per cow (for three-quarters of an hour, $112.50 divided by 20), trip cost of $1.65 per cow ($33 divided by 20), shipping cost of $.50 per cow ($10 divided by 20) accession fee per cow of $.50 ($10 divided by 20), and testing fee of $1.75 per cow (sample). Total per cow cost is $10.02 and the annual amortized cost per cow is $3.60.

iii. For a 50-cow herd the costs per cow are $7.31 (vet time $4.50, $.66 trip charge, $.20 shipping, $.20 accession fee, $1.75 testing). The annual amortized cost is $2.69 for the 50-cow herd.

iv. For the 100-cow herd, costs are $6.41 per cow ($4.13 vet fee, $.33 trip fee, $.10 shipping, $.10 accession fee, $1.75 for testing). The annual amortized cost is $2.34 per cow.

13. Milk Production per Cow by Herd Size. USDA, National Agricultural Statistics Service, reports that in 2007 Wisconsin average annual production of milk per cow, by herd size, was: for 1-29 cow herds is 12,869 lbs/cow; for 30-49 cow herds is 15,794 lbs/cow; for 50-99 cow herds is 17,972 lbs/cow; for 100-199 cow herds is 19,303 lbs/cow. The analysis assumes that 100 pounds of milk is equivalent to 11.63 gallons.

14. Method to Calculate Cost per gallon: Total cost per gallon is = (total cost/cow) divided by (average pounds per cow divided by 100 times 11.63)

15. Method to Calculate Cost to the Consumer: Cost of raw milk to the consumer varies from $5/gallon to $10/gallon. Assuming that the producer passes along all regulatory cost to the consumer, the percent increase in price depends on the herd size and initial price. For the cost analysis, the lower estimated prices of $5/gallon and $7/gallon for raw milk purchased on the farm were used. (In comparison, the retail price of 1 gallon of organic milk (which is pasteurized) ranges between $5.50 to $6.50 depending on whether the consumer purchases two half gallons, one gallon, or another container size.)

Note: Detailed information on these cost estimates is available by contacting the Wisconsin Department of Agriculture, Trade, and Consumer Protection.

Appendix 13

Seven State Matrix: Wisconsin, California, Pennsylvania and Washington State

On-Farm Testing of Animals, Well Water, and Unpasteurized Milk

Comparing the Wisconsin Proposal with Selected States Allowing Unpasteurized Milk Sales
Comparing State Tests, Test Standards and Frequency of Testing

	Proposed Wisconsin	California*	Pennsylvania	Washington State
Test	**Test Standard** ***Frequency of Test***	**Test Standard** ***Frequency of Test***	**Test Standard** ***Frequency of Test***	**Test Standard** ***Frequency of Test***
Standard Plate Count (SPC)	≤ 20,000 cfu/mL *Prior to Licensing, then Weekly Testing*	≤ 15,000 cfu/mL *Test 4 out of 6 months*	≤ 20,000 cfu/mL *Test 2 times/month*	≤ 20,000 cfu/mL *Monthly Testing*
Somatic Cell Count (SCC)	≤ 400,000 cells/mL *Prior to Licensing, then Weekly Testing*	≤ 600,000 cells/mL *Test 4 out of 6 month*	≤ 1,000,000 cells/mL** *Monthly Testing*	≤ 750,000 cells/mL *Monthly Testing*
Coliform Bacteria in Milk	≤ 10 cfu/mL *Prior to licensing, then Weekly Testing*	≤ 10 cfu/mL *Test 4 out of 6 months*	≤ 10 cfu/mL *Test two times/month*	≤ 10 cfu/mL *Monthly Testing*
Antibiotic Drug Residue	Negative Result on FDA Approved Test *Prior to licensing, then Test each lot of milk produced going into a container for sale*	Negative Result on FDA Approved Test *Each bulk milk tanker truck tested prior to receipt for bottling*	Negative Result on FDA Approved Test *Test two times a month*	Negative Result on FDA Approved Test *Monthly*

	Proposed Wisconsin	California*	Pennsylvania	Washington State
Coliform Bacteria in Well Water	Wisconsin Drinking Water Standard *Prior to licensing, then Annual Testing*	CA Drinking Water STD *Prior to licensing, then every 3 years, and when opened for repairs. Bottling plants ea. 6 mo.*	None can be Found *Every six months*[i]	PMO Standard *Once every three years*
Pathogen: *Campylobacter*	None can be Detected *Prior to licensing, then Monthly Testing*	None can be Detected *Test 4 out of 6 months*	None can be Found *Annual Testing*	No
Pathogen: *Salmonella*	None can be Detected *Prior to licensing, then Monthly Testing*	None can be Detected *Test 4 out of 6 months*	None can be Found *Annual Testing*	None can be Detected *Monthly Testing*
Pathogen: *Listeria*	None can be Detected *Prior to licensing, then Monthly Testing*	None can be Detected *Test 4 out of 6 months*	None can be Found *Annual Testing*	None can be Detected *Monthly Testing*
Pathogen: *E. coli* O157:H7	None can be Detected *Prior to licensing, then Monthly Testing*	None can be Detected *Test 4 out of 6 months*	None can be Found *Annual Testing*	None can be Detected *Monthly Testing*
Other Pathogen Tests?	No	No	No	?
Animal Health: Brucellosis	Brucellosis Free Herd *Prior to License, All New Animals Coming In, and Certified BR-Free or Every 3 Years*	Brucellosis Free Herd *Annual Testing*	Brucellosis Free Herd *Annual Blood Testing*	Brucellosis Free Herd[ii] *Annual Testing*

	Proposed Wisconsin	California*	Pennsylvania	Washington State
Animal Health: Tuberculosis	Tuberculosis Free Herd *Prior to License, All New Animals Coming In, and Accredited TB-Free or Every 3 Years*	Tuberculosis Free Herd *Annual Testing*	Tuberculosis Free Herd *Annual Blood Testing*	Tuberculosis Free Herd[iii] *Annual Testing*
Animal Health: Other Animal Health Testing or Regulations?	*Streptococcus agalactiae* *Prior to License, New Animals Coming In, Milk Cultured when SCC >400,000 cells/mL*	No	Herd health evaluation by licensed veterinarian *Done Annually*	*Coxiella burnetii* (Q Fever) *Herd must test negative prior to licensing, then tested annually*

Matrix (Continued) with Connecticut, Idaho, New York, & South Carolina

On-Farm Testing of Animals, Well Water, and Unpasteurized Milk

Comparing the Wisconsin Proposal with Selected States Allowing Unpasteurized Milk Sales

Comparing State Tests, Test Standards and Frequency of Testing

	Connecticut	Idaho	New York State	South Carolina
Test	**Test Standard** ***Frequency of Test***	**Test Standard** ***Frequency of Test***	**Test Standard** ***Frequency of Test***	**Test Standard** ***Frequency of Test***
Standard Plate Count (SPC)	≤ 30,000 cfu/mL *Monthly Testing*	≤ 15,000 cfu/mL *Test 4 out of 6 months*	≤ 30,000 cfu/mL *Monthly Testing*	≤ 10,000 cfu/mL *Test 4 out of 6 months*
Somatic Cell Count (SCC)	≤ 750,000 cells/mL *Monthly Testing*	≤ 500,000 cells/mL *Test 4 out of 6 months*	≤ 750,000 cells/mL *Monthly Testing*	≤ 500,000 cells/mL *Test 4 out of 6 months*
Coliform Bacteria in Milk	≤ 50 cfu/mL *Monthly Testing*	≤ 25 cfu/mL *Test 4 out of 6 months*	Test for Escherichia coli rather than Coliform.[iv] *Quarterly*	≤ 10 cfu/mL *Test 4 out of 6 months*
Antibiotic Drug Residue	None Over FDA Tolerance Level *Daily by producer with more than 10 milking animals*	Negative Result on FDA Approved Test *Test 4 out of 6 months*	Negative Result on FDA Approved Test *Monthly*	Negative Result on FDA Approved Test *Test 4 out of 6 months*
Coliform Bacteria in Well Water	Drinking Water Standard *Annual testing*	PMO Standard *Once every three years*	PMO Standard *Once every three years*	Coliform Absent *Once every three years*

	Connecticut	Idaho	New York State	South Carolina
Pathogen: *Campylobacter*	None can be Detected *Quarterly Testing*	No	None can be Detected *Quarterly*	None can be detected *Test 4 out of 6 months*
Pathogen: *Salmonella*	None can be Detected *Quarterly Testing*	No	None can be Detected *Quarterly*	None can be detected *Test 4 out of 6 months*
Pathogen: *Listeria*	None can be Detected *Quarterly Testing*	No	None can be Detected *Quarterly*	None can be detected *Test 4 out of 6 months*
Pathogen: *E. coli* O157:H7	None can be Detected *Quarterly Testing*	No	None can be Detected *Quarterly*	None can be detected *Test 4 out of 6 months*
Other Pathogen Tests?	No	No	No	No
Animal Health: Brucellosis	Brucellosis Free Herd *Annual Testing*	Brucellosis Free Herd *At least semiannually and all female dairy animals must be vaccinated between 4 and12 months of age*	Brucellosis Free Herd *Annual Testing*	Brucellosis Free Herd *Test every 12 months*
Animal Health: Tuberculosis	Tuberculosis Free Herd *Annual Testing*	Tuberculosis Free Herd *Annual Testing*	Tuberculosis Free Herd *Test only If animal is exposed to TB*	Tuberculosis Free Herd *Test every 12 months*
Animal Health: Other Animal Health Testing or Regulations?	Must be enrolled in the Connecticut State Mastitis Program	No	*Staphylococcus aureus* [v] <10,000/mL *Quarterly testing*	No

The information in this chart was gathered from the state agencies regulating the raw milk law for that state. Information was not collected from other states on testing requirements prior to licensing farms.

* The State of California allows the sale of raw milk, but counties may prohibit the sale. Three California counties prohibit the sale of raw milk.

** A current Pennsylvania rulemaking proposal is being considered to lower the SCC standard to less than or equal to 750,000cells/mL.

[1] Pennsylvania requires producers to provide its Department of Agriculture with water testing lab results done during the six months prior to renewing a raw milk permit. In addition, the water must be retested anytime there is a repair or change made to the farm's water system.

[1] Animals must be Brucellosis-Free within the previous 12 months.

[1] Animals must be Tuberculosis-Free within the previous 12 months.

[1] New York standard for *Escherichia coli* test is <10 and recall at $\geq$ 10/mL.

[1] New York standard for *Staphylococcus aureus* test is <10 and recall at 100,000/mL.

Appendix 14

Testing Regulations Recommended for Wisconsin

Testing Summary for Raw Milk, Well Water, and Cows

Test	Test Standard *Frequency of Test*
Standard Plate Count (SPC)	≤ 20,000 cfu/mL *Prior to Licensing, and then Weekly Testing*
Somatic Cell Count (SCC)	≤ 400,000 cells/mL *Prior to Licensing, and then Weekly Testing*
Coliform Bacteria in Milk	≤ 10 cfu/mL *Prior to Licensing, and then Weekly Testing*
Antibiotic Drug Residue	Negative Result on the FDA Approved Test *Test Done on Each Lot of Milk Produced Going into a Container for Sale*
Coliform Bacteria in Well Water	Wisconsin Drinking Water Standard *Prior to Licensing, and then Annual Testing*
Pathogen: *Campylobacter*	None can be Detected *Prior to Licensing, and then Monthly Testing*
Pathogen: *Salmonella*	None can be Detected *Prior to Licensing, and then Monthly Testing*
Pathogen: *Listeria*	None can be Detected *Prior to Licensing, and then Monthly Testing*
Pathogen: *E. coli* O157:H7	None can be Detected *Prior to Licensing, and then Monthly Testing*
Animal Health: Brucellosis	Brucellosis Free Herd *Prior to License, All New Animals Coming In, and Certified BR-Free or Every 3 Years*
Animal Health: Tuberculosis	Tuberculosis Free Herd *Prior to License, All New Animals Coming In, and Accredited TB-Free or Every 3 Years*
Animal Health: *Streptococcus agalactia*	*Streptococcus agalactia* *Prior to License, All New Animals Coming In, and Milk Cultured when SCC exceeds > > >400,000 cells/mL*

DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

175

REVIEW AND APPROVAL OF DEPARTMENT FEES

I. BACKGROUND

Many of the Department's programs are funded wholly or partially by fees paid by individuals and businesses. The Department collects a variety of fees for services provided to businesses and industry, for licensing, certification and other regulatory functions. Fees are authorized by statute and fee amounts are set by statue, rule, or administratively. Fees collected by the Department are deposited to specific appropriations, generally to fund specific programs.

The legislature establishes spending authority by fiscal year for revenues collected by the Department. The amount of revenue collected is distinct from the level of spending authority granted. Revenues must be sufficient to fund a program's cost.

II. POLICY

The Department and the Board of Agriculture, Trade and Consumer Protection should set fees consistent with these guidelines.

A. The Department and Board should consider providing any service or program with general purpose revenue, when any of the following apply:
   1. The public is chief beneficiary.
   2. Business and industry receives little, if any, direct benefit.
   3. The service is mandated by statute or regulation.

B. The Department and the Board should consider providing a service through a reasonable cost-sharing arrangement, when any of the following apply:
   1. The affected parties directly benefit.
   2. The public also is a direct beneficiary.
   3. The service may or may not be mandated by statute or regulation.

C. The Department and Board should consider recovering all costs of service when any of the following apply:
   1. The affected parties are the principal, direct beneficiaries.
   2. The public receives primarily secondary benefits.
   3. Industries or businesses requested the service.
   4. The service is not mandated by statute or regulation.

III. **PROCEDURES**

A. **Division Responsibility.** Divisions are responsible for reviewing and monitoring fees to assure they are consistent with the guidelines and sufficient to cover program costs and their spending authority.

B. **Fee Approval Process.** All fees and changes to fees must be approved by the Bureau of Budget and Accounting and the Secretary's Office before they are implemented. In some cases , the proposed fee must also be approved by the Board of Agriculture, Trade and Consumer Protection. Divisions must submit any request for a fee increase to their Division Administrator for approval. Once approved, the proposed fee is submitted to the Bureau of Budget and Accounting and then to the Secretary's Office for review and approval. This applies to requests for fee increases outside the biennial budget process. Division staff should provide thorough data and analysis to support the need for a fee or fee change.

C. **Biennial Fee and Program Cost Review.** The Department will review fees and program costs every other year, during the months of September through December in odd numbered years, prior to initiating the biennial budget process.

IV. **APPLICABILITY**

This policy applies to all fees collected and administered by the Department except photocopy fees.

Alan T. Tracy
Secretary

02-13-95
Date

Appendix 16

JIM DOYLE
GOVERNOR
STATE OF WISCONSIN

May 19, 2010

TO THE HONORABLE MEMBERS OF THE SENATE:

I am vetoing 2009 Wisconsin Senate Bill 434 in its entirety. I commend the Legislature for their thoughtful consideration of this issue, but the public health community has been nearly unanimous in their opposition to this proposal. I cannot ignore the potential harmful health effects of consuming unpasteurized milk that have been raised by many groups, including: the Wisconsin Chapter of the American Academy of Pediatrics, the Wisconsin Public Health Association, the Wisconsin Association of Local Health Departments and Boards, the Wisconsin Academy of Family Physicians, the Wisconsin Medical Society, Marshfield Clinic, Gundersen Lutheran and the Wisconsin Veterinary Medical Association.

The sale of unpasteurized milk has become an increasingly contentious issue in Wisconsin and around the country. I recognize that there are strong feelings on both sides of this matter, but I must side with public health and the safety of the dairy industry. Therefore, I am vetoing this bill.

Farmers who sell unpasteurized milk under the bill would be required to test the milk monthly and if pathogens are found, the Department of Agriculture, Trade and Consumer Protection could suspend a farmer's registration. However, these monthly tests would not be enough to ensure that all of the farmer's milk is free from harmful contaminates. This could result in serious illness or even death. Other states that allow the sale of raw milk have had to strengthen standards that are stricter than those in the bill following outbreaks of illness from drinking unpasteurized milk. The State of California requires a more comprehensive testing approach than what is contained in this bill. Their testing regimen quantifies coliform bacteria, a broad group of organisms that includes some types of pathogens, but also provides an overall indication of the hygiene level of the milk. This bill does not contain adequate testing requirements to ensure the safety of the public when consuming unpasteurized milk.

The dairy industry is the centerpiece of Wisconsin agriculture. We have worked successfully over the last seven years to modernize Wisconsin's dairy industry. An outbreak of disease from consumption of unpasteurized milk could damage the state's reputation for providing good, healthy dairy products, and hurt sales of pasteurized milk and other dairy products, resulting in significant financial loss for the entire dairy industry at a time when dairy farmers are already suffering.

(over)

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I recognize that there has been thoughtful and spirited discussion of this issue from proponents and opponents of the bill. The hard work of legislators in crafting this bill is to be commended. However, significant questions must be answered and improvements should be made, particularly in strengthening testing requirements of unpasteurized milk, before enacting this type of legislation. In January 2010 the Department of Agriculture, Trade and Consumer Protection created a Raw Milk Working Group comprised of a wide array of stakeholders and experts charged with reviewing the legal and regulatory framework that might allow for the sale of unpasteurized milk to consumers without compromising public health. I believe the Working Group should be allowed to complete its analysis prior to making changes to the legal framework surrounding unpasteurized milk.

I believe this veto is the right decision to protect the health and safety of Wisconsin citizens.

Respectfully submitted,

JIM DOYLE
Governor

Appendix 17

Meeting Dates and Information

on the

Raw Milk Policy Working Group

The Raw Milk Policy Working Group met 12 times for full day meetings between January 2010 and March 2011. All the meetings were held in Madison, Wisconsin. The working group meeting agendas and meeting summaries are posted on the DATCP website at http://datcp.wi.gov/.

The working group met on: March 15, April 30, May 17, June 11 and 29, July 14 and 29, August 17 and 31, October 5, December 17, 2010 and February 14, 2011.

Seven of the 12 working group meetings were filmed by *Wisconsin Eye,* Public Affairs Network, Inc. and are available for viewing at http://www.wiseye.org/. *WisconsinEye* provides online access to state and local government public policy debates and decision-making forums and activities for educational benefit of the public. *WisconsinEye* videotaped the working group meetings on June 11 and 29, July 14, August 17 and 31, October 5, and December 17, 2010.

Copies of this report may be found at the website of the Wisconsin Department of Agriculture, Trade, and Consumer Protection at http://datcp.wi.gov/.

Questions, comments, and information about the Raw Milk Policy Working Group and its report can be asked of the Secretary's Office of the Wisconsin Department of Agriculture, Trade, and Consumer Protection at (608) 224-5015 or by writing to the Secretary's Office, Department of Agriculture, Trade, and Consumer, P. O. Box 8911, Madison, WI 53708-8911 or via the internet at DATCPfood@wi.gov