# Indiana State Board of Animal Health
# Report on the Issue of Selling Unpasteurized Milk to Consumers

## Prepared for the Indiana General Assembly

**11/1/2012**

The 2012 Indiana General Assembly directed the Indiana State Board of Animal Health (BOAH) to conduct a study of the issue of farmers selling unpasteurized milk to consumers. The BOAH prepared this Report on the issue in response to the General Assembly's request.

# Summary

There is a significant risk that raw milk may contain pathogens. Pasteurization has worked well for many years to reduce substantially the risk of human illness from pathogens that may contaminate milk. The U.S. Food and Drug Administration, U.S. Centers for Disease Control and many other members of the public health community support required pasteurization of milk.

Even with the known risks associated with consuming unpasteurized milk, some consumers are demanding legal access to raw milk. Advocates assert that raw milk tastes better, is more nutritious and healthier. Advocates assert that they should be free to choose pasteurized or unpasteurized milk and that raw milk presents an economic opportunity for farmers.

Currently individuals are acquiring raw milk from producers through cow or herd share arrangements and pet food sales believing that these transactions are outside the current state statute requiring milk to be pasteurized. The current pasteurization statute does not explicitly contemplate these arrangements, creating uncertainty for regulators, producers and consumers as to the legal status of these transactions and arrangements.

Both sides of the raw milk debate have sincere deeply held positions on the issue. No consensus middle ground exists between the public health community that wants no raw milk sales to consumers and advocates who want raw milk sales to consumers.

BOAH believes that pasteurization is a practice that is highly effective in reducing the risk of human illness from pathogens in raw milk. Distributing raw milk for human consumption will increase the risk that someone will become ill from consuming raw milk. But the decision to authorize or not the sale of unpasteurized milk to consumers is ultimately a political decision. BOAH recommends that the Indiana General Assembly consider the following options when considering this issue:

**Option A.** Maintain the current requirement for milk to be pasteurized prior to sale and amend the statute to clarify that all persons producing milk for consumption must comply with state sanitation standards and pasteurize the milk regardless of the method used to distribute the milk, including cow or herd share arrangements and products labeled for pet food.

**Option B.** Change the current law requiring pasteurization to allow limited distribution of raw milk directly from the farmer producing the milk to consumers and authorize the BOAH to establish minimum sanitary requirements that may reduce the risk of human illness.
If Indiana is to move away from the current laws requiring pasteurization of milk and milk products sold to the public, the following principles should be followed:

1. The Indiana State Board of Animal Health should have the authority to adopt rules requiring permits and establishing sanitation standards for raw milk producers.
2. All farmers producing raw milk for consumption should be held to the same standards.
3. The sale of raw milk should be limited to the farmer producing the milk selling directly to consumers.

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## Introduction

The 2012 Indiana General Assembly adopted House Enrolled Act 1129 (HEA 1129). HEA 1129 includes non-code provisions requiring the Indiana State Board or Animal Health (BOAH) to **"conduct a study of the issue of farmers selling unpasteurized milk to consumers."** The Act requires BOAH to prepare a report setting forth the results of the study not later than December 1, 2012.[i]

BOAH has conducted a study of the issue of unpasteurized milk sales and has prepared this document to report the agency's findings.

## Study Process

In this report the BOAH has attempted to compile, summarize and represent information surrounding the arguments for and against selling raw milk to consumers. In preparing this report, BOAH collected information and ideas from many sources through the following processes:

**BOAH Research.** BOAH conducted research and compiled information on the issue in the following areas:

- Background information.
- Public health information.
- Raw milk advocates' information.
- How other states and countries have addressed the issue.

**Advisory Committee.** BOAH convened a volunteer advisory committee to study the issue of selling raw milk to consumers in Indiana. The Committee included representatives from many dairy interests with a varied set of experiences and knowledge. A list of the committee members is included in **Appendix A**. The Committee included members who were in favor of allowing raw milk sales to the public and members who opposed raw milk sales to the public. BOAH asked the Committee to put aside their opinions on whether or not raw milk sales should be legalized and consider the question: "If there were to be an Indiana program for the sale of raw milk, what should the program include?" The Committee's consensus thoughts and conclusions on that question are included in **Appendix B**.

**Virtual Public Hearing.** BOAH initiated a method to allow any member of the public to provide information or comments via a "virtual public hearing". The hearing began on June 1 and ended on September 1. Comments were submitted via the BOAH website or mailed to the agency. The BOAH received 831 comments via the virtual public hearing. The comments included 789 comments from Indiana residents. The BOAH did not view this process as a

referendum vote on whether or not raw milk should be allowed. BOAH's intent was to gather as many ideas as possible on the issue to inform the study. The people who submitted comments did not disappoint and provided many valuable ideas that informed the writing of this report.

**Dairy Farm Survey.** BOAH conducted a survey of state-permitted dairy farms to collect dairy farmers' opinions on the raw milk for consumption issue. In the survey, BOAH attempted to gather some information on how many current licensed dairy farms would be interested in selling raw milk for consumption if it were legal in Indiana. BOAH received 242 survey responses, a 15.8% response rate. Of the farmers who responded, 158 indicated they would sell raw milk to consumers if it was legalized in Indiana. Of the respondents who reported they would not sell raw milk to consumers if legalized, 34% cited liability concerns and 30% cited concerns with maintaining their relationship with their current cooperative.

## The Indiana Dairy Industry

A complete discussion of the make-up and economic impact of the Indiana dairy industry is beyond the scope of this report. A brief summary of the Indiana dairy sector includes the following:

- There are approximately 176,000 dairy cows in Indiana on 1527 dairy farms.
- These cows produce 3.4 billion pounds of milk per year, or 300 million pounds per month.
- This production places Indiana 14th in the rank of states by total milk production.
- Indiana's is home to 36 dairy processing plants that make a wide array of products. Indiana ranks number 2 among states in the production of low-fat ice cream in the U.S.

## Indiana Dairy Law

The State of Indiana has regulated the production of milk and dairy products since at least the 1920s. In 1925 the Indiana General Assembly passed a law requiring pasteurization of milk or tuberculin testing of cattle.[ii] The Milk Control Act was enacted on March 12, 1935.[iii] The Indiana Supreme Court ruled the Act was constitutional on March 26, 1936.[iv]

The current Indiana dairy inspection program is governed by the Indiana State Board of Animal Health. Ind. Code § 15-17-2-8 and Ind. Code § 15-18-1. The state dairy law requires a permit from BOAH prior to operating a dairy farm, milk plant, receiving or transfer station, milk tank truck or bulk milk hauler, or a milk container manufacturing facility. Ind. Code § 15-18-1-3.

The BOAH is authorized to adopt rules governing standards for the production of milk and milk products. Ind. Code 15-18-1-14. BOAH currently recognizes two grades of milk and milk products: Grade A and manufacturing grade.

Grade A milk is milk produced at a farm holding a Grade A dairy farm permit and meets the standards for Grade A milk. Grade A milk products are those produced at a plant holding a Grade A dairy plant permit. Grade A milk products must be made from Grade A milk and must meet the standard for Grade A products. There are many types of Grade A products, such as fluid milk, yogurt and various dairy ingredients. 345 IAC 8-2-1.5. **In Indiana, 1275 farms currently hold a Grade A dairy farm permit and 15 dairy plants holding a Grade A dairy plant permit.**

BOAH is required to adopt rules to establish standards for Grade A milk and milk products that are at least as effective in protecting public health as the standards adopted by the National Conference on Interstate Milk Shipments (NCIMS). IC 15-18-1-14 and 345 IAC 8. The NCIMS is a body made up of representatives from each state and the U.S. Food and Drug Administration. Farmers, processors, academia and advocacy groups also participate. The NCIMS cooperates with the U.S. Food and Drug Administration through a memorandum of understanding. The NCIMS conducts a conference every two years to establish and modify Grade A standards. The NCIMS standards are published in the Pasteurized Milk Ordinance (PMO) that provides the model standards for states to utilize when governing the production of Grade A milk and milk products. The NCIMS recently published a 2011 revision of the PMO.[v]

Manufacturing grade raw milk is milk produced on a dairy farm that does not have a Grade A dairy farm permit or otherwise does not meet the standard for Grade A raw milk. Manufacturing grade milk products are milk products that are not Grade A, such as cheese, butter, ice cream and other frozen desserts. 345 IAC 8-2-1.1(a)(29)-(30). The BOAH has established standards for manufacturing grade dairy farms and manufacturing grade dairy plants. 345 IAC 8-2-2 through 345 IAC 8-2-3. **In Indiana, 252 farms currently hold a manufacturing grade dairy farm permit and 21 dairy plants hold a manufacturing grade dairy plant permit.**

**The state dairy statute requires pasteurization of milk for human consumption.** The state dairy law prohibits the offering, display for sale, selling, delivering or possession with the intent to sell or deliver milk or milk products for human consumption unless "every particle of the final mixture of the milk or milk products used in processing manufacture has been thoroughly pasteurized by equipment approved by the board." Ind. Code § 15-18-1-21(a). A copy of this section is included in **Appendix C**.

The pasteurization requirement applies to Grade A and manufacturing grade milk and milk products. However, the pasteurization requirement does not apply to certain cheeses manufactured from raw milk if the cheeses are manufactured and aged in accordance with the statute and rules adopted by the BOAH. Ind. Code § 15-18-1-21(b) and 345 IAC 8-3-1(e).

The Indiana dairy inspection program at BOAH has a long-standing policy interpreting the pasteurization law not to apply to a dairy farmer utilizing unpasteurized milk from his or her farm in his or her household, for members of his or her household, and non-paying guests.

## United States Food and Drug Administration Regulation

**The U.S. Food and Drug Administration (FDA) prohibits the interstate sale of raw milk for human consumption through a regulation adopted in 1987.** The FDA rule governs only the interstate sale of unpasteurized milk to consumers. Each state governs the intrastate sale of unpasteurized milk to consumers.

The FDA regulation was adopted after a series of events beginning in 1973 that culminated in a decision issued by the United States District Court for the District of Columbia that ordered the FDA to "approve a rule banning the interstate sale of all raw milk and all raw milk products, both certified and non-certified".[vi] The published opinion includes a recounting of the history of the FDA rule. A copy of the opinion is included in **Appendix D**.

The current FDA regulation includes the following prohibition:

> Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.
> (a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties. 21 CFR § 1240.61(a).

A copy of the entire regulation is included in **Appendix E**.

The FDA has stated publicly an enforcement policy for the pasteurization regulation. The FDA states it has never initiated an enforcement action against individuals who transport raw milk across state lines solely for personal consumption and that it has no present intent to do so. The FDA maintains it will only enforce the regulation against persons who produce and/or distribute unpasteurized milk in interstate commerce. **Appendix F.**

There have been several recent attempts to modify or overturn the FDA regulation:

1. An on-line petition was submitted to the Office of the White House requesting support to modify the FDA regulation. The Office of the White House denied the request in February 2012. **Appendix G.**

2. Two bills were introduced into the 112th United States Congress to overturn the FDA regulation.[vii] **Appendix H**. Congress did not act on either bill.

3. The Farm-to-Consumer Legal Defense Fund filed a lawsuit challenging the constitutionality of the FDA regulation. This action was dismissed by the United States District Court for the Northern District of Iowa on March 30, 2012.[viii] The suit was dismissed on the grounds that the plaintiffs lacked standing because there was no injury in fact because the FDA made it "abundantly clear" that the FDA has not and does not intend to enforce the regulations against "an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption".[ix]

The FDA has engaged in recent activity to enforce their interstate rule:

In February 2012 the FDA obtained a permanent injunction preventing a farmer holding a Pennsylvania license to sell unpasteurized milk to consumers from transporting his unpasteurized products across state lines.[x] **Appendix I**.

News reports indicate the FDA has recently investigated a Northern Indiana farm for alleged violations of the FDA regulation.[xi] **Appendix J**.

## What is Pasteurization?

**Pasteurization is the process of exposing a food to an elevated temperature for a period of time sufficient to destroy certain microorganisms without radically altering the food.[xii]**

For the production of milk and dairy products, pasteurization standards are established by the U.S Food and Drug Administration (FDA) by regulation.[xiii] Pasteurization is further defined by the states through the NCIMS process and states' adoption of the Pasteurized Milk Ordinance (PMO) standards.[xiv]

The pasteurization standards for milk and milk products require heating every particle of milk and milk product in properly designed and operated equipment to a temperature for a designated time. Recognized time, temperature and equipment combinations are set forth in rules. Other time, temperature and equipment processes may be recognized by the Food and Drug Administration as meeting the pasteurization requirements if the FDA determines them to be equally efficient in the destruction of microbial organisms of public health significance.[xv]

The pasteurization standards further define specific processes such as:

"ultra-pasteurization" that produces a product with extended shelf-life under refrigerated conditions; and

"aseptic processing" that produces a product to maintain commercial sterility under normal unrefrigerated conditions.[xvi]

Pasteurization virtually eliminates pathogens in milk. Pasteurized milk must be handled appropriately, such as maintaining refrigeration, to prevent reintroduction and growth of bacteria that may contaminate the product.

## History of Pasteurization

**Raw milk was recognized as a source of severe infections more than 100 years ago. Pasteurization of milk to prevent these infections is considered one of the public health triumphs of the 20th century.**

In 1938, milkborne illness outbreaks constituted twenty-five percent of all disease outbreaks due to infected foods and contaminated water. Today milk and fluid products are associated with less than one percent of such reported outbreaks. [xvii] The reduction in the number of milkborne illnesses over this time reflects the implementation of improvements in many areas including the following:

i. Programs to control animal diseases, such as brucellosis, tuberculosis and mastitis;
ii. Enhanced farm sanitation practices;
iii. Temperature control of milk products from the farm to the consumer; and
iv. Pasteurization of the majority of commercial dairy products.[xviii]

Routine pasteurization of milk began in the 1920s and became widespread in the United States by 1950 as a means to reduce contamination and resulting illness. This led to dramatic reductions in diseases previously associated with milk. Many public health experts consider pasteurization to be one of public health's most effective food safety interventions.[xix]

A chart summarizing the history of pasteurization is included in **Appendix K**.[xx]

## The Argument for Pasteurizing Milk.

**The U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) have repeatedly issued warnings that raw milk may harbor dangerous microorganisms that can pose serious health risks to people. Appendix L.** The proponents of pasteurization and prohibiting raw milk sales make the following points[xxi]:

1. Unpasteurized milk can carry dangerous organisms that are a threat to the public's health.
   - Unpasteurized milk can carry dangerous bacteria, such as *Salmonella enterica*, *E. coli* O157:H7, *Campylobacter jejuni* and *Listeria monocytogenes*, which are responsible for causing numerous foodborne illnesses.

- In recent years, pathogenic microorganisms have been isolated in bulk milk tank samples at rates ranging from 0.87% to 12.6% of total samples collected, indicating a measurable probability of encountering pathogenic bacteria in raw milk.[xxii]
- Harmful bacteria in raw milk can seriously affect the health of anyone who drinks raw milk, or eats foods made from raw milk. The bacteria in raw milk can be especially dangerous to pregnant women, children, the elderly, and people with weakened immune systems.
- Getting sick from raw milk can mean many days of diarrhea, stomach cramping, and vomiting. Most healthy people will recover from an illness caused by harmful bacteria in raw milk.
- Some people who become ill from harmful bacteria in raw milk can develop symptoms that are chronic, severe, or even life-threatening. Such illnesses can lead to kidney failure, paralysis, chronic disorders, and even death. For example, a person can develop Guillain-Barré syndrome, which can cause paralysis and hemolytic uremic syndrome that can result in kidney failure and stroke.
- Raw milk does not kill dangerous pathogens by itself.

2. Milk may be contaminated on the farm in any of the following ways:
   - Cow feces coming into direct contact with the milk.
   - Infection of the cow's udder (mastitis).
   - Animal diseases. Animals that shed organisms capable of causing disease in humans in the animal's milk, such as bovine tuberculosis and brucellosis.
   - Bacteria that live on the skin of cows.
   - Bacteria in the environment (e.g., feces, dirt, processing equipment).
   - Insects, rodents, and other animal vectors.
   - Humans, for example, by cross-contamination from soiled clothing and boots.

3. Adherence to good hygienic practices during milking can reduce, but not eliminate, the risk of milk contamination.
   - The dairy farm environment is a reservoir for illness-causing organisms.
   - No matter what precautions farmers take, they cannot guarantee that their milk or the products made from their milk are free of harmful organisms.
   - Even if tests of raw milk for pathogens are negative, there is no guarantee that the milk does not contain harmful organisms.
   - Animals that carry harmful pathogens usually appear healthy.

4. Pasteurization of milk is an effective method for reducing the public health risk of pathogenic organisms in raw milk.

- Pasteurization does kill harmful bacteria.
- Pasteurization kills harmful organisms responsible for diseases such as listeriosis, typhoid fever, tuberculosis, diphtheria, and brucellosis.
- Pasteurized milk contains low levels of the type of nonpathogenic bacteria that can cause food spoilage, so storing pasteurized milk in the refrigerator is still important. It is not safe to leave milk out of the refrigerator for extended time, particularly after it has been opened.
- Pasteurization does save lives.
- Preventing food-borne illnesses saves tax money that would otherwise be spent on investigating food-borne illness outbreaks and treating victims.

5. Pasteurization does not reduce milk's nutritional value.
    - Research shows no meaningful difference in the nutritional values of pasteurized and unpasteurized milk.
    - Pasteurized milk is rich in proteins, carbohydrates, and other nutrients. Heat slightly affects a few of the vitamins found in milk: thiamine, vitamin B12, and vitamin C, but milk is only a minor source of these vitamins.
    - Pasteurizing milk does not cause lactose intolerance and allergic reactions. Both raw milk and pasteurized milk can cause allergic reactions in people sensitive to milk proteins.
    - Pasteurization has helped provide safe, nutrient-rich milk and cheese for more than 120 years.

Numerous organizations support pasteurizing milk and prohibiting the sale of unpasteurized milk to consumers. The following organizations have issued statements taking this position on the subject:

American Association of Food and Drug Officials
American Association of Public Health Veterinarians
American Medical Association
American Veterinary Medical Association
Association of Food and Drug Officials
Cornell University Food Science Department
Indiana State Medical Association
International Dairy Foods Association
International Association for Food Protection (IAFP)
National Environmental Health Association
National Mastitis Council
National Milk Producers Federation

**Appendix M**.

## Food Borne Illness Outbreaks and Raw Milk

Unpasteurized milk may contain pathogenic organisms. But has raw milk made people sick? **Recent studies and reports indicate that people have become sick from consuming raw milk.**

Pasteurization, correctly applied, eliminates pathogens in milk. However, from time-to-time outbreaks of human illness are associated with pasteurized milk and milk products due to post-pasteurization contamination. If a person may become sick from consuming pasteurized milk and may become sick from consuming unpasteurized milk, is there additional risk from consuming unpasteurized milk?

Scientists associated with the Centers for Disease Control (CDC) compile data on disease outbreaks. The CDC has analyzed dairy-associated disease outbreak occurrences and reports the following:

> **States that allow the legal sale of raw milk for human consumption have more raw milk-related outbreaks of illness than states that do not allow raw milk to be sold legally.**
>
> Among dairy product-associated outbreaks reported to CDC between 1973 and 2009 in which the investigators reported whether the product was pasteurized or raw, 82% were due to raw milk or cheese. From 1998 through 2009, 93 outbreaks due to consumption of raw milk or raw milk products were reported to CDC. These resulted in 1,837 illnesses, 195 hospitalizations, and 2 deaths. Most of these illnesses were caused by *Escherichia coli*, *Campylobacter*, or *Salmonella*. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; among the 93 raw dairy product outbreaks from 1998 to 2009, 79% involved at least one person younger than 20 years old.[xxiii]
>
> A study released by CDC in February 2012 examined the number of dairy outbreaks in the United States during a 13-year period. Between 1993 and 2006, 60% (73/121) of dairy-related outbreaks reported to CDC were linked to raw milk products. Three-quarters of these outbreaks occurred in states where the sale of raw milk was legal at the time. Experts also found that those sickened in raw milk outbreaks were 13 times more likely to be hospitalized than those who got ill from pasteurized milk during an outbreak.[xxiv]

A copy of this CDC article is included in **Appendix N.**

The CDC data on pasteurized and unpasteurized dairy-associated outbreaks has been compiled by the working group associated with the website www.realrawmilkfacts.com. Copies of these tables are included in **Appendix O** of this report.[xxv]

Proponents of raw milk consumption argue that the incidence of foodborne illness from dairy products, whether pasteurized or not, is extremely low. They accuse the CDC of using data selectively and misinterpreting data to make raw milk look dangerous by:

1. Focusing on outbreaks rather than the number of people who became ill and the severity of the illness.
2. Aggregating incidences of raw milk and raw milk products rather than identifying certain raw milk products, such as non-aged queso fresco raw milk cheese, that have caused a greater number of illnesses thereby distorting the safety of raw milk.
3. Underestimating the number of Americans who consume raw milk to distort the statistics. [xxvi] **Appendix P.**

## The Argument for Unpasteurized Milk and Opposition to Pasteurization

**Proponents of unpasteurized milk consumption argue that raw milk provides benefits to consumers and farmers and is no more risky than other food products.** Proponents make various claims about the dangers of pasteurizing milk. Not all proponents of raw milk agree on all aspects of the pro-raw milk argument. The following is a list of arguments various proponents have advanced in favor of consuming unpasteurized milk[xxvii]:

1. Raw milk contains beneficial properties and pasteurizing milk changes or destroys these properties.
   - Raw milk has a higher content of butterfat.
   - Raw milk has no additives.
   - Pasteurization destroys or inactivates enzymes in raw milk.
   - Pasteurization destroys the following properties of raw milk: B-lymphocytes, macrophages, neutrophils, lymphocytes, IgA/IgG antibodies, B12 binding protein, bifidus factor, medium-chain fatty acids, fibronectin, gamma-interferon, lactoferrin, lactoperoxidase, lysozyme, mucin A/Oligosaccharides, hormones and growth factors.
   -Pasteurization denatures proteins in raw milk.
   -Pasteurization destroys vitamins such as C, B12, and B6.
   -"Good" bacteria are destroyed through heat treatment (pasteurization). Good bacteria inhibit the growth of pathogens. Therefore, pasteurization leads to an increased risk of pathogens in milk.

2. Consuming raw milk cures or is beneficial to the treatment of certain conditions and consuming pasteurized milk causes or exacerbates certain conditions.
   - Consuming raw milk prevents or aids in the treatment of allergies, tooth decay, colic (infants), osteoporosis, arthritis, heart disease and cancer.
   - Pasteurization can worsen the symptoms of asthma and allergies.
   - Pasteurization causes lactose intolerance.
   - Raw milk helps people develop a strong immune system.

- Raw milk has healing powers.
- Raw milk is not homogenized. Homogenization is linked to heart disease.
- Raw milk has a probiotic effect.

3. Pasteurization does not guarantee safe milk. Pasteurization does not completely eliminate the risk of pathogens in milk. Pasteurization does not protect against the risk of all diseases that may be spread through milk. Some risk is associated with pasteurized milk and some risk is associated with raw milk. Therefore, pasteurized milk should not be required and unpasteurized milk should not be prohibited.
   - There have been outbreaks of human illness from pasteurized milk.
   - The sale of raw milk has been authorized in some states and countries for decades providing a track record of production that is not perfect, but compares favorably to the safety record of other foods.

4. Advancements in technology have solved the problems that led to the requirement for milk pasteurization.
   Management of the herd and the milking process determine the safety of milk. Pasteurization was developed a long time ago at a time when animal health and farm sanitation were inadequate for the production of safe raw milk. Dairy farms are different now and pasteurization is no longer needed because of the following developments:
   - Modern materials such as stainless steel are utilized to handle and store milk.
   - Advances in equipment technology, such as milking machines as opposed to hand milking, protect against contamination of milk.
   - Refrigeration of bulk tanks and refrigerated transportation provide readily available methods for safer storage and handling of raw milk.
   - Advances in sanitation technology and methods reduce the risk of milk contamination.
   - Advances in animal health and nutrition have reduced the risk of disease transfer from cows through milk. Advocates routinely link the safety and nutrition of raw milk to feeding cows grass through grazing as opposed to feeding grain.
   - Advances in testing for diseases and pathogens in animals, water and milk provide effective tools that can be used to manage the risk of pathogens in milk.

5. The sale of raw milk can save small family farms and promote rural development.
   - The demand for raw milk is an opportunity for small dairies to produce a product and sell it to consumers at a price that is profitable, rather than selling their raw milk to a processor for pasteurization at a lower price.

6. Consumers should have the freedom to choose to drink raw milk even if there are risks.
   - People should be free to choose what they eat without interference from government.

- Consumers may legally buy other raw foods that may carry pathogens, such as raw meat, raw chicken, raw eggs, raw fish, raw oysters, raw spinach, raw lettuce and more.
- Raw milk is as safe or safer than other foods that are commonly purchased raw.
- Raw milk tastes better.
- The benefits of raw milk outweigh the risks.

## Demand for Raw Milk

**Some Indiana consumers want unpasteurized milk. The extent of Indiana consumers' demand for unpasteurized milk is not known.** Farmers and consumers have engaged in various schemes to obtain unpasteurized milk. BOAH is aware that each of the following schemes have been and are likely currently being utilized in the state to distribute unpasteurized milk to consumers:

### Direct Sales

Some consumers may obtain raw milk directly from a farmer without regard for the current legal prohibition on raw milk sales.

### Pet Food Sales

The Office of the Indiana State Chemist (OISC) at Purdue University implements the Indiana Commercial Feed Law.[xxviii] The Feed Section of the Office of the Indiana State Chemist regulates commercial animal feeds, including pet and specialty pet food manufactured or distributed in Indiana. The OISC reports increased interest in farmers obtaining a commercial feed license to sell unpasteurized milk and milk products made from unpasteurized milk as animal food.

The Indiana State Board of Animal Health, the OISC, and local health departments have reported an increase in recent years in the number of retail stores and booths at farmers markets selling unpasteurized milk and milk products labeled as animal food. Some of these sales have been accompanied by literature or other promotions urging unpasteurized milk be used for human consumption.

In 2012 the Indiana General Assembly enacted amendments to Indiana Code 15-19-7-40 to require distribution of raw milk for use as commercial feed with a prominent label stating "Not for Human Consumption". The amendments further prohibited promoting or advertising animal feed as suitable for human consumption unless the products have met all legal requirements to be sold as human food.[xxix]

The American Veterinary Medical Association recently issued a policy discouraging the feeding of any animal-source protein to cats and dogs that has not first been subjected to a process to eliminate pathogens because of the risk of illness to cats and dogs as well as

humans. The AVMA statement includes feeding raw milk from a different species to a dog or cat.[xxx] **Appendix Q.**

Cow and Herd Shares

The Indiana dairy inspection program at BOAH has a long-standing policy interpreting the pasteurization law not to apply to the owner of a dairy farm utilizing unpasteurized milk in his or her household for members of his or her household and non-paying guests. Some proponents of unpasteurized milk have sought to exploit this policy to find a way to obtain "legally" unpasteurized milk. The types of schemes undertaken vary case-by-case but are often referred to as "cow share" or "herd share" arrangements.

Indiana has no uniform definition of what a cow share and herd share arrangement means. Many share arrangements involve the consumer signing a document that purports to transfer partial ownership of a cow, some cows, or an entire herd to the consumer. The agreement often specifies the quantity of milk the consumer may expect to receive from his or her share in the cow(s) or herd. The consumer pays money to the farmer for the share. Most agreements require an ongoing payment by the consumer to the farmer for the farmer to board the cow(s) and for the service of milking the cow(s) and bottling the milk for the consumer.

State and federal officials have successfully challenged some cow and herd share arrangements as merely disguised sales that are prohibited by state or federal pasteurization statutes.[xxxi] Other states have been only partially successful or unsuccessful in their challenges to cow and herd share arrangements.[xxxii] A small number of states have explicitly authorized cow and herd share arrangements. [xxxiii] The Indiana dairy inspection law[xxxiv] does not directly address the issue and the issue has not been litigated in Indiana.

Distribution Agreements

Farmers and consumers have attempted to circumvent the pasteurization requirement by distributing unpasteurized milk using numerous variations of farm-centric distribution channels. Examples include:

> A community supported agriculture (CSA) program where consumers purchase a membership or subscription that entitles them to a share of the farm's production.
>
> Buying clubs where consumers order products directly from the farm. The products may be delivered by the farmer or picked up by consumers.

The reasoning used to justify unpasteurized milk distribution in this manner varies. Often the claim includes the idea that these distribution channels are closed or limited to members only; therefore, state regulations, including the pasteurization requirement, do not apply.

**Insurance for Product Liability Risk**

Farmers selling unpasteurized milk to consumers are exposed to the risk that they will be held liable for injuries to consumers should customers become sick from their product. Is it possible for Indiana farmers to insure against the risk from liability resulting from selling raw milk?

The Indiana Department of Insurance reported to the BOAH the following concerning insurance coverage availability for liability resulting from the sale of raw milk products as of May 14, 2012:

> "Neither of the two largest property and casualty insurance bureaus have filed raw milk exclusion forms in Indiana. One of the bureaus indicated that they are monitoring the issue and plan to explore it further. The other bureau indicated that they make available sample endorsements to affiliates (subscribers) to assist with the development of custom or independent forms, although they have not developed sample exclusionary language applicable to liability resulting from a virus, bacterium or other microorganism that is within or on any products intended for human consumption.
>
> There are 5 insurance carriers that represent approximately 75% of the Farmowners market in Indiana. Of the top 5 carriers writing Farmowners coverage in Indiana (by Farmowners written premium reported), 2 exclude coverage for raw milk liability and 3 do not.
>
> The largest Farmowners carrier (by written premium) does have a raw milk exclusion in their Farmowners program, which accounts for nearly half of the Indiana marketplace.
>
> Insurer #1 – Market Share 46.75% - Raw Milk Exclusion
> Insurer #2 – Market Share 15.60% - No Raw Milk Exclusion
> Insurer #3 – Market Share 4.57% - No Raw Milk Exclusion
> Insurer #4 – Market Share 4.45% - No Raw Milk Exclusion
> Insurer #5 – Market Share 4.01% - Raw Milk Exclusion
>
> As bureau forms excluding liability for raw milk exposures are not generally available to insurance carriers in Indiana at this point in time, insurers who wish to eliminate or reduce this exposure are filing independent exclusion forms or reducing their exposure through underwriting practices."[xxxv]

## Intrastate Sales of Raw Milk in Other States

The National Association of State Departments of Agriculture (NASDA) conducted a survey of the states concerning the regulation and sale of raw milk to consumers. The reported survey results indicate that twenty states prohibit the sale of unpasteurized milk to consumers, including Indiana. The report indicates thirty states authorize the sale of unpasteurized milk to consumers in some manner.[xxxvi] **Appendix R.**

The states that allow the sale of unpasteurized milk to consumers regulate production and sale of the milk in various ways attempting to influence the risks associated with the practice. BOAH conducted a review of state laws governing the sale of unpasteurized milk to consumers and found that state regulations vary widely across the country.

**There is no standardized method utilized by the states to regulate the production or sale of unpasteurized milk to consumers. But, almost all of the states that allow unpasteurized milk sales limit access to raw milk and regulate the production and sale of the product.** The following is an outline of different methods utilized by states to regulate unpasteurized milk sales. A copy of a summary created by BOAH of various state law provisions is included in **Appendix S** of this report.

Regulations affecting where and how unpasteurized milk is sold.

Nearly all of the states that allow the sale of unpasteurized milk prohibit resale of the product and prohibit the sale of raw milk in restaurants, hotels, schools, health care facilities and other institutions.

Eighteen of the thirty states that authorize the sale of raw milk to consumers restrict sales to the farm where the milk was produced. Many states authorizing on-farm sales impose additional restrictions on sales, such as:

- Four states limit sales to goat milk only.
- Four states restrict sales to “incidental sales” only.
- A minority of states authorizing on-farm sales permit the farmer to deliver product direct to the consumer.

Twelve of the thirty states that authorize the sale of raw milk to consumers allow sales at retail stores and farmers markets in some manner. Some states authorizing retail sales impose additional restrictions on sales, such as restricting sales to stores owned by the farmer and restricting sales to goat milk only.

A minority of states have explicitly addressed cow or herd share arrangements. The states that have addressed these arrangements are split between those that exempt the arrangements from some regulations and states that treat the arrangements no differently than any other farm producing raw milk.

Many of the states authorizing raw milk sales restrict sales in other ways, such as the following:

A majority of states allow the sale of milk or milk and cream only, prohibiting the sale of milk products (butter, yogurt, etc.) made from unpasteurized milk.

A minority of states restrict the number of animals that may be milked or the volume of product that may be sold.

Licensing and Inspections

Nearly all of the states that allow the sale of unpasteurized milk to consumers require the farmer producing and packaging the milk to obtain a permit from the state and undergo sanitary inspections.

Minimum Sanitary Requirements

Most states authorizing the sale of unpasteurized milk to consumers have established standards for farmers to meet in the following areas:

- Cow health
- Milking parlor construction and sanitation
- Equipment construction and sanitation
- Milk quality, microbial and contamination standards and testing programs (somatic cell count, bacteria, coliform, pathogens, and drug residues)
- Cooling temperatures and storage
- Milk plant construction and sanitation
- Containers, filling and capping
- Labeling, including warning labels on containers and signage.

## Regulation of Raw Milk Sales in Other Countries

The BOAH did not attempt to conduct a comprehensive survey of the raw milk laws in other countries. The BOAH did accumulate some information on the following countries:

Canada

Federal law prohibits the sale of raw milk to consumers.

European Union

Member states are able to introduce or maintain national rules prohibiting or restricting sales of raw milk or raw cream intended for direct human consumption.

England and Wales

The United Kingdom Food Standards Agency reviewed the raw cow milk policy between 1997 and 1999 and concluded that the balance of stakeholder opinion was strongly in favor of the right to informed choice. The Agency revisited its raw milk policy in 2002 and concluded that relatively few people drink raw milk and those who do, do so regardless of the exiting health warnings. The Agency concluded that the most balanced approach would be to maintain the existing regulatory policy. The policy includes the following:

- Raw milk may be sold directly to consumers by registered milk production facilities, at the farm gate, in a farmhouse catering operation, through milk deliverymen or at farmers markets. Sales through other outlets have been banned since 1985.
- Herd health standards must be met.
- Producers of raw milk must comply with hygiene rules.
- Products must contain a health warning.
- Products are sampled and tested. [xxxvii]

Scotland

Raw milk and raw cream intended for direct human consumption is prohibited. The ban for cow milk has been in place since 1983 and was extended to include all milk in a January 2006 regulation. [xxxviii]

Italy

Since 2004, raw milk sales are allowed by local officials in territories. Italy formally authorized vending machine sales through automatic vending devices in 2007. Raw milk sales are regulated.

Germany

Raw milk sales from the farm are legal. Sales off of the farm and through vending machines allowed with additional regulation.

## Conclusion

Both sides of the raw milk debate have sincere deeply held positions on the issue. No consensus middle ground exists between the public health community that wants no raw milk sales to consumers and advocates who want raw milk sales to consumers.

There is a significant risk that raw milk may contain pathogens. Pasteurization effectively eliminates pathogens from milk therefore substantially reducing the risk that people will become ill from consuming milk containing pathogens. Passing a law allowing the sale of unpasteurized milk will likely lead to an increase in the number of farmers selling unpasteurized milk to consumers, an increase in the volume of unpasteurized milk sold to consumers and an increase in the number of people consuming raw milk. With more people exposed to greater volumes of unpasteurized milk, the risk that someone will become ill from consuming milk that contains pathogens will increase. Therefore, changing Indiana law to allow the sale of unpasteurized milk will increase the risk that consumers will become ill from consuming pathogens in unpasteurized milk.

The U.S. Food and Drug Administration has evaluated the risks associated with selling unpasteurized milk to consumers, decided the risks outweigh the benefits, and has acted to prohibit the sale of unpasteurized milk to consumers in interstate commerce.

Twenty states have evaluated the risks associated with selling unpasteurized milk to consumers, decided the risks outweigh the benefits, and have acted to prohibit the sale of unpasteurized milk to consumers within their states.

Thirty states have evaluated the risks associated with selling unpasteurized milk to consumers and decided to allow access to raw milk in some manner within their states. Almost all of these states limit consumer access to raw milk and regulate the production and distribution of raw milk in a manner designed to reduce, but not eliminate, the risks associated with unpasteurized milk.

**BOAH Recommendations**

Pasteurization has worked well for many years to reduce substantially the risk of human illness from pathogens that may contaminate milk.

Even with the known risks associated with consuming unpasteurized milk, some consumers are demanding legal access to raw milk. BOAH cannot quantify this demand. Currently individuals are acquiring raw milk from producers through cow or herd share arrangements and pet food sales believing that these transactions are outside the current state statute requiring milk to be pasteurized. The current pasteurization statute does not explicitly contemplate these arrangements, creating uncertainty for regulators, producers and consumers as to the legal status of these transactions and arrangements.

BOAH believes that pasteurization is a practice that is highly effective in reducing the risk of human illness from pathogens in raw milk. Distributing raw milk for human consumption will increase the risk that someone will become ill from consuming raw milk. But the decision to authorize or not the sale of unpasteurized milk to consumers is ultimately a political decision. BOAH recommends that the Indiana General Assembly consider the following options when considering this issue:

**Option A.** Maintain the current requirement for milk to be pasteurized prior to sale and amend the statute to clarify that all persons producing milk for consumption must comply with state sanitation standards and pasteurize the milk regardless of the method used to distribute the milk, including cow or herd share arrangements and products labeled for pet food.

**Option B.** Change the current law requiring pasteurization to allow limited distribution of raw milk directly from the farmer producing the milk to consumers and authorize the BOAH to establish minimum sanitary requirements that may reduce the risk of human illness.
If Indiana is to move away from the current laws requiring pasteurization of milk and milk products sold to the public, the following principles should be followed:

4. The Indiana State Board of Animal Health should have the authority to adopt rules requiring permits and establishing sanitation standards for raw milk producers.
5. All farmers producing raw milk for consumption should be held to the same standards.
6. The sale of raw milk should be limited to the farmer producing the milk selling directly to consumers.

## ENDNOTES

[i] House Enrolled Act 129.1.43 includes the following non-code provision:
SECTION 43. [EFFECTIVE UPON PASSAGE] **(a) As used in this SECTION, "board" refers to the Indiana state board of animal health established by IC 15-17-3-1.**
**(b) The board shall conduct a study of the issue of farmers selling unpasteurized milk to consumers.**
**(c) The study required by subsection (b) must be concluded before November 1, 2012.**
**(d) At the conclusion of the study, the board shall prepare a report setting forth the results of the study not later than December 1, 2012. The board shall:**
**(1) present the report to:**
**(A) the governor; and**
**(B) the legislative council in an electronic format under IC 5-14-6; and**
**(2) make copies of the report available to the public.**
**(e) This SECTION expires June 30, 2013.**

[ii] *Public Health in Indiana*, The Indiana Historian, Indiana Historical Bureau, http://www.in.gov/history/2917.htm (last visited September 21, 2012) .

[iii] Acts of 1935, Chapter 281, p. 1365.

[iv] *Alvert et al. v. Milk Control Board of Indiana*, 210 Ind. 283; 200 N.E. 688 (1936).

[v] The PMO is available online at the following site: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/default.htm

[vi] *Public Citizen v. Heckler*; 653 F. Supp. 1229 (D.D.C. 1986)

[vii] H.R. 1830, 112th Cong., 1st Sess. (2012) and S. 1955, 112th Cong., 2d Sess. (2012)

[viii] *Farm-to-Consumer Legal Defense Fund v. United States Department of Health and Human Services*; No. 5:10-cv-04018 (N. D. Iowa, filed Feb. 20, 2010)

[ix] *Farm-to-Consumer Legal Defense Fund v. United States Department of Health and Human Services*; No. 5:10-cv-04018, 2012 U.S. Dist. LEXIS 46290, at 2 (N. D. Iowa. March 30, 2012)

[x] *United States of America v. Daniel L. Allgyer*; No. 11-02651 (E. D. PA, February 2, 2012).

[xi] Roger Schneider, *Middlebury Dairy Farmer, Sheriff Stand up to FDA*, Goshen News, December 17, 2011.

[xii] "pasteurization" *Merriam-Webster.com*. Merriam-Webster, 2012. Web. 28 March 2012.

[xiii] 21 C.F.R. § 1240.61 (2011)

[xiv] 345 IAC 8-2-1.7

[xv] 21 C.F.R. § 1240.61(d) (2011)

[xvi] 345 IAC 8-2-1.7(d) and (e)

[xvii] U.S. Department of Health and Human Services, Public Health Service and Food and Drug Administration. 2011. Grade "A" Pasteurized Milk Ordinance. 2011 Revision. Available at: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/default.htm

[xviii] Position Statement on Raw Milk Sales and Consumption, Cornell University Food Science Department, *available at*: http://foodscience.cornell.edu/cals/foodsci/extension/milk-quality-improvement-program.cfm#Factsheets

[xix] Letter from Robert Tauxe, MD, MPH, Deputy Director, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, to State and Territorial Epidemiologists and State Public Health Veterinarians (July 18, 2012)(on file with the Indiana State Board of Animal Health).

[xx] Adapted from information on the web site: http://www.idfa.org/news--views/media-kits/milk/milestones

[xxi] Compiled from various sources, including the following:

Comments submitted to the Indiana State Board of Animal Health during a virtual public hearing held between Jun 1, 2012 and September 1, 2012.

U.S. Food and Drug Administration documents on raw milk are available at the following web sites: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm277854.htm

http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/default.htm

U.S. Centers for Disease Control and Prevention documents on raw milk are available at the following web site: http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html

*Position Statement on Raw Milk Sales and Consumption*, Cornell University Food Science Department, available at http://foodscience.cornell.edu/cals/foodsci/extension/milk-quality-improvement-program.cfm

*Raw milk Legislation Packet*, Real Raw Milk Facts (July 2012), http://www.realrawmilkfacts.com/legislation-packet/

[xxiii] http://www.cdc.gov/Features/RawMilk/

[xxiv] Adam J. Langer, ET AL., Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws- United States, 1993-2006, Emerging Infectious Diseases Journal, Vol. 18, No.3, March 2012, *available at* www.cdc.gov/eid,

[xxv] http://www.realrawmilkfacts.com/outbreak-tables

[xxvi] Press Release, The Weston A. Price Foundation, CDC Cherry Picks Data to Make Case Against Raw Milk, (February 22, 2012)

[xxvii] Compiled from various sources, including the following: Comments submitted to the Indiana State Board of Animal Health during a virtual public hearing held between Jun 1, 2012 and September 1, 2012; www.realmilk.com; http://www.thecompletepatient.com/; www.raw-milk-facts.com.

[xxviii] Indiana Code 15-5-3.

[xxix] P.L.99-2012

[xxx] *Raw or Undercooked Animal-Source Protein in Cat and Dog Diets,* American Veterinary Medical Association (July 2012), https://www.avma.org/KB/Policies/Pages/Raw-or-Undercooked-Animal-Source-Protein-in-Cat-and-Dog-Diets.aspx

[xxxi] *United States of America v. Daniel L. Allgyer*; No. 11-02651 (E. D. PA, February 2, 2012).

[xxxii] *State Appeal Dropped in Raw Milk Investigation*, AP March 21, 2007, available in LEXISNexis, AP State and Regional Wires – Ohio Stories.

[xxxiii] Colorado Revised Statutes 25-5.5-117 (2011); Idaho Administrative Code 02.04.13.008 (2011)

[xxxiv] Ind. Code 15-18-1.

[xxxv] E-mail from Kate E. Kixmiller, Deputy Commissioner, Indiana Department of Insurance to Doug Metcalf, Chief of Staff, Indiana Board of Animal Health (May 14, 2012, 11:31 AM)(on file at the BOAH).

[xxxvi] Ehart, Bob. "NASDA Releases Raw Milk Survey." www.nasda.org. July 19, 2011.

[xxxvii] *Raw drinking milk and raw cream control requirements in the different countries of the UK, May 11 2009*, http://www.food.gov.uk/business-inidustry/guidancenotes/hygguid/rawmilkcream (last visited July 16, 2012).

[xxxviii] Id.

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix A

Appendix A

INDIANA STATE BOARD OF ANIMAL HEALTH

Mitchell E. Daniels, Jr., Governor
Bret D. Marsh, DVM, State Veterinarian

Office of the State Veterinarian
Discovery Hall, Suite 100
1202 East 38th Street
Indianapolis, IN 46205
Phone: 317/544-2400

May 4, 2012

Dear Colleagues,

With the passage of House Bill 1129 this year, members of the Indiana General Assembly tasked the Indiana State Board of Animal Health with conducting a study of the issue of farmers selling unpasteurized milk to consumers. Since the Governor signed the bill, the BOAH staff has been developing a plan of action to complete this study and the requested report by the December 1 deadline. The report will be submitted to the Legislative Council and the Governor.

As part of this study, we would like to convene a voluntary advisory panel of stakeholders to gather input. We would like for you to be a member of that panel.

Currently, the sale of raw milk directly to consumers is prohibited by state law. Because the issue arose in this year's state legislative session, a proposal to allow legal sales could arise again. The state legislators will ultimately decide if that prohibition will continue.

The mission of the advisory panel is to formulate what we are calling a "Plan B." The "Plan B" will serve as a recommendation to legislators should they decide to change the prohibition on raw milk sales. In other words, if Indiana decides to change the law, what parameters should be established on this practice in the interest of public health?

BOAH plans to host at least two day-long, facilitated meetings of this advisory panel. **Please mark your calendars for Friday, June 15 and Friday, July 20. We'll convene at the BOAH central office at 10 a.m.** Each meeting should adjourn at approximately 3:30 p.m., and lunch will be provided. The need for future meeting(s) will be determined by the panel members.

In addition to the advisory panel, BOAH will be hosting a public comment period from June 1 to September 1, 2012. A web page on the BOAH site will be established to collect public input about the many aspects of this issue. Comments may be submitted online or by U.S. Mail.

The BOAH staff is doing additional research that will be included in the final report. BOAH is collecting information on how the issue is addressed in other states, as well as documented public health implications. This will be provided as background information to the advisory panel to serve as a foundation for developing "Plan B."

BOAH would appreciate your assistance with this project. Please RSVP your participation by May 11 to Denise Derrer, via email at dderrer@boah.in.gov or by phone at 317-544-2414.

We have made a concerted effort to ensure that members of this advisory panel represent different viewpoints and sectors that are affected by this issue. Invitees to the panel include:

- Sarah Wagler—Dairy Farmer, Coop Field Rep and Dairy Representative to the Board of Animal Health
- Joe Kelsay—Dairy Farmer and Director, Indiana State Department of Agriculture
- Jennifer House, DVM—Indiana State Department of Health
- Steve Bonney—Farmer and President, Sustainable Earth
- Adam Moody—Livestock Producer and Owner, Moody Meats
- Alan Yegerlehner—Dairy Farmer and Processor, The Swiss Connection
- John Baugh—Assistant to the Dean, Purdue University College of Agriculture
- Mike Schutz—Dairy Specialist, Purdue University Animal Science Department
- Roy Ballard—Purdue Extension Service, Hancock County
- Doug Leman—Executive Director, Indiana Professional Dairy Producers
- LuAnn Troxell—Dairy Farmer and President, Indiana Professional Dairy Producers
- Kristy Kikly—Dairy Farmer and Processor, Caprini Dairy
- Lindsay Klaunig—Processor, Traders Point Creamery
- Helen Piotter—Dean Foods Company
- Chuck McQuaig—Prairie Farms
- Greg Slipher—Indiana Farm Bureau
- Bret D. Marsh, DVM—Indiana State Veterinarian

We look forward to your participation in this important study.

Sincerely,

Bret D. Marsh, DVM
State Veterinarian

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix B

# Indiana State Board of Animal Health (BOAH)

A Plan for Farmers Selling
Raw Milk to Consumers in Indiana

October 16, 2012

## Background

The Indiana State Board of Animal Health (BOAH) convened a volunteer advisory committee to study the issue of selling raw (i.e., not pasteurized) milk to consumers in Indiana. The Committee included representatives from many dairy interests with a varied set of experiences and knowledge. A list of the committee members is included in Appendix # . The Committee included members who were in favor of allowing raw milk sales to the public and members who oppose raw milk sales to the public. BOAH asked the Committee to put aside their opinions on whether or not raw milk sales should be legalized and consider the question: "If there were to be an Indiana program for the sale of raw milk, what should the program include?" This document is a summary of the Committee's consensus thoughts and conclusions on that question. This document should not be interpreted to suggest that any particular Committee member endorses or supports legalizing raw milk sales.

The decision to allow or not the sale of unpasteurized milk from Indiana farms to consumers within the state is a political decision for the members of the Indiana General Assembly to make. If Indiana is to move away from the current laws requiring pasteurization of milk and milk products sold to the public, the Committee recommends the General Assembly authorize the sale of raw milk for consumption as outlined in this document by authorizing the Indiana State Board of Animal Health (BOAH) to adopt specific rules governing the practice that may help reduce the risk to consumers who choose to consume raw milk.

All milk has health benefits and risks. There will be pathogens present on animals and farms. Raw milk may contain pathogens that make people sick. Removing the pasteurization step prior to offering milk and milk products for sale for consumption removes an effective step that nearly eliminates the consumer's exposure to pathogens. Following minimum standards for the production, handling and distribution of raw milk may decrease the likelihood that consumers become exposed to pathogens from consuming raw milk. No standard for the production, handling and distribution of raw milk will guarantee the absence of pathogens in raw milk. The Committee did not find an existing or proposed set of state requirements that will be as effective as pasteurization in protecting consumers from pathogens in unpasteurized milk.

## Summary

The Committee recommends that if Indiana is to move away from the current laws requiring pasteurization of milk and milk products sold to the public, the following principles should be our guide:

1. The Indiana State Board of Animal Health should have the authority to adopt rules requiring permits and establishing sanitation standards for raw milk producers.

2. All farmers producing raw milk for consumption should be held to the same standards.

3. The minimum standards for producing raw milk for consumption should be at least the standards used to produce raw milk for pasteurization. The standards should be modified and augmented in a manner that may reduce the risk for raw milk consumers.

4. The sale of raw milk should be limited to the farmer producing the milk selling directly to consumers.

## Recommendations

**I. If Indiana is to move away from the current law requiring pasteurization of milk sold to the public, the General Assembly should authorize the sale of raw milk for consumption in accordance with the following parameters and authorize the Indiana State Board of Animal Health to adopt rules establishing standards that may reduce the risk of illness from raw milk consumption.**

### A. Sales of Raw Milk to Consumers

A change in Indiana law that will allow the sale of raw milk for consumption should limit distribution to transactions by the farmer producing the raw milk directly to the consumer. Distribution through wholesalers and other third-party distributors should be prohibited. The serving of raw milk to consumers in restaurants, hotels, schools, day cares, health care facilities and other institutions should be prohibited. The resale or redistribution of raw milk by the consumer should be prohibited.

The Committee spent considerable time discussing the location and manner of raw milk sales. The following is a summary of these issues.

1. Sales on the Farm

   The Committee reached a consensus that sales and delivery to the consumer at the farm where the raw milk was produced would be appropriate. The benefits in requiring the purchasing consumer to visit the production location to purchase raw milk include:

a. Consumers have the opportunity to learn about the source of the product in a manner that is direct and meaningful. Consumers who make the effort to travel to the farm to purchase are more likely to be informed about the risks associated with raw milk consumption.
b. Farmers may have a stronger incentive to maintain higher standards of sanitation if they know their customers are going to visit the site of production.
c. On-site purchasing supports the concept and practice of local food production, consumption of locally produced food and rural economic development.

2. Sales at Other Locations and Delivery

The Committee was unable to reach a consensus on the location and manner of sales from the farmer to consumers. Some members of the Committee were in favor of restricting sales and delivery at the farm where the product was produced only. Other members of the Committee wanted sales and delivery from the farmer to the consumer at other locations, including the following:

a. A retail store that is owned by the farmer who is producing the raw milk.
b. A farmers market booth operated by the farmer who is producing the raw milk.
c. Delivery from the farmer direct to the consumer.
d. Delivery from the farmer to central distribution point where consumers pick up the product.

The Committee reached a consensus that the Indiana State Board of Animal Health should have the authority to adopt rules authorizing or restricting vending machine sales.

A change in Indiana law that will authorize the sale of raw milk for consumption should make clear that all exchanges involving raw milk are included in the new law. Any person producing raw milk for consumption will fall under the new law, regardless of the method the person chooses to distribute the product, including sales on the farm, cow- or herd-share programs, pet milk operators and buying clubs. All farmers producing raw milk for consumption should be held to the same set of standards.

3. Cow- and Herd-Shares

"Cow-share" and "herd-share" arrangements consist of a person signing documents indicating that they intend to:

- purchase a share of a cow or a herd of cows;
- board the animal(s) at the farm (usually the farm that is "selling" the cows);
- pay fees; and
- receive from the farm a portion of the raw milk from the cow(s).

The details of how these arrangements are practiced may vary widely.

The result of a cow-share and herd-share arrangement is the distribution of raw milk produced by a farmer to consumers. Therefore, farmers producing raw milk for consumers participating in cow-share and herd-share arrangements should meet the same standards that other farmers producing raw milk for consumers meet. Benefits in treating

farmers who board animals and custom milk the same as other raw milk producers include:

- Providing the same potential risk reduction benefits to all consumers, however they choose to procure their raw milk.
- Maintaining a level playing field for all farmers who choose to provide raw milk to consumers.

4. Animal Food

"Animal food" raw milk and "pet food" raw milk is the practice of a farmer selling raw milk labeled as animal or pet food. Many of the farmers engaging in this practice obtain a license from the Indiana State Chemist to produce animal food. Usually, the intent of those engaged in the selling and buying of animal and pet food raw milk products is that the products will be used for human consumption.

Because many raw milk animal food products are likely used for human consumption, farmers producing raw milk for animal or pet food should meet the same standards that any other farmer producing raw milk must meet. None of the requirements would preempt or conflict with the requirements of the Indiana State Chemist for the sale of animal feed. Benefits in treating farmers who produce "pet food" milk the same as other raw milk producers include:

- Providing the same potential risk reduction benefits to all consumers, however they choose to procure their raw milk.
- Maintaining a level playing field for all farmers who choose to provide raw milk to consumers.
- Providing risk reduction benefits for animals should the products actually be used to feed animals.

5. Buying Clubs and Subscription Services

Farmers and consumers may enter into many different variations of farm-centric sales and distribution arrangements to supply raw milk such as:

- A community-supported agriculture (CSA) program where consumers purchase a membership or subscription that entitles them to a share of the farm's production.
- Buying clubs where consumers order products directly from the farm. The products may be delivered by the farmer or picked up by consumers.

A change to Indiana law that will authorize the sale of raw milk for consumption should make clear that all sales and distribution arrangements, however crafted, are included in the new law.

## B. Permits

All raw milk for consumption should be produced under a sanitation standard. The Indiana State Board of Animal Health currently issues the following dairy farm and plant permits:

Grade A dairy farm
Manufacturing grade dairy farm
Grade A milk plant

Manufacturing grade milk plant.

A law authorizing raw milk sales to consumers should authorize the BOAH to create a new class of permit a person must obtain to produce raw milk for consumption. In this document the new permit is labeled a "raw milk products permit". Any person producing raw milk products will be required to obtain this new permit. The permit must be obtained no matter what method the person chooses to distribute the product, including sales on the farm, cow or herd share programs, pet milk operators and buying clubs. The fee for obtaining this new permit should be same as the fee for obtaining other dairy permits (currently Indiana has no fees for dairy permits).

A person should not be prohibited from obtaining more than one permit for the same farm, for example a Grade A farm permit and a raw milk products permit on the same farm. BOAH will adopt standards governing the separation of milk intended for pasteurization and milk intended for direct consumption produced on the same farm. The new law should not require purchasers of raw milk for pasteurization to allow raw milk sales in their contracts with farmers.

If raw milk sales become legal, a person making raw milk cheese should follow the current requirements for making raw milk cheese. A raw milk products permit would not be required to make raw milk cheese. If a raw milk products permit is obtained, it would not obviate the need for a manufacturing grade milk plant permit to make cheese and would not change the current rules for production, including aging, of raw milk cheese.

Each cow has the potential to produce milk that contains pathogens. The number of cows a farmer milks is not a reliable indicator of sanitation or milk safety. No exemptions or lower standards for farms with fewer cows should be allowed.

## C. Products

A new law on raw milk sales should allow a person holding a raw milk products permit to produce milk from hooved mammals. The PMO definition of "hooved mammals" should be used and includes cattle, water buffalo, sheep, goats, camels, deer, and horses. No other species may be used to produce raw milk products for consumption. This documents will refer to milk from cows. However, all of the provisions are to apply to milk from hooved mammals unless specifically stated otherwise.

The holder of a raw milk products permit will be authorized to produce and sell raw milk. The Indiana State Board of Animal Health should have the authority to:

1. Study the issue of allowing the manufacture and sale of raw milk products such as cream, butter, cottage cheese, and yogurt.
2. Adopt rules authorizing the manufacture and sale of raw milk products.
3. Adopt rules establishing standards for the manufacture and sale of raw milk products.

**D. Adulteration and Misbranding**

Generally applicable laws that prohibit the sale of adulterated or misbranded food should apply to the sale of raw milk products.

**II. If Indiana is to move from a total pasteurization requirement, the General Assembly should authorize the Indiana State Board of Animal Health to adopt rules governing the production of raw milk that may reduce the risk of illness from raw milk consumption. BOAH should adopt rules for the practice in accordance with the parameters outlined below:**

**A. Recall Plans**

Producers of raw milk products for consumers should be prepared to handle an incident involving an unsafe product leaving the control of the producer. Even if a farmer follows all of the required standards, a chance exists that a recall of his raw milk product may be necessary. A condition of obtaining a raw milk products permit will be that the permit holder will prepare and maintain current written procedures for the recall of milk products produced and sold. The person must make the recall plan available to BOAH upon request.

**B. Production Standards and Raw Milk Products Standards**

References to the "PMO" in this document refer to the Grade A Pasteurized Milk Ordinance, U.S. Department of Health and Human Services Food and Drug Administration, 2011 Revision. References to "Grade A" standards refer to the standards in the PMO.

Grade A dairy farms are currently required to meet PMO standards for the production of milk for pasteurization and milk plants are required to meet the PMO standards for the processing and bottling of milk for human consumption. The Grade A standards in the PMO are useful as a base standard for the production of raw milk products for consumption.

The minimum standard for producing raw milk for consumption should be the Grade A standard set forth in the PMO. A farmer who milks cows and bottles raw milk for sale to consumers must meet the PMO standard for his or her farm and the PMO standard for his or her bottling operation as a condition of obtaining a raw milk products permit. All PMO standards should apply, except:

a. Standards that require pasteurization will not apply.
b. Standards governing vitamin fortification will not apply (such as Appendix O).
c. Standards that Indiana establishes for raw milk products permits that are specifically different than the PMO standard as described in this document.
d. Section 11 of the PMO regarding milk produced outside of Indiana will not apply. The U.S. Food and Drug administration prohibits the interstate sale of raw milk for consumption. Indiana law prohibits the sale of raw milk to consumers in Indiana, even if it is produced legally in another state. The raw milk products permit will only

authorize the sale of raw milk products to consumers in Indiana that are produced on an Indiana-permitted farm.

The PMO requirements were established to complement the pasteurization process with an understanding that the milk would be pasteurized prior to sale. The PMO standards should be supplemented for application to the production of raw milk products to account for the lack of a pasteurization step. There is no way to quantify how effective these supplemented standards will be in preventing pathogens in raw milk products. We know that the standards will not eliminate the risk of human infection and illness from the consumption of unpasteurized milk products. The recommended standards include modifications of the PMO standards in the following areas:

1. Limiting transactions in raw milk to direct transactions between the farmer producing the raw milk and the consumer.
2. Animal health (additional testing for Tuberculosis, Brucellosis and *Streptococcus agalactiae*)
3. Cooling (cooler maximum temperatures for holding raw milk)
4. Labeling (warning label and sell-by dates required)
5. Product standards (a lower somatic cell count and bacteria standard)
6. Pathogen testing (potential for additional testing for pathogens)
7. Additional inspections by BOAH (minimum of 4 inspections each year rather than 2).

**III. The following sections of this document provide more specific information on the recommended standards for the production of raw milk products.**

## A. Farm Standards

1. Animal health

   The health of dairy animals producing milk for consumption is very important because milk may transfer diseases from animals to humans. Pasteurization is a critical step in preventing disease transmission from animals to humans through milk. Without pasteurization, additional precautions should be taken to ensure each cow providing milk for consumption is healthy. BOAH will establish rules for herd health standards. The initial standards will include the following:

   a. Tuberculosis

   Each cow must be tested prior to entering the milking herd the first time. The whole herd must be tested annually.

   b. Brucellosis

   Each cow must be tested prior to entering the milking herd the first time. The whole herd must be tested annually.

   c. *Streptococcus agalactiae*

   Each cow must be tested prior to entering the milking herd the first time. Positive animals must be excluded from the milking herd until they test negative.

2. Facilities and Equipment
The cleanliness of facilities and equipment used to produce milk is a critical factor in reducing the risk of contamination of raw milk. The PMO contains standards that are designed to reduce these risks that will serve as the core standards for raw milk products permitted farms. The PMO standards include the following:

Construction and cleanliness of the milking barn, stable and parlor. (PMO Section 7, Items 2r through 7r and Appendix C).

The water supply used in the milking operation. (PMO Section 7, Item 8r and Appendix D).

The utensils and equipment used in the handling, storage and movement of milk. (PMO Section 7, Items 9r through 12r).

Insect and rodent control. (PMO Section 7, Item 19r).

3. Milking Process
The procedures used in the milking process have a direct impact on the risk that milk will become contaminated. The standards for the milking process will be the Grade A standards (PMO Section 7, Items 13r through 17r).

4. Cooling and storing bulk milk
Cooling raw milk quickly and keeping it cool for as long as possible is important to reduce the growth of harmful bacteria in raw milk. Cooling will not kill harmful bacteria but will slow its growth.
   a. Milk must be stored in bulk tanks that are equipped with automatic cooling and agitating equipment and approved temperature-recording devices. Bulk milk may not be stored in cans and may not be cooled utilizing only water baths.
   b. Milk must be cooled to 40° F or lower within two hours after milking and must be maintained at that temperature or less prior to bottling. Subsequent milkings may raise the temperature of the blended milk to 45° F as long as the tank is cooled to 40° F or lower within two hours after milking is completed.
   c. Bulk milk tanks must be washed and sanitized after each use and at least every 48 hours.

**B. Milk Plant Standards**

1. Facilities and Equipment
The cleanliness of facilities and equipment used to bottle milk is a critical factor in reducing the risk of contamination of raw milk. The PMO contains standards that are designed to reduce these risks that will serve as the core standards for the bottling of raw milk for consumption. The PMO standards include the following:

Construction and cleanliness of the milk plant. (PMO Section 7, Items 1p through 10p).

The water supply used in the milk plant. (PMO Section 7, Item 7p).

The construction, repair, and sanitation of containers and equipment used in the handling, storage and movement of milk. (PMO Section 7, Items 11p through 15p)

2. Bottling milk

A farm may not commingle its milk with milk from any other farm. Milk must be bottled at the farm where the cows were milked. Milk must be bottled within 48 hours after milking is completed.

The transfer of milk from the bulk tank to the milk plant for bottling must be according to the PMO standards.

The bottling, packaging and container filling of milk will be governed by the PMO standards. (PMO Section 7, Items 18p through 19p). These standards do not require automated systems but do require filling and capping by approved mechanical equipment. Containers, caps and seals must be from approved sources under the PMO. Containers may be either single-use or multi-use. The BOAH may require a specific color cap to distinguish raw milk from pasteurized milk.

3. Labeling

Raw milk products will be subject to the generally applicable laws governing the labeling of food. Raw milk products will be labeled according to the PMO standards for labeling milk. Packages containing raw milk products should include additional information to provide accurate product and health information to consumers so that they make an informed choice about their purchase and act to manage the risks associated with the product. BOAH should adopt rules specifying labeling requirements that include the following information prominently displayed on the package:

a. The product will clearly be labeled "raw, unpasteurized".
b. A disclaimer statement to be developed by BOAH that warns the product has not been pasteurized, may contain disease-causing micro-organisms and that certain populations are most at risk if they consume raw milk.
c. The BOAH will determine an appropriate "sell by" and/or "use by" date. The rule will prohibit a person from selling raw milk after the sell by date and returning expired product for reuse.
d. The following statement: "Keep Refrigerated at or below 40° F" or "Keep Refrigerated below 40° F".
e. The following statement: "Not for Resale or Redistribution".

The term "Grade A" may only be used to identify pasteurized milk and milk products under the PMO. A raw milk products label may not identify the product using the term "Grade A" or any other grade designation.

4. Storing bottled milk
   Bottled milk must be maintained at a temperature of 40° F or less until sold to the consumer.

## C. Milk and Products Standards

1. Sampling and Testing Procedures
   BOAH will establish sampling and testing procedures for raw milk and milk products. BOAH will begin with the PMO procedures (PMO SECTION 6) and make adjustments BOAH determines are necessary. Sampling and testing procedures will include all relevant procedures, such as the following:
   Frequency of testing, responsibility for sample collection and testing, responsibility for paying for testing, chain of custody procedures, certified laboratory approvals, sampler approvals, reporting and oversight.

2. BOAH will establish milk and milk products standards and procedures to verify that the standards are met. The following standards should be met for all raw milk for consumption:
   Abnormal milk and contaminated milk must be discarded and may not be sold using the Grade A standard (PMO Section 7, Item 1r).

   Somatic cell count for hooved mammal milk: Not more than 400,000 per mL
   Somatic cell count for goat milk: Not more than 1,000,000 per mL

   Bacteria count: Not more than 20,000 cfu per mL

   Coliform count: Not more than 10 cfu per mL

   Pathogens: No detectable

   Standard of Identity: At least 3.25% milkfat and 8.25% solids-not-fat.

   Added water: PMO standard

3. Pathogen Testing
   Testing raw milk for harmful bacteria that may infect and cause illness in a person may be utilized as a part of a program to monitor raw milk safety. However, testing for pathogens is imperfect and does not provide a fail-safe method to ensure safety. It is practically impossible to test raw milk for all potential pathogens. Selecting the pathogens that most frequently contaminate raw milk and infect and cause illness in people is a reasonable way to design a testing program. But there will always be potential pathogens that are not selected for testing. Even if a product is tested for specific bacteria, it cannot be guaranteed as being free from that bacteria. Farmers

and consumers may not be aware of these testing limitations and may have a false sense of security about the benefits of testing and the meaning of test results.

With the above limitations in mind, raw milk for consumption should be tested according to the PMO standards with the addition of a monthly test from the bulk tank for pathogens as determined by the BOAH. The initial list of pathogens will likely include the following:

- E. Coli 0157:H7, Salmonella, Listeria monocytogenes, Campylobacter.

4. Drug Residue Testing
   Milk will be tested for drug residues utilizing the standards and procedures for Grade A milk. (PMO Appendix N). A member of the committee expressed concern that drug residue testing would be too expensive for a very small producer and considered it unnecessary on farms that bottle their own milk.

5. Chemical Testing
   Testing and standards for pesticides, other chemicals and other adulterants will be pursuant to the PMO procedures and standards. A member of the committee expressed concern that chemical residue testing is unnecessary on farms that bottle their own milk.

6. Violative Samples
   a. PMO procedures will be used for notice, warning and suspension of permits.
   b. Pathogen testing: A positive result means an immediate suspension of the permit by BOAH until the health hazard is mitigated.

**D. Inspections**

BOAH will inspect farms producing raw milk products not fewer than four times each year. (The PMO standard for farms is at least two times per year and for plants is quarterly). BOAH may inspect farms that do not meet the standards more often (a risk-based inspection program).

**E. Record Keeping**

BOAH will develop a rule governing records a farmer holding a raw milk products permit must keep, such as animal health, raw milk testing, temperature and water testing records. Records must be provided to BOAH upon request.

**F. Personnel Health**

Some communicable diseases may be transmitted from person to person through the contamination of food. Any person producing raw milk products should exclude employees and any other person who is affected with such a disease from the production process. The standards in PMO Sections 12 and 14 should govern the exclusion of sick people from the production of raw milk for consumption.

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# Appendix C

and milk products or manufacturing grade milk products than those provided for in this chapter.

(2) Prohibit the sale of milk or a milk product if the milk or milk product has been produced and processed in accordance with this chapter.

(c) A milk product other than a milk product that bears a Grade A label must meet the requirements for the production, processing, and handling of Grade A milk. This labeling requirement does not apply to butter or to any other product that is excluded by rules of the board.

*As added by P.L.2-2008, SEC.9.*

**IC 15-18-1-21**

**Pasteurization; exceptions**

Sec. 21. (a) A person may not offer, display for sale, sell, deliver, or have possession of with intent to sell or deliver milk or milk products for human consumption unless every particle of the final mixture of the milk or milk products used in processing or manufacture has been thoroughly pasteurized by equipment approved by the board.

(b) The provisions of this chapter governing pasteurization do not apply to a person selling or offering for sale cheddar cheese that has been made from unpasteurized milk if:

(1) the cheese was made from unpasteurized milk and has been cured or ripened for at least sixty (60) days at a controlled temperature of at least thirty-five (35) degrees Fahrenheit; or

(2) the cheese is manufactured solely to be made into processed cheese that is pasteurized during the blending or manufacturing process.

Varieties of cheese other than that of the cheddar type made from unpasteurized milk must be ripened for the time and under the conditions prescribed by rule of the board. Cheese made from unpasteurized milk and offered or displayed for sale to the consumer must be labeled by the manufacturer or distributor with the manufacturer's or distributor's name and address or an equivalent identifying number or symbol and with the date of manufacture or a statement to the effect that the cheese has been cured or ripened for at least sixty (60) days.

(c) A pasteurizer of any milk or milk products must be equipped with accurate indicating thermometers and accurate recording thermometers and, for vat pasteurization equipment, an accurate airspace thermometer of a type approved by the board. Each recording thermometer chart must be dated and numbered and must show the amount in gallons, the kind of product pasteurized, the accurate readings of the indicating thermometers and airspace thermometers, the time the reading was made, and the operator's initials. Each chart may not be used for more than one (1) day of operations. The records of the pasteurization of each batch pasteurized must be retained for at least ninety (90) days.

*As added by P.L.2-2008, SEC.9.*

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# Appendix D

**PUBLIC CITIZEN, et al., Plaintiffs, v. Margaret HECKLER, Defendant**

**Civ. A. No. 85-1395**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA**

***653 F. Supp. 1229; 1986 U.S. Dist. LEXIS 15705***

**December 31, 1986**

**SUBSEQUENT HISTORY:** [**1] Reported at: *653 F. Supp. 1229 at 1242.* Reported at: *653 F. Supp. 1229 at 1242.*

**COUNSEL:** Eric R. Glitzestein, William B. Schultz, Alan B. Morrison, Public Citizen Litigation Group, Washington, District of Columbia, for Plaintiffs.

Jacqueline H. Eagle, Office of Consumer Litigation, Civ. Div., U.S. Dept. of Justice, Washington, District of Columbia, for Defendant.

**JUDGES:** Norma Holloway Johnson, District Judge.

**OPINION BY:** JOHNSON

**OPINION**

[*1231] MEMORANDUM OPINION

NORMA HOLLOWAY JOHNSON, District Judge.

The plaintiffs in this case are Public Citizen, a non-profit public interest organization whose objectives include improving the public health; Sidney M. Wolfe, M.D., Director of Public Citizen Health Research Group; the American Public Health Association, a nonprofit public health professional society; and George J. Drabble, a resident of California, where most raw milk is produced and consumed. Plaintiffs challenge as arbitrary, capricious, and not in accordance with law, the denial by the Secretary of Health and Human Services ("HHS" or "the Secretary") of Public Citizen's citizen petition for the issuance of a rule banning the sale of unpasteurized milk [1] in the United States. Plaintiffs [**2] also challenge the Secretary's failure to terminate a 1974 stay of a 1973 Food and Drug Administration ("FDA") regulation that revised the existing standards of identity for milk and milk products moving in interstate commerce, and in effect prohibited the sale of all unpasteurized milk in interstate commerce. *38 Fed.Reg. 27924* (Oct. 10, 1973, stayed in 39 Fed.Reg. 42351 (Dec. 5, 1974)). On December 5, 1974, the regulation was stayed as to the sale of only certified raw milk [2] pending a public hearing on the safety of [*1232] certified raw milk which was to be held by the FDA. Although evidence adduced at that hearing conclusively shows, and the Secretary now concedes, that the consumption of certified raw milk presents a serious risk to human health, the 1974 stay has not been lifted.

1 Unpasteurized milk is commonly referred to and marketed as "raw milk".

2 "Certified raw milk" is unpasteurized milk produced by methods which comport with the standards established by the American Association of Medical Milk Commissions, a private trade organization whose primary member is the Alta-Dena Dairy, one of the two major producers of certified raw milk in the country.

[**3] Plaintiffs request this Court to compel HHS to (1) complete the thirteen year old pending rulemaking

proceeding to require that *all* milk and milk products sold in interstate commerce be pasteurized; and (2) initiate a new rulemaking proceeding banning both interstate and intrastate sales of raw milk. The case is currently before this Court on the parties' cross-motions for summary judgment.

After careful consideration of the cross-motions for summary judgment, the pleadings, supporting and opposing memoranda, and the entire administrative record, this Court concludes that partial summary judgment must be entered for HHS on the issue of HHS's failure to terminate the 1974 stay of its 1973 pasteurization requirement, and partial summary judgment must be entered for plaintiffs on the issue of HHS's denial of Public Citizen's petition for new rulemaking.

BACKGROUND

On October 10, 1973, in a standard of identity proceeding, the Food and Drug Administration adopted a regulation pursuant to section 401 of the Food, Drug and Cosmetic Act, *21 U.S.C. § 341 (1982)*, that required that all products labeled "milk" moving in interstate commerce be pasteurized. *38 Fed.Reg. 27924* (October [**4] 10, 1973). The Association of Medical Milk Commissions, Inc., the Certified Milk Producers Association of America, Inc., and two of the three dairies that produce certified raw milk formally objected to the regulation. They asserted that certified raw milk (as opposed to uncertified raw milk or raw milk) was a safe product, and that section 401 of the Federal Food, Drug and Cosmetic Act did not give the Commissioner authority to establish a standard of identity solely for health reasons.

In response to this objection, the FDA ruled that because substantial issues of fact existed with regard to the safety of certified raw milk, the 1973 requirement would be stayed pending a public hearing on the matter. 39 Fed.Reg. 42351 (December 5, 1984). The pasteurization regulation remained in effect with regard to non-certified raw milk. In the stay order, the FDA Commissioner noted that section 361 of the Public Health Service Act, *42 U.S.C. 264 (1982)*, as well as section 401 of the Federal Food, Drug, and Cosmetic Act, authorizes the FDA to enact a pasteurization requirement. The Commissioner also stated that "if certified raw milk is found to contain harmful bacteria or to be in violation [**5] of other provisions of the Federal Food, Drug and Cosmetic Act, appropriate action will be taken." *Id.*

From 1974 to 1982 the FDA collected and evaluated scientific and medical information to determine if the outbreak of certain diseases was associated with the consumption of certified raw milk. The FDA worked closely with the Center for Disease Control ("CDC"), a branch of HHS, and encouraged the states to test milk and milk products for bacteria or microorganisms and to report outbreaks of milk-borne disease to the CDC.

The process of collecting and reviewing data and information led the FDA to conclude that the consumption of certified raw milk and all forms of raw milk and raw milk products was linked to the outbreak of serious disease. [3] In 1982, the FDA began drafting a proposed regulation banning the interstate sale of all raw milk and raw milk products.

3 In particular, as documented by the Center for Disease Control, there has been a number of outbreaks of two serious bacterial diseases, campylobacteriosis and salmonellosis, which on rare occasions result in death. The link between raw milk and Salmonella Dublin Bacterium ("S. Dublin") was particularly strong, and the especially virulent S. Dublin often invades sites outside the intestine such as the lung and spinal fluid.

[**6] On April 23, 1983, then-FDA Commissioner Arthur Hull Hayes sent a memorandum [*1233] to the Secretary requesting her approval of the proposed rule. Plaintiffs' Exhibit H. Rather than hold the evidentiary hearing which the FDA announced in its stay order of 1974, however, Commissioner Hayes proposed that new regulations be issued under the Public Health Service Act which "would provide a more uniform and efficient regulatory mechanism than a standard of identity proceeding, to assure public health protection." *Id.*

The FDA's proposal received widespread support from others within HHS. For example, in a February 1984 memorandum, HHS's Assistant Secretary for Health Edward Brandt, Jr., presented "further compelling evidence on the association of S. Dublin salmonella and the consumption of raw milk." Plaintiffs' Exhibit I. Likewise, in May 1983, the Director of the Center for Disease Control stated that "because the accumulated evidence indicates that unpasteurized [raw] milk is inherently unsafe, the Center for Disease Control

supports pasteurization of milk and other dairy products." Plaintiffs' Exhibit J. The Director of CDC further indicated that CDC can conceive of no [**7] practical way raw milk can assuredly be safely marketed." *Id.*

In a February 1984 memorandum, the Chief of the Bureau of Foods Epidemiology and Clinical Toxicology Division provided emphatic statistical support for the FDA's proposed regulation. Following a review of data provided by the California Department of Health Services, the memorandum concluded that an individual who consumed certified raw milk produced by the Alta-Dena dairy was 51 times more likely to be infected with S. Dublin than an individual who consumed pasteurized milk. Plaintiffs' Exhibit K.

Public Citizen filed a citizens petition with the FDA on April 10, 1984, requesting a ban on all domestic sales of raw milk and raw milk products. Plaintiffs' Exhibit L. The Secretary did not rule on the merits of the petition and by letter to Dr. Sidney Wolfe of Public Citizen, she stated that the matter "is under active consideration." No schedule for reaching a conclusion was given, but the Secretary indicated she would hold a public hearing on the matter. Plaintiffs' Exhibit M.

In a second letter to Dr. Wolfe, the Secretary indicated that the certified raw milk issue "has been periodically reviewed within the Department [**8] for many years without definitive resolution." *Id.* Again, she refused to indicate when a resolution might be made. Plaintiffs filed suit in the District Court for the District of Columbia on September 19, 1984, to compel the Secretary to respond to the petition for a ban on raw milk sales in a timely fashion. *Public Citizen v. Heckler, 602 F. Supp. 611 (D.D.C.1985).*

In accordance with the Secretary's first letter to Dr. Wolfe, on October 11 and 12, 1984, an informal hearing was held by HHS on two issues: (1) whether the consumption of raw milk is a public health concern; and (2) if so, whether requiring pasteurization of all raw milk is the most reasonable regulatory option. The notice of hearing published in the Federal Register stressed that the purpose of the hearing was to develop an administrative record upon which agency action would be based. *49 Fed.Reg. 31066* (August 3, 1984).

The Secretary did not suggest in the notice that there was any question of who, as between the federal government and the individual states, should regulate raw milk. No public comment was solicited on that issue. Over 25 state and local public health departments submitted comments to the FDA [**9] supporting a federal ban on raw milk sales. Not a single state or local government agency contended either that raw milk was not a significant public health problem or that pasteurization was not the proper regulatory approach to the danger posed by raw milk. In fact, the National Conference on Interstate Milk Shipments, whose members consist of the milk regulatory agencies of the 50 states, had adopted an ordinance calling for the pasteurization of all Grade A milk and milk products.

The October hearing resulted in a 330 page transcript and well over 300 comments totalling approximately 4000 pages. [*1234] Those testifying against any Federal regulation of certified raw milk and certified raw milk products pointed out that many other foods (for example, raw meat) against which no Federal action was contemplated, are also sources of exposure to harmful microorganisms. It was made clear, however, that those other unregulated food products are normally cooked before consumption, and the cooking process kills the salmonella bacteria.

Comments opposing a pasteurization requirement included several witnesses' testimony that in the absence of a definitive case-control study, there [**10] was no way to determine whether the apparent association between drinking raw milk and being infected by harmful microorganisms was causal and encouraged HHS to sponsor such a study. Other proponents of raw milk testified that raw milk offers nutritional benefits that are destroyed by pasteurization and that raw milk tastes better than pasteurized milk.

The American Academy of Pediatrics, the National Association of State Departments of Agriculture, the Association of State and Territorial Health Officials, the United States Conference of Local Officials, the National Conference for Food Protection, the American Veterinarians Medical Association, the National Milk Producers Associations, the National Conference on Interstate Milk Shipments, the Association of Food and Drug Officials, the National Dairy Counsel, the American Society for Microbiology, the Milk Industry Foundation, the Mid-American Dairymen's Association, and others, all supported the pasteurization requirement. These witnesses argued that the risks associated with the consumption of raw milk, even certified raw milk,

heavily outweigh any benefits from its consumption.

Some witnesses suggested that labeling would be [**11] an appropriate alternative to a ban. Others stated that because raw milk is often consumed by the very young, the elderly and the infirm, labeling would not adequately protect them from the inherent risk associated with the product.

No organization or individual commented or testified at the FDA hearing that the states are in a better position to respond to the problems posed by raw milk consumption than is the federal government. [4] Evidence in the record of the inability of certain states to overcome the resistance of the certified raw milk producers and deal with the problem at the state level suggests just the opposite. The record shows that the individual states in fact favored federal regulation.

> 4 The American Academy of Pediatrics was permitted to submit an amicus brief in support of the plaintiffs' position. In that brief they cite an instance of the failure of state regulation in which the Mathis Dairy in Decatur, Georgia, attempted to sell raw milk in Florida, where raw milk sales are illegal, by labelling the raw milk as "cat food".

[**12] No individual or organization commented or testified that because of the relatively small percentage of interstate sales of raw milk in comparison to intrastate sales the FDA should be prevented from banning interstate sales of raw milk. The evidence did indicate that even if the incidence of raw milk consumption resulting from interstate sales were low, the risk of contracting a serious illness as a result of that consumption remained high.

No participant in the hearing suggested that the Secretary lacked the necessary statutory authority to ban raw milk sales in the United States. That assertion was raised for the first time in HHS's litigation memoranda. In its denial letter, HHS stated that on the facts known it did not have statutory authority to impose an *intrastate* ban. There was no assertion made by the Secretary in her denial letter that HHS lacked authority to ban intrastate sales if it became necessary to effectuate an interstate ban, or that HHS lacked authority to ban interstate sales.

On January 14, 1985, in *Public Citizen v. Heckler, 602 F. Supp. 611 (D.C.C.1985)*, Judge Gesell ruled that the Secretary had unreasonably delayed in responding to plaintiffs' [**13] petition in view of the fact that "officials at the highest levels of the Department [*1235] of Health and Human Services have concluded that certified raw milk poses a serious threat to the public health . . ." and that the Secretary's justifications for delay were "lame at best and irresponsible at worst." *Id. at 613.*

Judge Gesell rejected the Secretary's contention that the relatively small sales of interstate raw milk justified the delay in responding to plaintiffs' petition. The court stated that the percentage of interstate sales are "meaningless if the risk per sale is high, as the Department's own statistics indicate." *Id.* The court recognized that HHS "has both the authority and the heavy responsibility to act to protect the nation's health in situations such as this one." *Id.* [5]

> 5 The statutory source of HHS's authority was found by the court to have been granted by both the Public Health Service Act's authorization of regulations to control communicable diseases, *42 U.S.C. § 264 (1982)*, and the Food, Drug and Cosmetic Act's provisions for the control of adulterated foods, *21 U.S.C. § 342 (1982)*, as Commissioner Hayes noted in the 1974 Stay Order.

[**14] On January 29, 1985, the FDA again urged the Secretary to "require the pasteurization of all milk and milk products moving in interstate commerce" because such a requirement "is supported by the administrative record compiled as a result of the [October 1984] hearing." Plaintiffs' Exhibit N at 2. The FDA transmitted to the Secretary a proposed rule banning interstate sales of raw milk and supported this proposed rule by stating that "there is a strong association between the consumption of certified raw milk and the outbreak of disease." FDA Proposal to Require Pasteurization of All Milk and Milk Products Sold for Human Consumption in Interstate Commerce (Docket No. 81N-0204C), Plaintiffs' Exhibit O.

The Secretary rejected the FDA's recommendation and directed the FDA to deny Public Citizen's petition in its entirety. By letter dated March 15, 1985, the Commissioner of the FDA denied the petition, stating that the agency would not ban either interstate or intrastate sales of raw milk. The letter acknowledged that "raw milk, including certified raw milk, is a vehicle for the transmission and spread of numerous diseases" and there is no "scientifically confirmed benefit established

[**15] for the consumption of raw milk, including certified raw milk."

The FDA concluded that "a federal ban would not be the most effective or appropriate means of dealing with the health problems posed by unpasteurized milk and milk products, based on the following considerations:

(1) most unpasteurized milk and milk products are marketed exclusively in intrastate commerce;

(2) most illnesses associated with unpasteurized milk and milk products are caused by such products marketed in intrastate commerce;

(3) there is no reason to believe that unpasteurized milk marketed in interstate commerce represents a greater source of risk than unpasteurized milk marketed intrastate;

(4) the Department does not have adequate legal authority, based on the facts available at this time, to prohibit the intrastate marketing of unpasteurized milk and milk products;

(5) even assuming that it did have such authority, the problems created by unpasteurized milk and milk products are most appropriately dealt with at the state and local level; and

(6) banning certified raw milk from interstate commerce would, because interstate sales of that product constitute a very small proportion of all raw milk sales, [**16] have a minimal effect on the public health problem attributable to unpasteurized milk." FDA Denial Letter of March 15, 1985, Plaintiffs' Exhibit M.

The FDA denial letter did not cite any documentary evidence from the record to support the statement that the problem of raw milk is most appropriately dealt with at the state and local level. Nor did the FDA cite any authority for the proposition [*1236] that the FDA does not have adequate legal authority to prohibit intrastate marketing of unpasteurized milk and milk products. No further articulation of the rationale for the Secretary's decision was offered.

*Analysis*

I. Reviewability of the Agency's Action

Judicial review of agency action is governed by the Administrative Procedure Act ("APA"), 5 U.S.C. 701-706 (1982). The standards of review set out in those sections apply to all agency action "except to the extent that (1) statutes preclude judicial review, or (2) agency action is committed to agency discretion by law." APA *§ 701(a)*. Relying on *Heckler v. Chaney, 470 U.S. 821, 105 S. Ct. 1649, 84 L. Ed. 2d 714 (1985)*, the Government raises a threshold challenge to plaintiffs' claim that the Secretary's denial [**17] of plaintiffs' petition violates the APA.

The Government argues that the Secretary's decision is precluded from review under APA *§ 701(a)(2)*. The *Chaney* Court, however, expressly stated that its holding does not "involve the question of agency discretion not to invoke rulemaking proceedings." *Chaney, at 1652 n. 2.*

Furthermore, in *Robbins v. Reagan, 250 U.S. App. D.C. 375, 780 F.2d 37 (D.C.Cir.1985)*, the court indicated that "the 'committed to agency discretion' provision is a 'very narrow exception'", *Robbins, at 44-45* (citations omitted), to the general rule that agency action is presumptively reviewable. The holding of *Chaney* is "applicable in decisions not to take enforcement action [and] must not be applied outside of that context." *Id.*

From the normal presumption that agency action is reviewable, the *Chaney* Court shifted to a presumption of non-reviewability on facts such as those present in *Chaney*. The reason for the shift in the presumption of reviewability is not present in the case at bar. In *Chaney*, the FDA decided not to take enforcement action against a particular party. The lack of clear statutory guidelines as to how an agency [**18] should exercise its enforcement discretion on an individual basis makes it "reasonable to require some extra degree of substantive guidance to give the court a focus and basis for its review." *Robbins, at 43.*

Here the action at issue is not an individual enforcement action, but an agency's refusal to engage in rulemaking. Unlike the enforcement situation, there are clear statutory mandates set forth in both the Food, Drug and Cosmetic Act and the Public Health Act to guide this Court in determining whether the agency abused its discretion. Accordingly, the action of HHS must be examined in light of those statutory mandates and according to the standard of review provided by the APA.

II. What Constitutes the Administrative Record

The APA requires that the reviewing court "hold

unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . . ." APA *§ 706(2)*. In determining if an agency's decision is valid, it is necessary for the court to review the administrative record which the agency relied on as the basis for its decision.

The parties in this case dispute what [**19] properly constitutes the administrative record. "If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision." *Walter O. Boswell Memorial Hosp. v. Heckler, 242 U.S. App. D.C. 110, 749 F.2d 788, 792 (D.C.Cir.1984)*; *accord Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420, 91 S. Ct. 814, 825, 28 L. Ed. 2d 136 (1971)* (Review to be based on full administrative record before Secretary at the time he made his decision.) The reason for this is simple. "To review less than the full administrative record might allow a party to withhold evidence unfavorable to its case, and so the APA requires review of the 'whole record'." *Boswell, at 792*. Therefore it is necessary for this Court to determine what is to be included in the administrative record under review.

[*1237] Plaintiffs have submitted as exhibits to their briefs, documents consisting of, *inter alia*, memoranda prepared by various FDA and CDC officials, as well a draft of a proposed FDA regulation banning the interstate sale of all raw milk. [6] Plaintiffs cite these documents to support their position that [**20] the agency abused its discretion in denying Public Citizen's petition. The documents show, for example, that there was strong support from the highest levels of the FDA for the issuance of the proposed regulation, and that both the FDA and the CDC, within whose particular area of expertise such matters lie, found all types of raw milk unsafe for human consumption and recommended that it be banned.

6 *See* Plaintiffs' Exhibits H, I, K, N, and O.

HHS makes a blanket objection to all of plaintiffs' exhibits on the basis that they are not part of the "administrative record" and therefore should not be considered. It is unclear, however, precisely which of the various exhibits HHS objects to, or on what grounds it objects. Many of the items included in plaintiffs' attachment, such as "Plaintiffs' Petition", (Plaintiffs' Exhibit L), are clearly unobjectionable and are included in the very administrative record filed by the HHS in this case. [7]

7 *See also* Plaintiffs' Exhibits A, B, C, E, J, L, M, P, Q, R, S, T, U, AA, and BB.

[**21] The Court assumes that it is the documents entitled "memoranda" prepared by various agency and departmental health officials, to which HHS objects, on the basis that they are internal agency memoranda. HHS relies on *San Luis Obispo Mothers for Peace v. NRC, 243 U.S. App. D. C. 68, 751 F.2d 1287, 1227 (D.C.Cir.1984) aff'd 245 U.S. App. D.C. 296, 760 F.2d 1320 (1985)* (en banc), for the proposition that "judges review administrative action on the basis of the agency's stated rationale and findings, and the court's correlative reluctance to supplement the record, is well established." Defendant's Reply to Plaintiffs' Motion for Summary Judgment at 3. While that may be true as a general proposition, certain exceptions have been recognized in the very case on which defendant relies. "Supplementation [of the record] might be required if petitioners made a prima facie showing that the agency excluded from the record evidence adverse to its position or that the agency's stated rationale is but a pretext masking the true basis of its decision." *San Luis Obispo*, at 1227.

Public Citizen has made that prima facie showing in this case. The documents HHS wishes to exclude from the [**22] administrative record were known to HHS at the time of their decisionmaking, are directly related to the decision made, and are adverse to the agency's position. These documents are indicative of a lack of rationality on the part of HHS in the decisionmaking process. For an agency to say one thing -- that all raw milk is a known public health risk, and do another -- refuse to ban all types of raw milk, is the essence of arbitrary action. *New England Coalition on Nuclear Pollution v. NRC, 234 U.S. App. D.C. 28, 727 F.2d 1127 (D.C.Cir.1984)*. It indicates that the Secretary's stated reason may very well be pretextual.

The only document to which HHS directly addresses an objection, is the draft of the FDA's proposed regulation which bans the sale of raw milk. (Plaintiffs' Exhibit O). That document is marked with the docket number given to all materials in the FDA file, pursuant to federal regulation, concerning the issue of the promulgation of raw milk regulations. As such, it has properly been made a part of the administrative file. It is

the denial of Public Citizen's petition asking HHS to engage in rulemaking, and we first consider the appropriate [*1239] scope of review. Notice and comment rulemaking conducted pursuant to section 553 of the APA is unlawful if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." APA *§ 706(2)(A).* This review is focused and restricted, and it does not permit the court to substitute its judgment for that of the agency. *Citizens to Preserve Overton Park, 401 U.S. at 416, 91 S. Ct. at 823.* "Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made'." [**27] *Motor Vehicles Manufacturers Ass'n v. State Farm Mutual, 463 U.S. 29, 103 S. Ct. 2856, 2866-67, 77 L. Ed. 2d 443* (citation omitted).

In this case, however, the agency decided after years of inquiry and lengthy proceedings, *not* to engage in rulemaking. The Secretary argues that the standard of review to be applied to denials of petitions for rulemaking is even narrower than that applied to review of the promulgation of a rule. "The law in this Circuit makes clear that the scope of review . . . of an agency decision to deny a rulemaking petition is *very narrow.* Such review is limited to ensuring that the agency has adequately explained the facts and policy concerns it relied on, and that the facts have some basis in the record." *Arkansas Power & Light Co. v. I.C.C., 233 U.S. App. D.C. 189, 725 F.2d 716, 723 (D.C.Cir.1984); see also New England Coalition on Nuclear Pollution.* It is this more deferential standard of review HHS would have this Court adopt.

A heightened degree of deference by the reviewing court is derived from policy considerations concerning the competence of the judiciary to 'second guess' a discretionary determination made by the agency charged [**28] with particular expertise in an area. The judiciary's expertise lies in statutory interpretation of Congress' mandate as expressed in statutes which give administrative agencies their authority to take certain types of action. When a court is acting in this capacity, the reasons for judicial deference are diminished. Alternatively, "an agency's discretionary decision *not* to regulate a given activity is inevitably based, in large measure, on factors not inherently susceptible to judicial resolution -- *e.g.*, internal management considerations as to budget and personnel; evaluations of its own competence; weighing of competing policies within a broad statutory framework." *NRDC v. SEC, 196 U.S. App. D. C. 124, 606 F.2d 1031 (D.C.Cir.1979).* In these types of cases judicial deference is appropriate.

These reasons for judicial deference to an agency's decision not to act, however, are not present in the case at bar. The Secretary's decision to refuse to regulate the sale of certified raw milk does not appear to be based on internal management considerations as to budget and personnel. Here, the sale of uncertified raw milk has already been regulated by the FDA. No evidence has [**29] been presented which shows that to additionally require the regulation of certified raw milk, contrary to the Secretary's bare assertion that resources will be diverted from truly national problems, will impose a significant burden on the agency's budget or personnel. In fact, the major expenditure of agency resources has already been incurred. No further investigation or hearings need be held, and no additional administrative record need be compiled as these events have already occurred. Accordingly, the incremental increase in expenditures HHS will incur, in order to regulate certified raw milk in addition to uncertified raw milk, is very small.

Nor can the Secretary's inaction be based on evaluations of the FDA's competence to regulate certified raw milk. If the FDA is able to competently regulate raw milk sales, there is no reason why it is not equally able to competently regulate the very limited certified raw milk sales.

The Secretary has not advanced any specific competing policy which outweighs its primary responsibility to protect the public health and welfare and makes regulation of raw milk sales impossible. Assertions of counsel made in litigation memoranda that this [**30] Court should review the Secretary's decision under a more deferential standard, [*1240] without any supporting justifications for deference, are not sufficient to overcome the strong presumption of reviewability of agency action under section 10(a) of the APA. There has been no "clear showing that pragmatic considerations [make] judicial review inappropriate." *Bargmann v. Helms, 230 U.S. App. D.C. 164, 715 F.2d 638, 640 (D.C.Cir.1983)* (citations omitted).

In review of a decision not to enact a rule, there "is the additional concern that . . . unless the agency has carefully focused its considerations, judicial review will

have an undesirably abstract and hypothetical quality." *NRDC at 1046-47.* The *NRDC* court explained that in a case where "the agency has in fact held extensive rulemaking proceedings narrowly focused on the particular rules at issue, and has explained in detail its reasons for not adopting those rules, . . . the questions posed will be amenable to at least a minimal level of judicial scrutiny. *Id.; accord National Black Media Coalition v. FCC, 191 U.S. App. D.C. 55, 589 F.2d 578 (D.C.Cir.1978); Action for Children's Television v. FCC, 183* [**31] *U.S. App. D.C. 437, 564 F.2d 458 (D.C.Cir.1977).*

This case, like NRDC, is one in which there were formal rulemaking proceedings in 1973, followed by 12 years of agency information gathering with regard to those rules, a public hearing on the matter in 1984, and the compilation of a full administrative record, all pertaining to the exact matter about which plaintiffs' petitioned HHS. It is unlikely that the issues involved or the proposed rule could become any more focused. Thus, there is no abstract or hypothetical quality about this Court's review of the Secretary's inaction.

The detail of explanation given by the Secretary in her reasons for refusing to promulgate a rule banning certified raw milk sales is rather brief and conclusory. That does not, however, indicate that the decision is any less amenable to judicial review, but rather that the Secretary lacked a reasoned basis for that decision.

Having determined that the Secretary's decision not to promulgate a rule is reviewable under the arbitrary and capricious standard, we must consider whether that decision was in fact arbitrary and capricious. An agency's decision is arbitrary and capricious

> if the agency has [**32] relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

*Motor Vehicle Mfr. Ass'n. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 103 S. Ct. 2856, 2867, 77 L. Ed. 2d 443 (1983).* In this case the Secretary has indeed offered an explanation for her decision that runs counter to the voluminous evidence to the contrary she had before her.

The crux of the Secretary's explanation for her decision to deny plaintiff's petition is that since a greater amount of raw milk is marketed and consumed locally, rather than shipped interstate, and most illness occurs within the producing locality, the problem is one more appropriately dealt with at the state level. The Secretary claims that interstate sales of certified raw milk are "negligible". There is evidence that most raw milk is produced and consumed locally (mainly in California and Georgia) consistent with state law that permits the sale of unpasteurized [**33] milk. The record also shows that there is a serious risk of illness resulting from the consumption of that raw milk which does travel across state lines. The risk is not at all diminished merely because the amount of milk which is sold outside of the producing state is smaller than that sold intrastate. The Secretary failed to recognize that although the relative amount of raw milk that is shipped interstate may be small, the chance of out-of-state residents becoming seriously ill from drinking raw milk remains quite high.

Federal regulation is warranted regardless of the absolute volume of certified raw milk sold interstate. Residents of non-producing states near the producing states do [*1241] not have access to, and are not represented in, the producing state's political process. A resident of Nevada, for example, who is at risk of becoming ill from the consumption of certified raw milk produced in California and sold in Nevada, cannot turn to a California Congressperson for recourse through the political process. It is precisely in this sort of situation, where a decision made at a local level affects unrepresented persons outside of the locality, that a higher level of [**34] government is needed to intervene to protect the interests of the unrepresented parties. While an interstate ban on all raw milk might not solve the problem the producing state faces if intrastate sales are permitted, the residents of the producing state are able to turn to the local political process for redress.

The Secretary's reason for her decision has no rational connection to the undisputed facts in the record. 11 As such, her decision cannot be upheld. *See State Farm.* Nothing in the record supports a conclusion that state regulation would be superior to federal regulation. Evidence in the record clearly reflects that the states have

been unsuccessful in their individual attempts to regulate the sale of raw milk. The individual states do not have the authority to prohibit sales of raw milk beyond their own boundaries. Only the federal government, under its *commerce clause* power, may institute a nationwide ban. Even in light of the deferential review this Court must perform, in this case, the action of the Secretary was clearly arbitrary and capricious and must be reversed.

> 11 Post hoc rationalizations of counsel, such as those made in this case in Defendant's Memorandum in Support of Motion for Summary Judgment, have traditionally been found to be an inadequate basis for review of an agency's decision. *Burlington Truck Lines v. United States, 371 U.S. 156, 168-69, 83 S. Ct. 239, 245-46, 9 L. Ed. 2d 207 (1962).*

[**35] A remand to the agency for further proceedings would serve no purpose and would only add to the delay already encountered. HHS has spent over thirteen years studying the matter and gathering evidence and a hearing has been held. It is undisputed that all types of raw milk are unsafe for human consumption and pose a significant health risk. The appropriate remedy in this case, therefore, is an order compelling the agency to promulgate a regulation prohibiting the interstate sale of certified raw milk and certified raw milk products, and non-certified raw milk and raw milk products.

"'Administrative rulemaking does not ordinarily comprehend any rights in private parties to compel an agency to institute such proceedings or promulgate rules'". *WWHT, Inc. v. FCC, 211 U.S. App. D.C. 218, 656 F.2d 807, 818 (D.C.Cir.1981)* (citations omitted). In rare and compelling circumstances, however, the courts have acted to overturn an agency judgment not to institute rulemaking proceedings. *Id.* The limited rule which emerges from those cases is that "an agency may be forced by a reviewing court to institute rulemaking proceedings if a significant factual predicate of a prior decision on the [**36] subject (either to promulgate or not to promulgate specific rules) has been removed." *Id.*

The extremely rare circumstances the *Arkansas* and *WWHT* courts referred to, which were necessary before rulemaking would be compelled, are present here. Over thirteen years ago, the Secretary recognized the hazard of raw milk consumption and formally regulated its sale in interstate commerce. That action was partially stayed, so that the Secretary could determine, through a public hearing, the factual issue of whether certified raw milk was safe to consume.

As the evidence accumulated over those thirteen years, and the results of that hearing have conclusively shown, and as the Secretary now concedes, certified raw milk is unsafe. There is no longer any question of fact as to whether the consumption of raw milk is unsafe. The factual predicate to the Secretary's lifting the 1973 stay has indisputably been removed.

Public Citizen asks this Court to compel the agency to promulgate a rule banning both interstate and intrastate sales of raw milk. While we must agree that a rule banning the interstate sale of raw milk is appropriate, at this time there is no indication that a rule banning [**37] the intrastate sale of raw milk is necessary to effectuate the interstate ban. Accordingly, the Court declines to order the promulgation of a rule banning intrastate sales of raw milk. Assuming the interstate ban is effective without an intrastate ban, it is up to the individual states to decide on such matters of purely local concern. Should it appear that the interstate sale of raw milk continues, it is within HHS's authority at that time to institute an intrastate ban as well. An Order consistent with this Memorandum Opinion will be entered this date.

[*1242] ORDER

Upon consideration of the parties' cross-motions for summary judgment, supporting and opposing memoranda, and the entire record, it is this 31st day of December, 1986,

ORDERED that plaintiffs' motion for summary judgment be granted; it is further

ORDERED that defendant's motion for summary judgment be denied; and it is further

ORDERED that Food and Drug Administration promulgate, and the Secretary of the Department of Health and Human Services approve a rule banning the interstate sale of all raw milk and all raw milk products, both certified and non-certified, based on the now completed rulemaking proceedings [**38] and consistent with the opinion herein.

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix E

Appendix E



bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

[40 FR 5620, Feb. 6, 1975, as amended at 60 FR 65202, Dec. 18, 1995]

### § 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

(b) Except as provided in paragraphs (c) and (d) of this section, the terms "pasteurization," "pasteurized," and similar terms shall mean the process of heating every particle of milk and milk product in properly designed and operated equipment to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

| Temperature | Time |
|---|---|
| 145 °F (63 °C) [1] | 30 minutes. |
| 161 °F (72 °C) [1] | 15 seconds. |
| 191 °F (89 °C) | 1 second. |

[1] If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F (3 °C).

| Temperature | Time |
|---|---|
| 194 °F (90 °C) | 0.5 second. |
| 201 °F (94 °C) | 0.1 second. |
| 204 °F (96 °C) | 0.05 second. |
| 212 °F (100 °C) | 0.01 second. |

(c) Eggnog shall be heated to at least the following temperature and time specification:

| Temperature | Time |
|---|---|
| 155 °F (69 °C) | 30 minutes. |
| 175 °F (80 °C) | 25 seconds. |
| 180 °F (83 °C) | 15 seconds. |

(d) Neither paragraph (b) nor (c) of this section shall be construed as barring any other pasteurization process that has been recognized by the Food and Drug Administration to be equally efficient in the destruction of microbial organisms of public health significance.

[52 FR 29514, Aug. 10, 1987, as amended at 57 FR 57344, Dec. 4, 1992]

### § 1240.62 Turtles intrastate and interstate requirements.

(a) *Definition.* As used in this section the term "turtles" includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order Testudinata, class Reptilia, except marine species (families Dermachelidae and Chelonidae).

(b) *Sales; general prohibition.* Except as otherwise provided in this section, viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution.

(c) *Destruction of turtles or turtle eggs; criminal penalties.* (1) Any viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution shall be subject to destruction in a humane manner by or under the supervision of an officer or employee of the Food and Drug Administration in accordance with the following procedures:

(i) Any District Office of the Food and Drug Administration, upon detecting viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix F

Appendix F

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Food

Home Food Food Safety Product-Specific Information

## Food Safety and Raw Milk

**November 1, 2011**

Pasteurization of milk was adopted decades ago as a basic public health measure to kill dangerous bacteria and largely eliminate the risk of getting sick from one of the most important staples of the American diet. In 1987, the agency issued a regulation prohibiting the interstate sale of raw milk.

In recent years, however, a small number of Americans (less than 1 percent) have rejected pasteurization in favor of raw (or unpasteurized) milk, citing a range of taste, nutritional and health benefits they believe are associated with raw milk consumption, as well as a general preference for unprocessed food. Today, 20 states explicitly prohibit intrastate raw milk sales in some form and 30 allow it.

While the perceived nutritional and health benefits of raw milk consumption have not been scientifically substantiated, the health risks are clear. Since 1987, there have been 143 reported outbreaks of illness – some involving miscarriages, still births, kidney failure and deaths – associated with consumption of raw milk and raw milk products that were contaminated with pathogenic bacteria such as *Listeria, Campylobacter, Salmonella, and E. coli.* Because *E. coli* can spread from one child to another, the risk is not just to the one that drank the milk.

As a science-based, public health regulatory agency, FDA strongly supports the application of effective measures, such as pasteurization, to protect the safety of the food supply and maintain public confidence in such important, healthy staples of the diet as milk.

However, in light of concerns that have been raised about potential FDA actions, we want to remind the public that FDA does not regulate the *intrastate* sale or distribution of raw milk. Whether to permit the sale and distribution of raw milk within a state is for the state to decide.

With respect to the *interstate* sale and distribution of raw milk, the FDA has never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption.

We urge consumers who purchase raw milk to understand the health risks involved. While raw milk puts all consumers at risk, the elderly, immune-compromised people, children and pregnant women are especially vulnerable to the hazards of raw milk consumption. FDA's consumer education will continue to focus on helping consumers understand the risk to these populations.

The FDA's position on raw milk is in concert with the Centers for Disease Control (CDC) and the American Academy of Pediatricians.

### For More Information

- Questions & Answers on Raw Milk [1]
- Consumer Update: Raw Milk May Pose Health Risk [2]
- Food Facts: The Dangers of Raw Milk - Unpasteurized Milk Can Pose a Serious Health Risk [3]
- Raw Milk Misconceptions and the Danger of Raw Milk Consumption [4]
- Food Safety and Raw Milk from the Centers for Disease Control and Prevention (CDC) [5]
- Milk, Cheese, and Dairy Products from FoodSafety.gov [6]

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**Links on this page:**

1. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm122062.htm
2. /ForConsumers/ConsumerUpdates/ucm232980.htm
3. /Food/ResourcesForYou/Consumers/ucm079516.htm
4. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm247991.htm
5. http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
6. http://www.foodsafety.gov/keep/types/milk/index.html

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- Website Policies

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

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- News & Events
- Training and Continuing Education
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U.S Department of Health & Human Services

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4. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm247991.htm
5. http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
6. http://www.foodsafety.gov/keep/types/milk/index.html

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

| | | |
|---|---|---|
| FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al., | ) | |
| Plaintiffs, | ) | |
| v. | ) | No. C 10-4018-MWB |
| KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al., | ) | |
| Defendants. | ) | |

**DEFENDANTS' COMBINED RESPONSE TO PLAINTIFFS' AMENDED BRIEFS IN SUPPORT OF SUMMARY JUDGMENT AND RESISTANCE TO FDA'S RENEWED MOTION TO DISMISS**

The Food and Drug Administration ("FDA") learned from an Internet posting that a group of raw milk consumers planned to protest at FDA headquarters on November 1, 2011, because they mistakenly believed that their activities solely as consumers of raw milk might lead the government to take enforcement action against them. In response, FDA posted a statement on its website (the "November Statement") to help the protesters and others understand FDA's positions on the established risks associated with consuming raw milk and the enforcement of 21 C.F.R. § 1240.61 against individuals who transport raw milk across state lines solely for personal consumption. *See* Nov. Statement (DR[1] 67-1 Ex. A). In the November Statement, FDA set forth its position on how it would exercise its enforcement discretion with respect to consumers, stating, "[w]ith respect to the interstate sale and distribution of raw milk, the FDA has

[1] "DR" refers to the docket report.

never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own *personal consumption*." *Id.* (emphasis added).

In their latest filings, plaintiffs allege that this statement represents a break from past policies. *See* Pls.' Mots. to Amend & Suppl. Their Brs. in Supp. of Mot. for Summ. J. & Resist. to Defs.' Mot. to Dismiss at 2 ("Pls.' Amends.") (DR 67, 68). Plaintiffs are wrong. The November Statement reflects *precisely* the position that FDA articulated in its letter of March 16, 2011, a copy of which was filed with the Court. *See* Defs.' Status Report of March 16, 2011, (DR 43-1 Ex. A) (the "Administrative Determination").

In responding to questions referred to it by this Court, FDA made clear in the Administrative Determination that it "has *never* sought to bring an enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her personal consumption." *Id.* at 6 (emphasis in original). With respect to the future, FDA stated that it "has *no present intent* to alter significantly its raw milk-related enforcement activities. Producers and distributors of raw milk will remain subject to regulatory action, but it is highly unlikely that FDA would ever bring an enforcement action directly against a person who carried raw milk across state lines solely for his or her personal consumption." *Id.* at 7 (emphasis added). FDA emphasized this point again later: "FDA has not brought enforcement actions against individual consumers in the past and, subject to the considerations described [ ], *has no present intent* to do so in the future." *Id.* at 9 (emphasis added). The considerations described included whether a consumer is "found to frequently distribute raw milk to others, such that the 'consumer' would be more aptly described as a 'distributor.'" *Id.* at 7.

FDA's positions in the November Statement and the Administrative Determination regarding its enforcement policy as to consumers are indistinguishable and clear: FDA does not intend to refer enforcement actions against individuals who transport raw milk across state lines solely for person consumption, but it "intends to continue to direct its limited resources to enforcement actions against those who produce and/or distribute raw, unpasteurized milk in interstate commerce." *See* Admin. Determination at 9; *see also* Nov. Statement.

Thus, plaintiffs' argument that the November Statement constitutes a "tacit recognition" that enforcement of 21 C.F.R. § 1240.61 would be unlawful is wrong. *See* Pls.' Amends. at 2. The Administrative Determination and defendants' prior briefs in this case explain clearly why any transportation of raw milk across state lines violates 21 C.F.R. § 1240.61.[2] Moreover, the November Statement does not address the text of the regulation, but rather how FDA will *enforce* that regulation. *See* Nov. Statement. Likewise, plaintiffs' argument that the November Statement is a "tacit admission" that raw milk poses "no public health risk" is not tethered to reality. *See* Pls.' Amends. at 2. The Administrative Determination, the Administrative Record filed in this case (DR 49), and the November Statement all describe the health risks related to consuming raw milk. *See, e.g.*, Admin. Determination at 2-4; Nov. Statement (devoting three of its seven paragraphs to the public health risks of consuming raw milk).

Ultimately, plaintiffs' arguments boil down to the flawed theory that, unless FDA enforces 21 C.F.R. § 1240.61 against *every* possible violator in *every* circumstance, the decision to take *any* action against a violator is "arbitrary and capricious and irrational."

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[2] *See* Admin. Determination at 4-6; Defs.' Renewed Mot. to Dismiss & Mot. for Summ.

*See* Pls.' Amends. at 3. But FDA's approach is rational precisely because it is based on a careful prioritization of agency resources and competing public health risks. As FDA stated in the Administrative Determination:

> Despite [its] clear and broad regulatory authority over the introduction of raw milk into interstate commerce, the Agency has consistently exercised its enforcement discretion with respect to consumers. . . . In so doing, FDA has never sought to bring an enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her personal consumption. Among other reasons, it would not constitute an efficient use of Agency resources to focus on end-users and consumers. This is true not only with respect to raw milk, but generally also with other products regulated by FDA.

Admin. Determination at 6. This position reflects an unquestionably reasonable exercise of the government's enforcement discretion.[3]

As set forth in prior filings, FDA's intentions with respect to consumers are relevant to this litigation for at least two reasons. First, the fact that FDA has not referred or threatened enforcement actions against consumers establishes that the "consumer-plaintiffs"[4] are bringing a *facial* challenge to 21 C.F.R. § 1240.61. *See* Defs.' Renewed Mot. to Dismiss & Mot. for Summ. J. at 16 (DR 51). Second, because *bona fide* consumers are not threatened with enforcement proceedings, it is not necessary for this Court to reach the consumer-plaintiffs' Constitutional claims. *See id.* at 43-44.

The consumer-plaintiffs previously claimed to live in constant fear of an enforcement action. *See id.* at 16. The November Statement is further and more recent

---

J. at 6-7 (DR 51); Defs.' Br. in Resist. to Pls.' Mot. for Summ. J. at 13-18 (DR 62).

[3] In *Heckler v. Chaney*, 470 U.S. 821 (1985), the Supreme Court held that FDA's decision whether or not to engage in enforcement "is . . . not subject to judicial review" because "agency refusals to institute investigative or enforcement proceedings" are "committed to agency discretion." *Chaney*, 470 U.S. at 837-38; 5 U.S.C. § 701(a)(2).

[4] The "consumer-plaintiffs" are plaintiffs Donnelly, Allen, Miller, Heckman, and Rose.

evidence that these claimed fears are baseless. Because the consumer-plaintiffs are not "*in immediate danger* of sustaining some direct injury as a result of the challenged statue or official conduct," *see* Memorandum and Opinion Order Regarding Defendants' Motion to Dismiss at 41 (DR 27) (citing *Pub. Water Supply Dist. No. 10 of Cass County, Mo. v. City of Peculiar, Mo.*, 345 F.3d 570, 573 (8th Cir. 2003) (emphasis in original)), plaintiffs' new filings demonstrate only that the consumer-plaintiffs' claims are unripe.

Respectfully Submitted,

Of Counsel:
WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Acting Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

THOMAS J. COSGROVE
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301-796-8613

STEPHANIE M. ROSE
United States Attorney

LAWRENCE D. KUDEJ
Assistant United States Attorney
401 First St. SE, Suite 400
Cedar Rapids, IA 52401-1825
319-363-6333
Larry.Kudej@usdoj.gov

By: /s/ Roger Gural
ROGER GURAL
Trial Attorney
Consumer Protection Branch
Department of Justice Civil Division
P.O. Box 386
Washington, D.C. 20044
202-307-0174
Roger.Gural@usdoj.gov

CERTIFICATE OF SERVICE

I certify that I electronically served a copy of the foregoing document to which this certificate is attached to the parties or attorneys of record, shown below, on November 15, 2011.

UNITED STATES ATTORNEY

BY: /s/ Roger Gural

COPIES TO:

David G. Cox
4240 Kendale Road
Columbus, OH 43220

Wallace L. Taylor
118 3rd Avenue, S.E.
Cedar Rapids, IA 52401-1210

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix G

Appendix G





This petition has been responded to by the White House. See the response below.

WE PETITION THE OBAMA ADMINISTRATION TO:

## Legalize raw milk sales on a federal level

Give the people the freedom to choose whether drinking raw milk products is right for them by enabling the legalized sale and distribution of raw milk products across all states.

There are substantial health benefits from raw milk that are not available in pasteurized milk products.

Many of the nutritional, anti-microbial and immune-enhancing components of raw milk are greatly reduced in effectiveness by pasteurization, and completely destroyed by ultra-pasteurization.

The risks associated with drinking raw milk are greatly exaggerated. Compared to raw milk there are 515 times more illnesses from L-mono due to deli meats and 29 times more illness from L-mono due to pasteurized milk.

The Westin A. Price Foundation has more information at:

http://www.realmilk.com/rawmilkoverview.html

**Created:** Sep 23, 2011

**Issues:** Agriculture, Health Care, Human Rights

TOTAL SIGNATURES

**6,078**

**Share this Petition**



OFFICIAL WHITE HOUSE RESPONSE TO

Legalize raw milk sales on a federal level

## Food Safety and Raw Milk

By Doug McKalip

Thank you for signing a petition about legalizing raw milk and for participating in the We the People platform on WhiteHouse.gov. We appreciate consumer concerns on food issues and understand the importance of letting consumers make their own food choices.

This Administration believes that food safety policy should be based on science. In this case, we support pasteurization to protect the safety of the milk supply because the health risks associated with raw milk are well documented.

Pasteurization of milk was adopted decades ago as a basic public health measure to kill dangerous bacteria and largely eliminate the risk of getting sick from one of the most important staples of the American diet. In 1987, the Food and Drug Administration (FDA) issued a regulation prohibiting the

interstate sale of raw milk to reduce the number of illnesses and outbreaks associated with its consumption.

In recent years, some Americans have rejected pasteurization in favor of raw (or unpasteurized) milk, citing a range of taste, nutritional, and health benefits they believe are associated with raw milk consumption, as well as a general preference for unprocessed food.

As a science-based regulatory agency, the FDA looks to the scientific literature for information on benefits and risks associated with raw milk. While the nutritional and health benefits of raw milk consumption have not been scientifically substantiated, the health risks are clear. Since 1987, there have been 143 reported outbreaks of illness – some involving miscarriages, still births, kidney failure and deaths – associated with consumption of raw milk and raw milk products that were contaminated with pathogenic bacteria such as *Listeria, Campylobacter, Salmonella, and E. coli.* The FDA's position on raw milk is in concert with the Center for Disease Control and the American Academy of Pediatricians.

The FDA does not regulate *intrastate* raw milk sales, or selling raw milk within a state, which is left up to the individual states. Today, 20 states explicitly prohibit the intrastate sale of raw milk in some form and 30 allow it. FDA bans *interstate* raw milk sales, or selling raw milk across state lines. The FDA has never taken, nor does it intend to take, enforcement action against an individual who purchases and transports raw milk across state lines solely for his or her own personal consumption.

Thank you for participating in this important process. We appreciate your opinions and look forward to hearing from you again soon.

*Doug McKalip is Senior Policy Advisor for Rural Affairs in the White House Domestic Policy Council*

**Signatures: 39 of 6,078**

CREATOR
Stephanie W
Los Altos, CA
September 23, 2011
Signature # 1

Tom S
Anchorage, AK
January 05, 2012
Signature # 6,078

Howard M
Brooklyn, NY
January 05, 2012
Signature # 6,077

Elizabeth T
, MN
January 05, 2012
Signature # 6,076

American C
January 05, 2012
Signature # 6,075

Aaron T
East Lansing, MI
January 05, 2012
Signature # 6,074

George D
Cleveland, WI
January 05, 2012
Signature # 6,073

Jenny L
Brooklyn, NY
January 05, 2012
Signature # 6,072

Christina M
High Ridge, MO
January 05, 2012
Signature # 6,071

Michael W
Grand Rapids, MI
January 05, 2012
Signature # 6,070

stephanie j
Leesburg, VA
January 03, 2012
Signature # 6,069

charlotte c
Alum Bridge, WV
January 03, 2012
Signature # 6,068

Joanie S
West Portsmouth, OH
January 03, 2012
Signature # 6,067

Erin M
Fort Worth, TX
January 03, 2012
Signature # 6,066

Sandi C
Frankfort, KY
January 03, 2012
Signature # 6,065

frieda w
January 03, 2012
Signature # 6,064

Zachary S
Bluffton, IN
January 02, 2012
Signature # 6,063

Scottee M
Burke, VA
January 02, 2012
Signature # 6,062

Lori G
Fullerton, CA
January 02, 2012
Signature # 6,061

Whitney S
Jacksonville, NC
January 02, 2012
Signature # 6,060

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix H

II

112TH CONGRESS
1ST SESSION

# S. 1955

To authorize the interstate traffic of unpasteurized milk and milk products that are packaged for direct human consumption.

---

IN THE SENATE OF THE UNITED STATES

DECEMBER 7, 2011

Mr. PAUL introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

# A BILL

To authorize the interstate traffic of unpasteurized milk and milk products that are packaged for direct human consumption.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. INTERSTATE TRAFFIC OF UNPASTEURIZED MILK AND MILK PRODUCTS.**

(a) SALE ALLOWED.—Notwithstanding the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), section 361 of the Public Health Service Act (42 U.S.C. 264), and any regulations or other guidance issued under such Act or section, a Federal department, agency, or court may not take any action (such as administrative,

civil, criminal, or other actions) that would prohibit, interfere with, regulate, or otherwise restrict the interstate traffic of milk, or a milk product, that is unpasteurized and packaged for direct human consumption, if such restriction is based on the determination that, solely because such milk or milk product is unpasteurized, such milk or milk product is adulterated, misbranded, or otherwise in violation of Federal law.

(b) DEFINITIONS.—In this section, the following definitions apply:

(1) The terms "interstate traffic", "milk", and "milk product" have the meanings given those terms in section 1240.3 of title 21, Code of Federal Regulations (as in effect on the date of enactment of this Act).

(2) The term "packaged for direct human consumption" means milk and milk products that are packaged for the final consumer and intended for human consumption. Such term does not include milk and milk products that are packaged for additional processing, including pasteurization, before being consumed by humans.

(3) The term "pasteurized" means the process of heating milk and milk products to the applicable temperature specified in the tables contained in sec-

tion 1240.61 of title 21, Code of Federal Regulations (or successor regulations), and held continuously at or above that temperature for at least the corresponding specified time in such tables.

○

I

112TH CONGRESS
1ST SESSION

# H. R. 1830

To authorize the interstate traffic of unpasteurized milk and milk products that are packaged for direct human consumption.

---

IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2011

Mr. PAUL introduced the following bill; which was referred to the Committee on Energy and Commerce

---

# A BILL

To authorize the interstate traffic of unpasteurized milk and milk products that are packaged for direct human consumption.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. INTERSTATE TRAFFIC OF UNPASTEURIZED MILK AND MILK PRODUCTS.**

(a) SALE ALLOWED.—Notwithstanding the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), section 361 of the Public Health Service Act (42 U.S.C. 264), and any regulations or other guidance issued under such Act or section, a Federal department, agency, or court may not take any action (such as administrative,

civil, criminal, or other actions) that would prohibit, interfere with, regulate, or otherwise restrict the interstate traffic of milk, or a milk product, that is unpasteurized and packaged for direct human consumption, if such restriction is based on the determination that, solely because such milk or milk product is unpasteurized, such milk or milk product is adulterated, misbranded, or otherwise in violation of Federal law.

(b) DEFINITIONS.—In this section, the following definitions apply:

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(2) The term "packaged for direct human consumption" means milk and milk products that are packaged for the final consumer and intended for human consumption. Such term does not include milk and milk products that are packaged for additional processing, including pasteurization, before being consumed by humans.

(3) The term "pasteurized" means the process of heating milk and milk products to the applicable temperature specified in the tables contained in sec-

tion 1240.61 of title 21, Code of Federal Regulations (or successor regulations), and held continuously at or above that temperature for at least the corresponding specified time in such tables.

○

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix I

Appendix I

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

News & Events



I

## FDA NEWS RELEASE

**For Immediate Release:** Feb. 22, 2012
**Media Inquiries:** Siobhan DeLancey, 301-796-4668, siobhan.delancey@fda.hhs.gov
**Trade Inquiries:** Sebastian Cianci, 240-402-2291, sebastian.cianci@fda.hhs.gov
**Consumer Inquiries:** 888-INFO-FDA

### Federal government gains permanent injunction against raw milk producer

*Farmer enjoined from distributing raw milk products across state lines*

A federal court has granted the U.S. Food and Drug Administration a permanent injunction preventing Daniel L. Allgyer and his Rainbow Acres Farm from distributing raw milk and raw milk products in final package form for human consumption across state lines.

U.S. District Judge Lawrence F. Stengel, of the Eastern District of Pennsylvania, also ruled that Allgyer's participation in a so-called "private buying club" does not shield him from federal oversight, and that Allgyer's "cow share" agreements are a subterfuge for sales of raw milk. Members of the private buying club had allegedly purchased "shares" of individual cows and then claimed that their reputed ownership entitled them to raw milk from those cows. Allgyer provided the association members who lived outside of Pennsylvania with containers of raw milk, even though federal law prohibits sales of raw milk for human consumption across state lines. Raw milk sales are legal within the state of Pennsylvania.

Allgyer also violated federal law by not providing any labeling on the raw milk containers sold to consumers.

The FDA sought the injunction against Allgyer after documenting multiple and repeated violations of federal law. The agency issued a warning letter to Allgyer in April 2010, informing him of these violations and requesting that he take corrective measures to avoid regulatory action. Despite such warning, Allgyer continued to operate in violation of federal law.

The permanent injunction requires Allgyer to place a statement on his products, invoices, and website that he will no longer distribute unpasteurized milk or milk products in interstate commerce. He also must keep complete records of each sale, including the name and address of each buyer, the date of sale or distribution, and the amount and type of products sold, and must provide a copy of the Court's order to all employees and persons who work with him to distribute unpasteurized milk and milk products.

Raw milk products for human consumption (with the exception of certain cheeses aged at least 60 days) have been prohibited in interstate commerce since 1987. But pasteurization was adopted as a common practice decades prior to the federal regulation to prevent foodborne illness from bacteria such as E.coli, Salmonella, Campylobacter, Yersinia, Brucella and the causative organism of tuberculosis.

A recent study published by the Centers for Disease Control and Prevention covering a 13-year period determined that raw milk products are 150 times more likely to cause a foodborne illness outbreak than pasteurized milk products. While pasteurization effectively kills bacteria through heating, milk is occasionally contaminated after pasteurization.

**For more information:**

Rainbow Acres Farm Warning Letter [1]

The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk [2]

CDC Study: Majority of dairy-related disease outbreaks linked to raw milk
http://www.cdc.gov/media/releases/2012/p0221_raw_milk_outbreak.html [3]

#

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**Links on this page:**

1. /ICECI/EnforcementActions/WarningLetters/2010/ucm209276.htm
2. /Food/ResourcesForYou/Consumers/ucm079516.htm
3. http://www.cdc.gov/media/releases/2012/p0221_raw_milk_outbreak.html

- Site Map
- Transparency
- Website Policies


U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA


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- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

U.S Department of Health & Human Services


**Links on this page:**

1. /ICECI/EnforcementActions/WarningLetters/2010/ucm209276.htm
2. /Food/ResourcesForYou/Consumers/ucm079516.htm
3. http://www.cdc.gov/media/releases/2012/p0221_raw_milk_outbreak.html

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix J

Appendix J

Goshen News, Goshen, IN

*December 17, 2011*

# Middlebury dairy farmer, Sheriff stand up to FDA

## Forest Grove Dairy the focus of federal investigation

*By ROGER SCHNEIDER*
**THE GOSHEN NEWS**

GOSHEN — David Hochstetler of rural Middlebury distributes raw milk to people who buy into his herd of Jersey cows. That action has drawn the ire of the Food and Drug Administration, which wants to inspect his farm because it believes it is the source of a 2010 bacteria outbreak in Michigan. But Sheriff Brad Rogers has a message for the FDA, which is "get a warrant."

The conflict between the local and federal authorities came to a head two weeks ago when Hochstetler was summoned to testify before a federal grand jury in Detroit. He declined to appear, invoking his 5th Amendment right. Sheriff Rogers also notified the Justice Department attorney that if FDA agents tried to inspect Hochstetler's farm without a signed warrant, they would be arrested on trespassing charges.

Since then the federal subpoena for Hochstetler has been withdrawn, according to Rogers.

The sheriff sees his action as protecting a local Amish resident, who he called "an honest man," from being harassed by federal officials.

"The thing is that if the FDA agents come in and they meet with the farmer and the farmer wants them to come in, I don't have a problem with that," Rogers said. "But in this case Mr. Hochstetler did not want the agents there. This is an administrative rule of the federal government and I think people are tired of the federal government walking all over everybody and it is time to take a stand for states' rights."

Rogers said sheriffs across the country are beginning to resist actions by federal regulatory agencies when a warrant has not been issued. He cited a 1997 Supreme Court ruling, Printz vs. The United States, that found in favor of a sheriff who did not want to enforce the federal Brady Act gun laws. That act required local law officers to enforce the federal law. The case was based on the 10th Amendment, which states that powers not specifically granted to the federal government are reserved for the states.

"This isn't about raw milk," Rogers said. "It's about fundamental rights."

### Federal stance

Ross Goldstein is the Justice Department attorney who is investigating Hochstetler's operation. Friday he declined to comment on the case, saying federal law prohibits him from talking about grand jury cases.

"We can't talk about it," Goldstein said, "because there is an ongoing federal investigation."

But Goldstein did email Rogers and warned him that interfering with a federal investigation could be prosecuted as a felony and would carry up to a three-year term in prison. Goldstein also cited the federal "supremacy clause" that the Supreme Court has interpreted as making federal rules and laws superior to local ones.

"The supremacy clause has been interpreted since the earliest days of the nation to mean that federal law trumps state law whenever the two conflict," Goldstein wrote.

And the attorney contends that federal law specifically allows the inspection of Hochstetler's farm without a warrant.

"Because Forest Grove Dairy manufactures, processes, packages or holds food, the provision of federal law authorizes FDA personnel to enter Mr. Hochstetler's property," Goldstein wrote. "Because it is a federal law, indeed an act of Congress, officers or employees of the FDA may do so lawfully without regard to any Indiana law to the contrary."

After receiving the email, Rogers indicated he is not changing his stance. He said he has talked to county attorneys about the issue, but in the end, any action or inaction is his call.

There have been no recent attempts by the FDA to inspect Hochstetler's farm, Rogers said. The last attempt was in March, at which time Hochstetler refused entry to the inspectors, according to the sheriff.

"He was desperate, frustrated at what he perceived as harassment,"Rogers said of Hochstetler, who contacted him for help. "This man is an Amish man, an honest man who is trying to make a living."

When contacted by The News, Hochstetler declined to comment for this article

**Others supportive**

Rogers said he has been receiving new email in support of his action about every 10 minutes since word about his warning to the FDA spread across the Internet.

One of those supporters is Deborah Stockton, executive director of the National Independent Consumers and Farmers Association. Her agency is an advocate for small farmers who want to sell ag products directly to consumers. She sees Rogers as a brave man taking on the massive and powerful established agriculture industry and government agencies that support that industry.

"I think it was a brave thing for him to do," she said. "This is increasingly occurring around the country."

She said the FDA has taken a strong stance against the consumption of raw milk, which puts the agency in conflict with thousands of consumers who see raw milk as a nutritious and healthy alternative to pasteurized and homogenized milk.

Congress banned the sale of raw milk in 1987, so consumers have bought shares in cow herds to get around that ban.

"There are very few instances where it was proved raw milk was linked to illnesses," Stockton said.

She also wondered why the FDA, which she claimed cited the lack of funds for other investigations, particularly an outbreak of illness traced to a peanut plant, has spent so much time going after Hochstetler.

"But they do have enough money to have a two-year undercover operation against an Amish farmer whose product has not hurt anyone," Stockton said.

**The allegations**

The Michigan Department of Health believes Hochstetler's raw milk has caused illnesses. The department issued a health warning March 19, 2010, which claimed that raw milk from Hochstetler's Forest Grove Dairy and distributed through a food co-op in Vandalia, Mich., was the source of campylobacter, a bacteria that sickened at least 13 people in Michigan who drank the milk.

In April 2010, Hochstetler told The Goshen News that he had an independent lab test of his milk for the bacteria and nothing was found.

On Friday, a spokeswoman for the Michigan Department of Health said her department has turned over test results from that outbreak in 2010 to the FDA.

"Our epidemiological evidence points to Forest Grove, that the milk came from Forest Grove," spokeswoman Angela Minicuci said. "From there it was turned over to FDA for investigation."

**The issue is rights**

Rogers said his whole point in confronting the FDA is to protect the Constitutional rights of local residents. He indicated he wants the federal agency to go through the court system and present its evidence to a judge, who could then decide if there was enough evidence to justify the issuance of a warrant allowing the inspection of Forest Grover Dairy.

"Due process is the important part of it... Quite frankly, we have state laws and county ordinances and so on," Rogers said. "For example, the health department does inspections. Even with those, I am very pro health department, but on the other hand, if the store owner says 'No, I don't want you coming in,' they will probably close them down, and that's fine. But they don't have to let them come in, in the true sense of the word. They have the right to go further with their due process."

And Rogers' reasoning is something Stockton finds refreshing.

"Sheriff Rogers has taken on the role that we hope every sheriff in the country will take... upholding his oath of office and protecting the inalienable rights of everyone," she said.

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix K

# History of Pasteurization

| Date: | Event: |
|---|---|
| 1822-1895 | French chemist and biologist Louis Pasteur, considered one of the fathers of microbiology, helped prove that infectious diseases and food-borne illnesses were caused by germs, known as the "germ theory." Pasteur's research demonstrated that harmful microbes in milk and wine caused sickness, and he invented a process—now called "pasteurization"—whereby the liquids were quickly heated and cooled to kill most of the microorganisms. |
| 1893 | Certification of Milk—milk-borne illness was a major problem. Milk produced at unhygienic production facilities (like distillery dairies[1]) served as a medium to spread diseases like typhoid and tuberculosis. These diseases created a public health crisis that led to skyrocketing infant mortality in the cities. As a result, "in 1889, two years before the death of his son from contaminated milk, Newark, New Jersey doctor Henry Coit, MD urged the creation of a Medical Milk Commission to oversee or "certify" production of milk for cleanliness, finally getting one formed in 1893." |
| 1895 | Commercial pasteurizing machines for milk were introduced to the United States. |
| 1899 | Auguste Gaulin obtained a patent on his homogenizer. The patent consisted of a 3 piston pump in which product was forced through one or more hair life tubes under pressure. |
| 1908 | First compulsory pasteurization law (Chicago) applying to all milk except that from tuberculin tested cows. |
| 1913 | A large typhoid epidemic in New York City was reported and attributed to contaminated milk. |
| 1914 | The first tank trucks for transporting milk were used. |
| 1917 | Pasteurization of all milk except that from cows proven to be free of tuberculosis was either required or officially encouraged in 46 of the country's 52 largest cities. The proportion of milk pasteurized in these cities ranged from 10% to 97%; in most it was well over 50%. |
| 1922 | Congress passed the Capper-Volstead Act, allowing producers of agricultural products, such as milk, to "act together in associations" to organize collective processing, preparation for market, handling, and marketing of milk and other agricultural goods. The act was of historic significance as it granted producers of milk and other agricultural products special exemptions from monopoly laws to help farmers raise the price for their products. |
| 1937 | Milk marketing orders came into existence as a result of the Agricultural Marketing Agreement Act of 1937. The rationale for the legislation was to reduce disorderly marketing conditions, improve price stability in fluid milk markets, and ensure a sufficient quantity of pure and wholesome milk. The orders are regulations approved by dairy farmers in individual fluid milk markets that require manufacturers to pay |

[1] In the early 19th century, the alcohol distillery business in the United States began to grow. Large amounts of swill (spent-grains) were produced as a byproduct of whiskey and other alcohol production. Many distilleries opened dairies and began feeding their dairy cows with the waste swill. The low nutritional content of the swill lead to sickness in the cows and in the humans who drank their milk.

| | |
|---|---|
| | minimum monthly prices for milk purchases. |
| 1939 | The U.S. Public Health Service had drafted the Model Milk Health Ordinance and was actively promoting it for adoption at the local level. |
| 1946 | Vacuum pasteurization method perfected. |
| 1948 | Ultra-high temperature pasteurization is introduced. |
| 1968 | Electronic testing for milk is introduced commercially marking the official acceptance of process. |
| 1974 | Voluntary nutrition labeling on fluid milk products was initiated after the FDA advised that all foods should have nutrition labels. |
| 1981 | UHT (ultra high temperature) milks gain national recognition. |
| 1983 | The Dairy Production Stabilization Act of 1983 authorized a national producer program for dairy product promotion, research, and nutrition education to increase human consumption of milk and dairy products and reduce milk surpluses. The self-help program is funded by a mandatory 15-cent-per hundred weight assessment on all milk produced in the contiguous 48 States and marketed commercially by dairy farmers. It is administered by the National Dairy Promotion and Research Board (Dairy Board). The Dairy Act provides that dairy farmers can direct up to 10 cents per hundred weight of assessment for contributions to qualified regional, State, or local dairy product promotion, research or nutrition education programs. |
| August 10, 1987 | The FDA published a final regulation mandating the pasteurization of all milk and milk products in final package form for direct human consumption. This regulation banned the shipping of raw milk in interstate commerce and became effective September 9, 1987. |
| 1998 | The Weston A. Price Foundation initiated the "Real Milk Campaign" to promote the health benefits of raw cow's milk and to advocate for the legalization of raw milk sales. The goal of this campaign is to make raw milk available to consumers in all 50 states and throughout the world. |

References:

http://www.idfa.org/files/249_Milestones%20of%20Milk.pdf

http://milk.procon.org/view.resource.php?resourceID=000832

http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?sid=b3a18e20-3b94-45c8-8876-5253c62429e9%40sessionmgr10&vid=2&hid=19

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix L

Public Health Service
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)

July 18, 2012

To: State and Territorial Epidemiologists
State Public Health Veterinarians

**The Ongoing Public Health Hazard of Consuming Raw Milk**

*The purpose of this letter is to provide state and territorial public health officials with information and resources on the risks of consuming raw milk and other unpasteurized dairy products. Please distribute this letter to those involved with raw milk issues in your state and territory, and to others who have an interest in this important public health issue.*

The role of raw milk and other unpasteurized dairy products in the transmission of infectious diseases is well documented. Pasteurization is the process of heating milk to a high enough temperature for a long enough time to kill disease-causing bacteria. Raw milk was recognized as a source of severe infections over 100 years ago, and pasteurization of milk to prevent these infections is one of the public health triumphs of the 20th century. Human pathogens such as *Escherichia coli* O157, *Campylobacter jejuni*, and *Salmonella* can contaminate milk during the milking process because they are shed in the feces of healthy-looking dairy animals, including cows and goats. Infection with these pathogens can cause severe, long-term consequences, such as hemolytic uremic syndrome, which can result in kidney failure, and Guillain-Barré syndrome, which can result in paralysis. These infections are particularly serious in those who are very young, very old, or who have impaired immune systems. They can even be fatal.

Adherence to good hygienic practices during milking can reduce, but not eliminate, the risk of milk contamination. Pasteurization is the only way to ensure that fluid milk products do not contain harmful bacteria. In order to be pasteurized, milk is legally required to meet the Grade A standard for cleanliness. Routine pasteurization of milk began in the 1920s and became widespread in the United States by 1950 as a means to reduce contamination and resulting illness. This led to dramatic reductions in diseases previously associated with milk. Many public health experts consider pasteurization to be one of public health's most effective food safety interventions. Pasteurization is recommended for all animal milk consumed by humans by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the American Academy of Pediatrics, the American Academy of Family Practitioners, the American Veterinary Medical Association, the National Association of State Public Health Veterinarians, and many other medical and scientific organizations.

In 1987, the FDA prohibited the distribution of raw milk over state lines for direct sale to consumers. Despite the federal ban on sale of raw milk across state lines and broad use of

pasteurization by the dairy industry, human illness and outbreaks associated with consumption of unpasteurized products continue to occur. Raw milk is still available for sale in many states, and CDC data shows that the rate of raw milk-associated outbreaks is higher in states in which the sale of raw milk is legal than in states where sale of raw milk is illegal.

Among dairy product-associated outbreaks reported to CDC between 1973 and 2009 in which the investigators reported whether the product was pasteurized or raw, 82% were due to raw milk or cheese. From 1998 through 2009, 93 outbreaks due to consumption of raw milk or raw milk products were reported to CDC. These resulted in 1,837 illnesses, 195 hospitalizations, and 2 deaths. Most of these illnesses were caused by *Escherichia coli*, *Campylobacter*, or *Salmonella*. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; among the 93 raw dairy product outbreaks from 1998 to 2009, 79% involved at least one person younger than 20 years old.

A study released by CDC in February 2012 examined the impact of laws preventing raw milk sales on the number of dairy outbreaks in the United States during 1993—2006. Three-quarters of the outbreaks reported occurred in states where the sale of raw milk was legal at the time. Experts also found that those sickened in raw milk outbreaks were 13 times more likely to be hospitalized than those who got ill from pasteurized milk during an outbreak. States that allow the legal sale of raw milk for human consumption have more raw milk-related outbreaks of illness than states that do not allow raw milk to be sold legally.

To protect the health of the public, state regulators should continue to support pasteurization and consider further restricting or prohibiting the sale and distribution of raw milk and other unpasteurized dairy products in their states.

CDC has a recently updated raw milk website that contains useful information and materials, including a list of relevant publications and other scientific resources on illnesses associated with raw milk consumption. This information can be shared with persons involved in foodborne outbreak investigations and the regulation of unpasteurized dairy products.

Sincerely,

Robert Tauxe, MD, MPH
Deputy Director, Division of Foodborne, Waterborne, and Environmental Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS C-09
Atlanta, Georgia 30333

## Raw Milk Resources

- **RESOURCES FOR CONSUMERS**
  - CDC: Food Safety and Raw Milk
    - http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
    - http://www.cdc.gov/foodsafety/rawmilk/raw-milk-videos.html
    - http://www2c.cdc.gov/podcasts/player.asp?f=8622941
  - FDA: Consumer Information About Milk Safety
    - http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/default.htm
  - FoodSafety.gov
    - http://www.foodsafety.gov/keep/types/milk/index.html
  - Real Raw Milk Facts
    - http://www.realrawmilkfacts.com/
- **RESOURCES FOR PUBLIC HEALTH OFFICIALS**
  - Selected MMWR Articles
    - CDC. Notes from the Field: *Salmonella* Newport infections associated with consumption of unpasteurized milk --- Utah, April--June 2010. MMWR Morb Mortal Wkly Rep 2010;59;817-818. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a6.htm?s_cid=mm5926a6_w
    - CDC. *Campylobacter jejuni* infection associated with unpasteurized milk and cheese--Kansas, 2007. MMWR Morb Mortal Wkly Rep 2009;57:1377-1379. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a2.htm
    - CDC. *Escherichia coli* 0157:H7 infections in children associated with raw milk and raw colostrum from cows---California, 2006. MMWR Morb Mortal Wkly Rep 2008;57:625-628. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5723a2.htm
    - CDC. Outbreak of multidrug-resistant *Salmonella enterica* serotype Newport infections associated with consumption of unpasteurized Mexican-style aged cheese--Illinois, March 2006---April 2007. MMWR Morb Mortal Wkly Rep 2008;57:432-435. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5716a4.htm
    - CDC. *Salmonella* Typhimurium Infection Associated with Raw Milk and Cheese Consumption --- Pennsylvania, 2007. MMWR Morb Mortal Wkly Rep 56;1161-1164. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5644a3.htm
    - CDC. *Escherichia coli* O157:H7 Infection Associated with Drinking Raw Milk --- Washington and Oregon, November--December 2005. MMWR Morb Mortal Wkly Rep 56;165-167. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a3.htm
    - CDC. Multistate Outbreak of *Salmonella* Serotype Typhimurium Infections Associated with Drinking Unpasteurized Milk --- Illinois, Indiana, Ohio, and Tennessee, 2002—2003. MMWR Morb Mortal Wkly Rep 52;613-615. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5226a3.htm

- CDC. Outbreak of *Campylobacter jejuni* Infections Associated with Drinking Unpasteurized Milk Procured through a Cow-Leasing Program --- Wisconsin, 2001. MMWR Morb Mortal Wkly Rep 51;548-549. http://198.246.98.21/mmWR/preview/mmwrhtml/mm5125a2.htm
- CDC. Outbreak of Listeriosis Associated With Homemade Mexican-Style Cheese --- North Carolina, October 2000--January 2001. MMWR Morb Mortal Wkly Rep 50;560-2. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5026a3.htm
- CDC. Outbreak of *Escherichia coli* O157:H7 Infection Associated With Eating Fresh Cheese Curds --- Wisconsin, June 1998. MMWR Morb Mortal Wkly Rep 49;911-3. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4940a3.htm
- CDC. *Campylobacter* Outbreak Associated with Certified Raw Milk Products-- California. MMWR Morb Mortal Wkly Rep. 1984;33(39):562. http://www.cdc.gov/mmwr/preview/mmwrhtml/00000412.htm
- CDC. Campylobacteriosis Associated with Raw Milk Consumption – Pennsylvania. MMWR Morb Mortal Wkly Rep. 1983;32;337-8,344. http://www.cdc.gov/mmwr/preview/mmwrhtml/00000104.htm

- Selected Publications (available online and through research libraries)
  - Langer AJ, Ayers T, Grass J, Lynch M, Angulo FJ, Mahon BE. Nonpasteurized dairy products, disease outbreaks, and state laws-United States, 1993-2006. Emerging infectious diseases. Mar 2012;18(3):385-391.
  - MacDonald PD, Whitwam RE, Boggs JD, et al. Outbreak of listeriosis among Mexican immigrants as a result of consumption of illicitly produced Mexican-style cheese. Clin Infect Dis. 2005 Mar 1;40(5):677-82.
  - Villar RG, Macek MD, Simons S, et al. Investigation of multidrug-resistant *Salmonella* serotype Typhimurium DT104 infections linked to raw-milk cheese in Washington State. JAMA. 1999 May 19;281(19):1811-6.
  - Headrick ML, Korangy S, Bean NH, et al. The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992. Am J Public Health. 1998 Aug;88(8):1219-21.
  - Altekruse SF, Timbo BB, Mowbray JC, Bean NH, Potter ME. Cheese-associated outbreaks of human illness in the United States, 1973 to 1992: sanitary manufacturing practices protect consumers. J Food Prot. 1998 Oct;61(10):1405-7.
  - Fishbein DB, Raoult D. A cluster of *Coxiella burnetii* infections associated with exposure to vaccinated goats and their unpasteurized dairy products. Am J Trop Med Hyg. 1992 Jul;47(1):35-40.

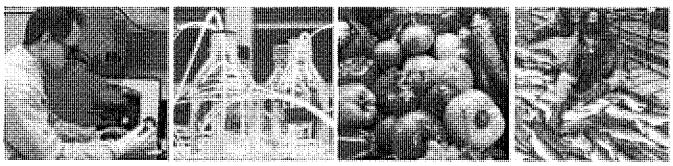
- Position Statements by National Organizations
  - National Environmental Health Association Position Statement http://www.neha.org/position_papers/position_raw_milk.htm
  - American Association of Public Health Veterinarians http://www.dairy.state.nv.us/Position%20Statements/PUBLIC%20HEALTH%20VETERINARIAN%20COALITION%20COMMITTEE.pdf
  - American Veterinary Medical Association Position Statement http://www.avma.org/issues/policy/milk.asp
  - American Medical Association (AMA) – Page 144 http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf

        - International Association for Food Protection Position Statement http://dairy.state.nv.us/Position%20Statements/International%20Association%20for%20Food%20Protection%20position%20statement%20Final.pdf
        - National Conference on Interstate Milk Shipments http://www.ohiodairyvets.org/wp-content/uploads/2007/08/ncims-raw-milk-resolution.pdf

    - FDA Health Education Materials
        - Educator's Toolkit on Preventing Listeriosis in Hispanic Populations (in English and Spanish) http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm062993.htm
        - Food Safety for Moms-to-Be Educator's Toolkit with section on Listeriosis (in English and Spanish) http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm081785.htm
        - Moms-to-Be video (with *Listeria* information section in English and Spanish) http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm089619.htm
        - Food Fact sheet on the Dangers of Raw Milk (in English and Spanish) http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079516.htm

    - Abuela Project http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1508756

- **RESOURCES FOR HEALTH CARE PROVIDERS**
    - American Academy of Pediatrics Committee on Infectious Diseases. Appendix VIII. Prevention of Disease From Potentially Contaminated Food Products Red Book.; 2009: 857-859. [Subscription Required] http://aapredbook.aappublications.org/cgi/content/full/2009/1/6.8

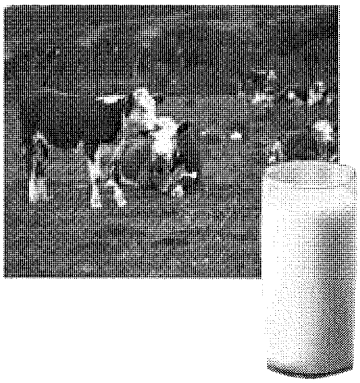


# FOODFACTS

*From the U.S. Food and Drug Administration*

# The Dangers of Raw Milk

## *Unpasteurized Milk Can Pose a Serious Health Risk*



Milk and milk products provide a wealth of nutrition benefits. But raw milk can harbor dangerous microorganisms that can pose serious health risks to you and your family. According to the Centers for Disease Control and Prevention, more than 800 people in the United States have gotten sick from drinking raw milk or eating cheese made from raw milk since 1998.

Raw milk is milk from cows, sheep, or goats that has not been pasteurized to kill harmful bacteria. This raw, unpasteurized milk can carry dangerous bacteria such as *Salmonella*, *E. coli*, and *Listeria,* which are responsible for causing numerous foodborne illnesses.

These harmful bacteria can seriously affect the health of anyone who drinks raw milk, or eats foods made from raw milk. However, the bacteria in raw milk can be especially dangerous to **pregnant women, children, the elderly, and people with weakened immune systems.**

## "Pasteurized Milk" Explained

Pasteurization is a process that kills harmful bacteria by heating milk to a specific temperature for a set period of time. First developed by Louis Pasteur in 1864, pasteurization kills harmful organisms responsible for such diseases as listeriosis, typhoid fever, tuberculosis, diphtheria, and brucellosis.

Research shows no meaningful difference in the nutritional values of pasteurized and unpasteurized milk. Pasteurized milk contains low levels of the type of nonpathogenic bacteria that can cause food spoilage, so storing your pasteurized milk in the refrigerator is still important.

### Raw Milk & Pasteurization: Debunking Milk Myths

While pasteurization has helped provide safe, nutrient-rich milk and cheese for over 120 years, some people continue to believe that pasteurization harms milk and that raw milk is a safe, healthier alternative.

Here are some common myths and proven facts about milk and pasteurization:

- Pasteurizing milk **DOES NOT** cause lactose intolerance and allergic reactions. Both raw milk and pasteurized milk can cause allergic reactions in people sensitive to milk proteins.
- Raw milk **DOES NOT** kill dangerous pathogens by itself.
- Pasteurization **DOES NOT** reduce milk's nutritional value.
- Pasteurization **DOES NOT** mean that it is safe to leave milk out of the refrigerator for extended time, particularly after it has been opened.
- Pasteurization **DOES** kill harmful bacteria.
- Pasteurization **DOES** save lives.

## Raw Milk and Serious Illness

### Symptoms and Advice

Symptoms of foodborne illness include:

- Vomiting, diarrhea, and abdominal pain
- Flulike symptoms such as fever, headache, and body ache

While most healthy people will recover from an illness caused by harmful bacteria in raw milk — or in foods made with raw milk — within a short period of time, some can develop symptoms that are chronic, severe, or even life-threatening.

If you or someone you know becomes ill after consuming raw milk or products made from raw milk — or, if you are pregnant and think you could have consumed contaminated raw milk or cheese — see a doctor or healthcare provider immediately.

### The Dangers of Listeria and Pregnancy

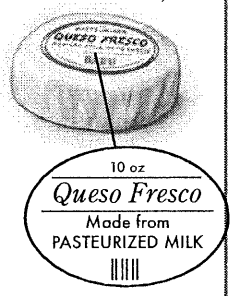
Pregnant women run a serious risk of becoming ill from the bacteria *Listeria*, which can cause miscarriage, fetal death or illness or death of a newborn. If you are pregnant, consuming raw milk — or foods made from raw milk, such as Mexican-style cheese like Queso Blanco or Queso Fresco — can harm your baby even if *you* don't feel sick.

# Protect Your Family with Wise Food Choices

Most milk and milk products sold commercially in the United States contain pasteurized milk or cream, or the products have been produced in a manner that kills any dangerous bacteria that may be present. But unpasteurized milk and products made from unpasteurized milk *are* sold and may be harmful to your health. To avoid getting sick from the dangerous bacteria found in raw milk, you should choose your milk and milk products carefully. Consider these guidelines:

## Okay to Eat

- **Pasteurized** milk or cream
- Hard cheeses such as cheddar, and extra hard grating cheeses such as Parmesan
- Soft cheeses, such as Brie, Camembert, blue-veined cheeses, and Mexican-style soft cheeses such as Queso Fresco, Panela, Asadero, and Queso Blanco made from **pasteurized** milk




- Processed cheeses
- Cream, cottage, and Ricotta cheese made from **pasteurized** milk
- Yogurt made from **pasteurized** milk
- Pudding made from **pasteurized** milk
- Ice cream or frozen yogurt made from **pasteurized** milk

## Unsafe to Eat

- Unpasteurized milk or cream
- Soft cheeses, such as Brie and Camembert, and Mexican-style soft cheeses such as Queso Fresco, Panela, Asadero, and Queso Blanco made from unpasteurized milk
- Yogurt made from unpasteurized milk
- Pudding made from unpasteurized milk
- Ice cream or frozen yogurt made from unpasteurized milk

## When in Doubt — Ask!

Taking a few moments to make sure milk is pasteurized — or that a product isn't *made* from raw milk — can protect you or your loved ones from serious illness.

- **Read the label.** Safe milk will have the word "pasteurized" on the label. If the word "pasteurized" does not appear on a product's label, it may contain raw milk.
- Don't hesitate to **ask your grocer or store clerk** whether milk or cream has been pasteurized, especially milk or milk products sold in refrigerated cases at grocery or health food stores.
- Don't buy milk or milk products at farm stands or farmers' markets **unless you can confirm** that it has been pasteurized.

## Is Your Homemade Ice Cream Safe?

Each year, homemade ice cream causes serious outbreaks of infection from *Salmonella*. The ingredient responsible? Raw or undercooked eggs. If you choose to make ice cream at home, use a pasteurized egg product, egg substitute, or pasteurized shell eggs in place of the raw eggs in your favorite recipe. There are also numerous egg-free ice cream recipes available.

***Everyone can practice safe food handling by following these four simple steps:***




For more information, contact: The U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Food Information Line at 1-888-SAFEFOOD (toll free), 10 AM to 4 PM ET, Monday through Friday. Or visit the FDA Web site at **www.fda.gov**.

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Food

Home Food Food Safety Product-Specific Information

## Food Safety and Raw Milk

**November 1, 2011**

Pasteurization of milk was adopted decades ago as a basic public health measure to kill dangerous bacteria and largely eliminate the risk of getting sick from one of the most important staples of the American diet. In 1987, the agency issued a regulation prohibiting the interstate sale of raw milk.

In recent years, however, a small number of Americans (less than 1 percent) have rejected pasteurization in favor of raw (or unpasteurized) milk, citing a range of taste, nutritional and health benefits they believe are associated with raw milk consumption, as well as a general preference for unprocessed food. Today, 20 states explicitly prohibit intrastate raw milk sales in some form and 30 allow it.

While the perceived nutritional and health benefits of raw milk consumption have not been scientifically substantiated, the health risks are clear. Since 1987, there have been 143 reported outbreaks of illness – some involving miscarriages, still births, kidney failure and deaths – associated with consumption of raw milk and raw milk products that were contaminated with pathogenic bacteria such as *Listeria, Campylobacter, Salmonella, and E. coli.* Because *E. coli* can spread from one child to another, the risk is not just to the one that drank the milk.

As a science-based, public health regulatory agency, FDA strongly supports the application of effective measures, such as pasteurization, to protect the safety of the food supply and maintain public confidence in such important, healthy staples of the diet as milk.

However, in light of concerns that have been raised about potential FDA actions, we want to remind the public that FDA does not regulate the *intrastate* sale or distribution of raw milk. Whether to permit the sale and distribution of raw milk within a state is for the state to decide.

With respect to the *interstate* sale and distribution of raw milk, the FDA has never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption.

We urge consumers who purchase raw milk to understand the health risks involved. While raw milk puts all consumers at risk, the elderly, immune-compromised people, children and pregnant women are especially vulnerable to the hazards of raw milk consumption. FDA's consumer education will continue to focus on helping consumers understand the risk to these populations.

The FDA's position on raw milk is in concert with the Centers for Disease Control (CDC) and the American Academy of Pediatricians.

### For More Information

- Questions & Answers on Raw Milk [1]
- Consumer Update: Raw Milk May Pose Health Risk [2]
- Food Facts: The Dangers of Raw Milk - Unpasteurized Milk Can Pose a Serious Health Risk [3]
- Raw Milk Misconceptions and the Danger of Raw Milk Consumption [4]
- Food Safety and Raw Milk from the Centers for Disease Control and Prevention (CDC) [5]
- Milk, Cheese, and Dairy Products from FoodSafety.gov [6]

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**Links on this page:**

1. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm122062.htm
2. /ForConsumers/ConsumerUpdates/ucm232980.htm
3. /Food/ResourcesForYou/Consumers/ucm079516.htm
4. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm247991.htm
5. http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
6. http://www.foodsafety.gov/keep/types/milk/index.html

- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
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Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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4. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm247991.htm
5. http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
6. http://www.foodsafety.gov/keep/types/milk/index.html

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Food

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## Questions & Answers: Raw Milk

March 1, 2007; Updated March 26, 2010; Updated November 1, 2011


1. Is it safe to consume raw milk?
2. Have any illnesses or deaths been caused by consuming raw milk products?
3. What are some of the symptoms of illnesses that can be caused by consuming raw milk?
4. Are there any benefits to drinking raw milk?
5. Is it legal to sell raw milk for human consumption?
6. How does the pasteurization of raw milk protect consumers?
7. Does pasteurization affect the nutrient content of milk?
8. Does pasteurizing milk alter it in a fashion that can cause allergic reactions?
9. Can drinking pasteurized milk cause lactose intolerance?
10. Does raw milk kill pathogens?
11. Does consuming raw milk cure some illnesses and allergies


### 1. Is it safe to consume raw milk?

No. FDA and other health agencies such as the Centers for Disease Control and organizations such as the American Academy of Pediatrics agree that raw milk is unsafe because it can contain disease-causing pathogens, including:

- Enterotoxigenic *Staphylococcus aureus*
- *Campylobacter jejuni*
- *Salmonella* species
- *E. coli*
- *Listeria monocytogenes*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*
- *Brucella* species
- *Coxiella Burnetii*
- *Yersinia enterocolitica*

Illnesses caused by these bacteria can be especially problematic for infants, young children, the elderly, and the immunocompromised. One complication that can arise as a result of infection with *E. coli* O157:H7 is hemolytic uremic syndrome (HUS), which can cause acute renal failure, especially in the very young or the elderly.

### 2. Have any illnesses or deaths been caused by consuming raw milk products?

Based on CDC data, literature, and state and local reports, FDA compiled a list of outbreaks that occurred in the U.S. from 1987 to September 2010. During this period, there were at least 133 outbreaks due to the consumption of raw milk and raw milk products. These outbreaks caused 2,659 cases of illnesses, 269 hospitalizations, 3 deaths, 6 stillbirths and 2 miscarriages. Because not all cases of foodborne illness are recognized and reported, the actual number of illnesses associated with raw milk likely is greater.

### 3. What are some of the symptoms of illnesses that can be caused by consuming raw milk?

Symptoms of illness caused by consuming raw milk include: vomiting, diarrhea, abdominal pain, fever, headache, and body ache. Most healthy people will recover from illness caused by harmful bacteria in raw milk - or in foods made with raw milk - within a short period of time, however, some individuals can develop symptoms that are chronic, severe, or even life threatening.

If you or someone you know becomes ill after consuming raw milk - or, if you are pregnant and think you could have consumed contaminated raw milk or cheese made from raw milk - see a doctor or healthcare provider immediately.

### 4. Are there any benefits to drinking raw milk?

No. As a science-based regulatory agency, the FDA looks to the scientific literature for information on benefits and risks associated with raw milk. While the perceived nutritional and health benefits of raw milk consumption have not been scientifically substantiated, the health risks are clear. Please see http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm247991.htm [1] for more information.

**5. Is it legal to sell raw milk for human consumption?**

Not in interstate commerce. Pasteurization of milk was adopted decades ago as a basic public health measure to kill dangerous bacteria and largely eliminate the risk of getting sick from one of the most important staples of the American diet. In 1987, the FDA issued a regulation prohibiting the interstate sale of raw milk. However, some states do permit the intrastate (within the borders) sale of raw milk intended for human consumption.

**6. How does the pasteurization of raw milk protect consumers?**

Pasteurization is a process that kills harmful bacteria by heating milk to a specific temperature for a set period of time. Pasteurization kills the bacteria responsible for diseases such as listeriosis, salmonellosis, campylobacteriosis, typhoid fever, tuberculosis, diphtheria, and brucellosis, as well as other bacteria. However, pasteurized milk still contains low levels of the type of nonpathogenic bacteria that can cause food to spoil, so it is important to keep pasteurized milk refrigerated.

**7. Does pasteurization affect the nutrient content of milk?**

Research shows no meaningful difference between the nutrient content of pasteurized and unpasteurized milk.

**8. Does pasteurizing milk alter it in a fashion that can cause allergic reactions?**

No. The milk proteins which cause allergic reactions in dairy-sensitive people are present in both raw milk and pasteurized milk.

**9. Can drinking pasteurized milk cause lactose intolerance?**

No. Lactose intolerance is due to an insufficient production in the body of the enzyme needed to break down lactose, beta-galactosidase. Lactose is present in both raw milk and pasteurized milk at the same concentration. Pasteurization does not impact the concentration of lactose.

**10. Does raw milk kill pathogens?**

No, it does not. In fact, raw milk potentially harbors a wide range of dangerous pathogens that can cause illness.

**11. Does consuming raw milk cure some illnesses and allergies?**

There is no scientific evidence to demonstrate that raw milk has any effect on illness or allergies.

## Related Information

- 03/26/2010 Public Health Agencies Warn of Outbreaks Related to Drinking Raw Milk [2]

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**Links on this page:**

1. http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm247991.htm
2. /NewsEvents/Newsroom/PressAnnouncements/2010/ucm206311.htm



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10903 New Hampshire Avenue
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## Raw Milk Misconceptions and the Danger of Raw Milk Consumption

**Updated November 1, 2011**

Raw milk can contain a variety of disease-causing pathogens, as demonstrated by numerous scientific studies. These studies, along with numerous foodborne outbreaks, clearly demonstrate the risk associated with drinking raw milk. Pasteurization effectively kills raw milk pathogens without any significant impact on milk nutritional quality.

In this document, the FDA provides a close examination of the myths associated with drinking raw milk. The review below is based on scientific literature.

### Raw milk does not cure lactose intolerance.

Lactose is a unique disaccharide found in milk. Lactose concentration in bovine milk is about 4.8%. People with lactose intolerance lack the enzyme, beta-galactosidase or lactase, to break down lactose into glucose and galactose during digestion. All milk, raw or pasteurized, contains lactose and can cause lactose intolerance in sensitive individuals. There is no indigenous lactase in milk.

Raw milk advocates claim that raw milk does not cause lactose intolerance because it contains lactase secreted by "beneficial" or probiotic bacteria present in raw milk. As discussed in a later section (claim 4), raw milk does not contain probiotic organisms.

Fermented dairy products, especially yogurt, have been reported to ease lactose mal-absorption in lactose intolerant subjects (McBean and Miller, 1984; Lin et al., 1991; Onwulata et al., 1989; Savaiano et al., 1984). This enhanced digestion of lactose has been attributed to the intra-intestinal hydrolysis of lactose by lactase secreted by yogurt fermentation microorganisms (Lin et al., 1991; Savaiano et al., 1984). However, raw milk does not contain the same types of microorganisms at the similar levels that are found in yogurt. Yogurt that showed a benefit towards lactose intolerance typically contained $10^7$cfu/ml or higher levels of *Streptococcus thermophilus* and *Lactobacillus bulgaricus*, and these microorganisms were **purposely** inoculated during yogurt manufacturing (Lin et al., 1991; Savaiano et al., 1984).

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### Raw milk does not cure or treat asthma and allergy.

The PARSIFAL study (Waser et al., 2007) has been misused by raw milk advocates ever since it was published. The PARSIFAL study found an inverse association of **farm milk** consumption, **not raw milk consumption**, with asthma and allergy. The authors of the PARSIFAL study clearly indicated in the paper that the "*present study does not allow evaluating the effect of pasteurized vs. raw milk consumption because no objective confirmation of the raw milk status of the farm milk samples was available.*" In fact, in the study, about half of the farm milk was boiled (Waser et al., 2007). The authors of the PARSIFAL study concluded that "*raw milk may contain pathogens such as salmonella or EHEC, and its consumption may therefore imply serious health risks... At this stage, consumption of raw farm milk cannot be recommended as a preventive measure.*" (Waser et al., 2007)

Regarding allergy, research has shown that raw milk and pasteurized milk do not differ in their anaphylactic-sensitizing capacity when tested in both animal models (Poulsen et al., 1987; McLaughlan et al., 1981) and in human clinical trials (Host and Samuelsson, 1988). Pasteurization conditions have little impact on casein structure and only cause limited whey protein denaturation. Therefore, it is not surprising that pasteurization does not change the allergenicity of milk proteins.

For example, Host and Samuelsson (1988) compared the allergic responses caused by raw, pasteurized (75°C/15 s), and homogenized/pasteurized milk in five children who are allergic to cow milk (aged 12 to 40 months). All children developed significant and similar allergic reactions from the consumption of the above three types of milk (Host and Samuelsson, 1988). The authors concluded that children with proven milk allergy can not tolerate milk, raw or pasteurized (Host and Samuelsson, 1988).

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### Raw milk is not more effective in preventing osteoporosis than pasteurized milk.

No scientific literature was found to substantiate the claim that pasteurized milk is linked to osteoporosis or raw milk promotes calcium deposition in bone. Studies have shown that both the concentration of calcium and its bio-availability are not affected by pasteurization (Rolls and Porter, 1973; Zurera-Cosano et al., 1994).

For example, Weeks and King (1985) showed no difference in calcium bioavailability among raw milk, homogenized HTST milk, and homogenized UHT milk in an animal study. Weanling rats were fed with the three types of milk for six to eight weeks and calcium from milk was their sole dietary calcium. Among rat groups consuming the three types of milk, there was no difference in intestinal absorption of calcium and no difference in calcium deposition in femur bone (Weeks and King, 1985). A similar conclusion was obtained in a human study using human milk. Williamson et al (1978) found no difference in the absorption and retention of calcium, phosphorous, and sodium between two groups of low birth-weight preterm infants who were fed human milk with and without heat treatment (63°C/30 min).

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### There are no beneficial bacteria in raw milk for gastrointestinal health.

Bacteria found in raw milk are not probiotic. Probiotic microorganisms must be non-pathogenic (Teitelbaum and Walker, 2000). In contrast, raw milk can host various human pathogens, including *E. coli* O157:H7, *Salmonella*, *Streptococcus spp. Yersinia enterocolitica*, *Campylobacter jejuni*, *Staphylococcus aureus*, *Listeria monocytogenes, Mycobacterium tuberculosis*, and *Coxiella burnetti* to name a few (Oliver et al., 2005; Hayes and Boor, 2001).

Probiotic microorganisms must be of human origin in order to have an impact on human health (Teitelbaum and Walker, 2000). Bacteria present in raw milk are from infected udder tissues (e.g., mastitis causing bacteria), the dairy environment (e.g., soil, water, and cow manure), and milking equipment. High bacteria counts in raw milk only indicate poor animal health and poor farm hygiene.

Bacteria in raw milk are typically not of human origin. An exception is *Streptococcus pyogenes*. *S. pyogenes* that has adapted to humans can be transmitted to animals. Once *S. pyogenes* is colonized in animals, it can be re-transmitted to humans as a **human pathogen** that causes strep throat. For example, *S. pyogenes* can infect a cow udder to cause mastitis. The infected cow udder can subsequently shed *S. pyogenes*, a pathogen, into raw milk.

Bifidobacteria have been mentioned by raw milk advocates as the "good bugs" in raw milk. Bifidobacteria are bacteria commonly found in human and animal gastrointestinal track and they are bacteria that make up the gut flora (Arunachalam, 1999). Since bifidobacteria are found in cow's GI track, they are present in cow's fecal matter. Raw milk collected with proper hygiene should not contain bifidobacteria. In fact, the presence of bifidobacteria in raw milk indicates fecal contamination and poor farm hygiene (Beerens et al., 2000; Beerens and Neut, 2005).

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### Raw milk is not an immune system building food and is particularly unsafe for children.

Children are typically more vulnerable than adults to the pathogens than can occur in raw milk. In 2005, an *E. coli* O157:H7 outbreak in Washington and Oregon was linked to raw milk sold in Washington state (CDC, 2007). Among the 18 patients, the 5 hospitalized were all children aged 1-13; 4 of them developed Hemolytic Uremic Syndrome (HUS) (CDC, 2007).

In September 2006 in California, two children developed HUS from drinking raw milk contaminated with *E. coli* O157:H7. Three weeks later, four more children acquired the same infection from raw milk or raw colostrum produced by the same dairy (CDC, 2008).

In Sep 2006, two children became sick after drinking unpasteurized milk from a licensed dairy in Washington State. The raw milk was contaminated with *E. coli* O157:H7. One child was hospitalized (WSDH, 2006).

In July 2008 in Connecticut, 14 people were sickened by raw milk contaminated with *E. coli* O157: H7. The three most seriously ill were children; two of them developed HUS (FoodHACCP.com, 2008).

In May 2008 in Missouri, four people became sick after drinking raw goat milk contaminated with *E. coli* O157: H7. The two severely ill were children and both were hospitalized (CDC, 2008).

In July 2010 in Colorado, eight people became sick after drinking raw goat milk contaminated with both *Campylobacter* and *E. coli* O157: H7. Two children were hospitalized (Boulder County Public Health, 2010a, b)

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### There are no immunoglobulins in raw milk that enhance the human immune system.

The concentration of immunoglobulins in bovine milk is low, typically about 0.6-1.0 mg/ml (Hurley, 2003). At these low concentrations, bovine immunoglobulins, when consumed directly from milk, are physiologically insignificant to humans (Fox, 2003).

The predominant fraction of immunoglobulins in bovine milk is IgG (about 85-90%). IgG is quite heat stable. In one study, LTLT pasteurization (63°C for 30 min) had no impact on the level of IgG, and HTST pasteurization (72°C/15s) resulted in only 1% denaturation of IgG (Mainer et al., 1997).

Kulczychi (1987) hypothesized that the heat-aggregated immunoglobulins may actually have better immunological function because aggregation can amplify the binding affinity of IgG to receptor sites.

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### There are no additional protease and lipases in raw milk that facilitate milk digestion.

***Milk Proteases***

Milk contains various indigenous proteases, including plasmin and somatic cell proteases (Kelly and McSweeney, 2003). The major proteolytic activity in milk is from plasmin. Plasmin is part of a complex enzyme system consisting of plasmin, plasminogen, plasminogen activator, plasmin inhibitor, and plasminogen activator inhibitor (Bastian and Brown, 1996).

The plasmin system plays important roles in milk quality and cheese ripening (Bastian and Brown, 1996). Increase in plasmin activity is often reported in low quality milk with high somatic cell counts (Ma et al., 2000; Kelly and McSweeney, 2003; Bastian and Brown, 1996). High plasmin activity in fresh milk reduces milk shelf-life due to the hydrolysis of milk casein and the production of bitter peptides. High residual plasmin activity in shelf-stable UHT milk has also been associated with age gelation, a product defect.

Plasmin is heat stable and large percentage of this enzyme survives pasteurization (Bastian and Brown, 1996; Richardson, 1993). Even after UHT treatment, 30-40% of the plasmin activity can still remain (Alichanidis et al., 1986).

Proteases of somatic cell origin become significant when cows are infected with mastitis (Verdi et al., 1987). Milk from mastitic cows is of low quality and is more likely to contain pathogens. The most prevalent mastitis causing organisms in dairy herds are *E. coli*, *Staphylococci*, and *Streptococci* (Hayes and Boor, 2001; Wilson et al., 1997). Mastitic cows can also shed other pathogens into raw milk, including *L. monocytogenes* (Schoder et al., 2003; Pearson and Marth, 1990; Jensen et al., 1996), *Salmonella* (Wood et al., 1991), and *Coxiella burnetti* (Barlow et al., 2008).

Milk can also contain exogenous proteases secreted from bacteria growing in milk. Proteases of microbial origin become significant when bacterial counts exceed $10^6$-$10^7$cfu/ml (Cousin, 1982). Therefore, any significant amount of protease of bacterial origin in raw milk only indicates that the raw milk is heavily contaminated. Heavily contaminated raw milk is more likely to contain pathogens.

There is no reported physiological role of milk indigenous or exogenous proteases in human protein digestion. These enzymes, like other proteins, are denatured in the acid gastric environment and digested by human proteases secreted in the gastrointestinal track.

***Lipase***

The main indigenous lipase in bovine milk is lipoprotein lipase (LPL). Other types of lipases that may present in milk are lipases from somatic cells and lipase secreted from microorganisms growing in raw milk under unsanitary conditions (Weihrauch, 1988). Lipases from somatic cells only become significant when the cow is infected with mastitis, and milk from mastitic cows is more likely to contain pathogens. Milk also contains several esterases. The concentrations of milk esterases are very low compared to LPL, and unlike LPL, milk esterases hydrolyze ester substrates in solution rather in an emulsified form (Deeth and Fitz-Gerald, 1995).

There is no physiological role of LPL in milk lipid digestion or utilization (Olivecrona et al., 2003; Weihrauch, 1988). Therefore, even though pasteurization does inactivate most of LPL activity (Shipe and Senyk, 1981), such effect has no impact on the nutritional values of milk. In fact, it is desirable to completely inactivate LPL since any residual LPL activity can cause the development of rancid off-flavor, a serious quality defect in milk (Shipe and Senyk, 1981). Gastric lipase and pancreatic lipase secreted in the human gastrointestinal track are responsible for the digestion of lipids (Gurr, 1995; Jensen and Jensen, 1992).

In human milk, there is another lipase called bile-salt stimulated lipase (BSSL). This enzyme can substantially improve the utilization of human milk lipids, particularly in premature infants (Andersson et al., 2007; Jensen and Jensen, 1992; Olivecrona et al., 2003; Williamson et al., 1978). However, BSSL is not present in bovine milk (Olivecrona et al., 2003).

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### Raw milk is not nutritionally superior to pasteurized milk.

Numerous studies have indicated that pasteurization has minimal impact on milk nutritional quality.

***Milk proteins***

Normal bovine milk contains about 3 to 3.5% total protein. The two major groups of milk protein are casein (about 80%) and whey proteins (about 20%). The protein quality of pasteurized milk is not different from that of raw milk (Andersson and Oste, 1995).

Using *in vitro* method, Carbonaro et al (1996) found no difference in protein digestibility between raw milk (80.2%), milk pasteurized at 75°C/15s (80.02%), and milk pasteurized at 80°C/15s (80.3%).

In an animal study (weaning Holtzman male rats), Efigenia et al (1997) evaluated the nutritional quality of bovine milk after pasteurization. After a study period of 28 days, there was no difference in animal weight gain, food intake, food efficiency ration, protein efficiency ratio, or apparent protein digestibility between the rat group that consumed raw bovine milk and the group that consumed pasteurized bovine milk (Efigenia et al., 1997).

Similar results were obtained in another animal study by Lacroix et al (2006). In this study, no difference in protein digestibility was observed between milk protein without heat treatment and the same protein heated at 72°C/20s or 96°C/5s (Lacroix et al., 2006).

In a recent human study, Lacroix et al (2008) evaluated the impact of heat treatment on protein quality by studying dietary nitrogen metabolism following a single meal. Human subjects were fed a meal formulated with milk protein with or without HTST pasteurization (72°C/20s). The same metabolic utilization of milk protein nitrogen was observed for both raw and pasteurized milk (Lacroix et al, 2008).

***Milk fat and the effect of homogenization***

Typical bovine milk contains about 3 to 4% milk fat, with 97.5% of the fat existing as triglycerides (Christie, 1995). Pasteurization has essentially no effect on milk fat composition (Rolls and Porter, 1973); and for that reason, research on this topic is minimal.

Work has been done on the effect of pasteurization on human milk fat. No change was observed in total fat content and fatty acid composition (saturated, monounsaturated, polyunsaturated) of human milk after pasteurization (62.5°C for 30 min) (Fidler et al., 2001). Even after heating pooled human milk for 100°C/5 min, no change in milk fatty acid composition (including polyunsaturated long chain fatty acids) was observed

(Romeu-Nadal et al., 2008).

Commercial milk is typically homogenized to increase physical stability, i.e. to prevent gravity separation of fat. Milk fat globules are reduced in size from 3 to 10 micron to less than 2 micron in diameter after typical homogenization (Swaisgood, 1985). The native fat globules are covered by the milk fat globule membrane (MFGM). After homogenization, casein and whey protein cover and stabilize the newly reformed fat globules.

The effect of homogenization on milk nutrition has been reviewed (Michalski, 2007; Michalski and Januel, 2006). It is concluded that "*regarding human nutrition, homogenized milk seems more digestible than untreated milk.*" (Michalski and Januel, 2006) People with lactose intolerance or milk allergy show similar response to non-homogenized and homogenized milk (Michalski, 2007; Michalski and Januel, 2006). Research is ongoing to determine whether there is any other physiological impact of homogenization on human nutrition. In one aspect, it is suggested that since homogenization releases milk fat globule membrane components, the functions of some of the bioactive components in MFGM may be enhanced (Michalski and Januel, 2006).

***Milk minerals***

Minerals are stable under pasteurization conditions and there is minimal change in their concentrations after pasteurization (Rolls and Porter 1973). Both *in vitro* and *in vivo* studies demonstrate that there is no impact of pasteurization on milk mineral content and mineral bioavailability (Van Dael et al.,1993; Weeks and King, 1985; Zurera-Cosano et al., 1994).

As discussed in a previous section (claim 3), the concentration and bioavailability of calcium, the most nutritionally important mineral in milk, is the same in raw and pasteurized milk. In another study, Van Dael et al (1993) demonstrated using *in vitro* method that the bioavailability of zinc and selenium in milk was not affected by pasteurization (73°C/15s) or sterilization (110°C/10 min).

***Milk vitamins***

Milk contains both fat soluble and water soluble vitamins. Fat soluble vitamins include A, D, E, and K. Water soluble vitamins included B1 (thiamin), B2 (riboflavin), niacin, pantothenic acid, B6, biotin, folic acid, B12, and vitamin C (Renner et al., 1989). In general, pasteurization has a little effect on milk vitamin levels (Bendicho et al., 2002; Renner et al., 1989). Vitamins that are present at high levels in milk, such as riboflavin, B6 and B12, are relatively heat stable. Other factors, such as storage temperature, dissolved oxygen, light exposure, packaging, and length of storage can have a much greater impact on milk vitamin stability (Gaylord et al., 1986; Kon, 1972; Lavigne et al., 1989; Pizzoferrato, 1992; Renner et al., 1989; Scott et al., 1984a; Scott et al., 1984b).

The only vitamin that is significantly heat labile is vitamin C but milk is an insignificant source for vitamin C. A cup of milk (240 ml) only provides about 5 mg of vitamin C (Renner et al., 1989).

Vitamin C is very susceptible to oxidation. Sample to sample variation can be considerable (Scott et al., 1984a) and degradation can happen immediately after milking due to photo-oxidation (Kon, 1972; Renner et al., 1989; Scott et al., 1984a). Reported values of vitamin C vary depending on seasonality, storage temperature, and elapsed time before analysis.

Lavigne et al (1989) reported that HTST at 72°C/16s reduced vitamin C in goat milk by 5%. Haddad and Loewenstein (1983) observed vitamin C level of 23.3 mg/liter in raw milk. After pasteurization at 72°C/16s, vitamin C was reduced by 16.6%. Similarly, Head and Hansen (1979) reported that in whole milk, vitamin C was reduced about 15% (from 24.3 mg/liter to 20.7 mg/liter) after pasteurization.

The loss of vitamin C increases with heating temperature and time and fits the first order kinetic model (Bendocho et al., 2002; Haddad and Loewenstein, 1983). Substantial loss only occurred after very high temperature heating for long time. For example, heating at 90°C for 10 min can cause 70% reduction in vitamin C (Bendicho et al., 2002).

Interestingly, Pizzoferrato (1992) indicated that vitamin C retention during storage is better in heated milk (72°C/15s, 75°C/15s, 80°C/15s) than in raw milk. The better retention was due to the removal of oxygen and the inactivation of peroxidase and microorganisms during heat treatment (Pizzoferrato, 1992).

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### Raw milk does not contain natural antimicrobial components that make milk safe.

The major antimicrobial compounds naturally present in milk include lactoferrin, lactoperoxidase, lysozyme, and xanthine oxidase. There is no scientific evidence to support the claim that the indigenous antimicrobial compounds in raw milk kill pathogens and ensure raw milk safety.

Raw milk does not contain high enough concentration of these antimicrobial compounds to exert such an effect. In the case of lysozyme and lactoferrin, if high concentrations of these components are observed in raw milk, it is often an indication of cow's compromised health condition (e.g. mastitis), simply due to cow's elevated natural defense system (Chaneton et al., 2008; Schmitz et al., 2004; Farkye, 2003).

The microflora in raw milk is complex and unpredictable. The antimicrobial components in milk can have either bactericidal, bacteriostatic, or no effect at all depending on the specific pathogenic species and strains involved (Naidu, 2000a).

Pasteurization is the only method to achieve complete elimination of vegetative pathogens. Contrary to raw milk advocates' claims, pasteurization does not completely inactive these indigenous antimicrobial components in milk.

***Lactoferrin***

The doses of lactoferrin required to have bactericidal or bacteriostatic effect are in the range of 1 to 8 g/L (Naidu, 2000b). The substantially lower concentration of LF in mature bovine milk, about 0.1 g/L, is simply too low to have an effect (Naidu, 2000b).

Commercial pasteurization causes no significant loss of LF antimicrobial activity (Paulsson et al., 1993; Sanchez et al., 1992). Retention of LF is estimated to be 97-99% after heating at 72°C for 15s and 87-95% after heating at 85°C for 15s (Sanchez et al., 1992). Purified lactoferrin solution (0.5 to 1 g/L) with and without heat treatment (62.8°C for 30 min, 72°C for 15s, or 72°C for 10 min) showed the same antimicrobial effects towards *E. coli* O157:H7, *Salmonella enteritidis*, and *Listeria monocytogenes* (Conesa et al., 2010)

***Lysozyme***

The concentration of lysozyme in bovine milk is very low (< 0.3 mg/100 ml), much lower than the level in human milk (10 mg/100 ml) (Renner et al., 1989; Silanikove et al., 2006). When cows are infected with mastitis, lysozyme level increases in milk (Farkye, 2003). Lysozyme is relatively heat stable (Griffiths, 1986). Heat at 82.2°C for 15s, a condition much severer than HTST, only reduces enzyme activity by 6.3% (Griffiths, 1986).

***Lactoperoxidase (LP)***

The term lactoperoxidase system (LP-s) refers to the integral system of lactoperoxidase, thiocyanate, and hydrogen peroxide. To be effective as an antimicrobial system in raw milk, lactoperoxidase needs to be activated by the addition of thiocyanate (SCN-) and a source of hydrogen peroxide ($H_2O_2$) to milk (Arques et al., 2008; Björck 1978; Björck et al., 1978; Rodríguez et al., 1997).

CODEX allows the use of activated LP-s to prevent spoilage during collection and transportation of raw milk when adequate refrigeration is not available (Codex CAC/GL 13-1991). Typically, per liter of milk, LP-s can be activated by the addition of 14 mg of sodium thiocyanate (equivalent to 10 ppm thiocyanate) and 30 mg of sodium percarbonate (equivalent to 8.5 ppm hydrogen peroxide) (FDO/WHO, 2005; Codex CAC/GL 13-1991). The addition of thiocyanate increases its overall level from about 5 ppm naturally present in milk to 15 ppm. FAO/WHO clearly states that the purpose of LP-s is "*not to render milk safer for consumption*" and that "*the safety of milk is only achieved through a combination of good hygienic practices and heat treatment of milk, independent of LP-s.*" (FAO/WHO, 2005)

***Xanthine oxidase (XO)***

Xanthine oxidase is a well-know enzyme found on milk fat globule membrane (MFGM) (Farkye, 2003; Harrison, 2006). XO is a non specific oxido-reductase involved in purine catabolism, catalyzing the oxidation of hypoxanthine to xanthine and of xanthine to uric acid (Farkey, 2003; Harrison, 2006).

The antimicrobial role of XO is centered on XO's ability to catalyze reactions that generates reactive oxygen species (e.g. superoxides and hydrogen peroxide) and reactive nitrogen species (e.g. nitric oxide and peroxynitrite) (Stevens, et al., 2000; Vorbach et al., 2003; Martin et al., 2004: Harrison, 2006). These highly reactive species are bactericidal or bacteriostatic. It has also been hypothesized that antimicrobial effect is derived from the formed hydrogen peroxide that participate in the lactoperoxidase system. However, the exact mechanisms involved in the antimicrobial phenomena are still "*unclear and undoubtedly complex*" (Harrison, 2006). The FDA is not aware of any publication that studied pathogen reduction by inherent levels of XO present in raw milk.

A paper published by Oster in 1971 postulated that XO absorbed onto homogenized milk fat droplets can cause tissue damage and initiate atherosclerotic process (Oster, 1971). However, additional research refuted this hypothesis (Clifford, et al., 2003).

Griffiths (1986) reported a D value of 303.8 s at 75°C for XO. This means that XO activity will be reduced by 10% after heat treatment at 75°C for

15s. Andrews et al. (1987) indicated that XO is the most heat stable milk fat globule membrane enzyme and less than 10% of its activity is lost after heat treatment at 80°C for 15s (Andrews, et al., 1987).

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### Raw milk does not contain nisin for pathogen inhibition.

Nisin is a small heat stable antimicrobial peptide produced by certain strains of *Lactococcus lactis subsp. lactis* (Arauz et al., 2009; Thomas et al., 2000). Raw milk advocates claim that indigenous microflora of raw milk produces nisin that kills pathogens. There is no scientific basis for such claim.

Nisin is only produced during the exponential growth phase of *Lactococcus* organisms (Arauz et al., 2009; Thomas et al., 2000) and these organisms do not grow well at refrigeration temperatures. Any substantial nisin production in raw milk will only suggest poor hygiene and poor refrigeration. Therefore, even if raw milk contained nisin-producing *Lactococcus*, the amount of nisin present in raw milk would be negligible.

Nisin is effective against gram-positive bacteria including strains of *Lactococcus*, *Streptococcus*, *Staphylococcus*, *Micrococcus*, *Pediococcus*, *Lactobacillus*, *Listeria*, and *Mycobacterium* (Arauz et al., 2009; Sahl et al., 1995). Nisin is generally not effective against gram-negative bacteria, fungi, and virus (Arauz et al., 2009; Boziaris and Adams 1999). Important milkborne pathogens such as *Salmonella*, *Campylobacter jejuni*, *E. coli* O157:H7, and *Yersinia enterocolitica* are gram negative and thus are not affected by nisin (Arauz et al., 2009).

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### Folate binding protein (FBP) is not denatured during pasteurization and folate utilization is not reduced in pasteurized milk.

The concentration of folate in milk is low, about 5 -8µg/100g (Renner et al., 1989; Andersson and Oste, 1994). Dietary reference intake for folate is 400 µg per day for male 19-30 years of age (http://iom.edu/~/media/Files/Activity%20Files/Nutrition/DRIs/DRI_Vitamins.pdf[9]). Milk is not a folate rich food.

Pasteurization has a limited impact on milk folate level. Folate remains bound to folate binding protein (FBP) after pasteurization (Wigertz et al., 1996). Andersson and Oste (1994) observed no change in milk folate content after pasteurization at 75°C for 16s. Wigertz and Jägerstad (1993) reported a slight decrease of folate content from 8µg/100 g to 6.4µg/100g after pasteurization at 74°C for 15s.

Studies have shown some decrease in the concentration of folate binding protein (FBP) after pasteurization but the decrease is typically small and a substantial amount of residual FBP is still present in the pasteurized milk. For example, Wigertz et al (1996) observed a FBP concentration of 211± 7 nmol/l in raw milk. After pasteruzation (74°C/15s), FBP concentration was about 168 ± 20 nmol/l (Wigertz et al, 1996). In a separate study, Wigertz and Jägerstad (1993) found no difference in FBP concentration before and after pasteurization (74°C/15s).

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### Pasteurized milk is safer than raw milk.

The outbreaks and illnesses attributed to raw milk are alarming when one considers the extremely low volume of raw milk consumed in the US (< 1% of total milk) (Headrick, et al., 1998).

Outbreaks due to raw milk and raw milk products continue to occur each year. In 2010 alone, raw milk has been associated with at least 8 documented outbreaks:

- New York, *Campylobacter* outbreak, 5 illnesses (New York Department of Health, 2010)
- Michigan, *Campylobacter* outbreak, 12 illnesses (FDA, 2010)
- Pennsylvania, *Campylobacter* outbreak, 10 illnesses (PRNewswire, 2010)
- Utah, *Campylobacter* outbreak, 9 illnesses (Utah Department of Health, 2010)
- Utah, *Salmonella* outbreak, 6 illnesses (Utah Department of Health, 2010)
- Minnesota, *E. Coli* O157:H7 outbreak, 8 illnesses and 4 hospitalizations (Minnesota Department of Health, 2010)
- Washington, *E. Coli* O157:H7 outbreak, 8 illnesses (Washington State Department of Health, 2010)
- Colorado, *Campylobacter* and *E. Coli* O157:H7 outbreak, 30 illnesses, 2 hospitalizations (Boulder County Public Health, 2010a, b)

Based on CDC data, literature, and state and local reports, FDA compiled a list of outbreaks that occurred from 1987 to September 2010 in the US. During this period, there were at least 133 outbreaks due to the consumption of raw milk and raw milk products. These outbreaks caused 2,659 cases of illnesses, 269 hospitalizations, 3 deaths, 6 stillbirths and 2 miscarriages. The numbers of outbreaks and illness cases were likely higher than the above estimates due to underreporting.

Of the 133 outbreaks occurring from 1987 to September 2010, 5 were multistate outbreaks with cases from at least two states. The remaining 128 outbreaks occurred in 30 states. Of these 30 states, 20 allowed some type or raw milk sale for direct human consumption according to the National Association of State Departments of Agriculture survey of 2008 (NASDA, 2008). Outbreaks from these 20 states accounted for 80% of all outbreaks in the US during this period. The three states that had the highest frequencies of outbreaks are California, Washington, and Utah, accounting for about 12%, 12%, and 8% of all outbreaks, respectively.

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**Raw milk causes a greater rate of foodborne outbreaks than pasteurized milk.**

In *The Verbal Argument by Mark McAfee*, the author cited various foodborne outbreaks where pasteurized milk was implicated. For these cited outbreaks, FDA was able to find scientific literature describing these outbreaks. In most cases, the implicated milk was contaminated post-pasteurization. Ironically, in many cases, the actual source of contamination was raw milk (Tacket et al., 1984; CDC, 1984; Fleming et al., 1985; Ryan et al., 1985; Linnan, et al., 1988; Olsen, et al., 2004).

1976 *Yersinia enterocolitica* outbreak in pasteurized chocolate milk

(Reference: Black, R. E., R. J. Jackson, T. Tsai, M. Medvesky, M. Shayegani, J. C. Feeley, K. I. E. MacLeod, and A. H. Wakelee. 1978. Epidemic *Yersinia enterocolitica* Infection Due to Contaminated Chocolate Milk. *New England Journal of Medicine*. 298:76-79.)

Pathogenic bacteria were likely introduced during hand mixing of chocolate syrup with previously pasteurized milk. No further heat treatment was applied after hand mixing.

1982 *Yersinia enterocolitica* outbreak from milk produced in Memphis TN

(Reference: Tacket, C. O., J. P. Narain, R. Sattin, J. P. Lofgren, C. Jr. Konigsbery, R. C. Rendtorff, A. Rausa, B. R. Davis, and M. L. Cohen. 1984. Multistate outbreak of infections caused by *Yersinia enterocolitica* transmitted by pasteurized milk. *Journal of the American Medical Association*. 251:483-486.)

The exact mechanism of contamination was not clear. However, it was suggested that even though typical pasteurization kills *Y. enterocolitica*, if the level of *Yersinia* contamination is very high in raw milk, a small amount of pathogen might have survived pasteurization.

1983 *Listeria monocytogenes* outbreak in MA

(Reference: Fleming, D., S. L. Cochi, K. L. MacDonald, J. Brondum, P. S. Hayes, B. D. Plikaytis, M. B. Holmes, A. Audrier, C. V. Broome, and A. L. Reingold. 1985. Pasteurized Milk as a Vehicle of Infection in an Outbreak of Listeriosis. *New England Journal of Medicine*. 31:404-407.)

The likely cause of this outbreak was the high levels of *L. monocytogenes* contamination in the starting raw milk. During the outbreak period, raw milk was sourced from farms that had dairy cows infected with listeriosis. In addition, multiple serotypes of *L. monocytogenes* were isolated from raw milk obtained from these farms after the outbreak.

1984 *Salmonella* Typhimurium outbreak in Kentucky

(Reference: CDC. 1984. Salmonellosis from Inadequately Pasteurized Milk – Kentucky. 1984. *Morbidity and Mortality Weekly Report*. 33:505-506.)

The outbreak was linked to milk that was under-pasteurized. The plant that produced contaminated milk did not have proper time-temperature recording and frequently did not meet the minimum PMO defined pasteurization conditions. Therefore, *Salmonella* Typhimurium that was present in raw milk was not adequately destroyed.

1985 *Listeria monocytogenes* outbreak in cheese in Los Angeles, CA

(Reference: Linnan, M. J., L. Mascola, X. D. Lou, V. Goulet, S. Mary, C. Salminen, D. W. Hird, M. L. Yonekura, P. Hayes, R. Weaver, A. Audurier, B. D. Plikaytis, S. L. Fannin, A. Kleks, and C. Broome. 1988. Epidemic Listeriosis Associated with Mexican-Style Cheese. *New England Journal of Medicine*. 319:823-828.)

The outbreak was linked to branded Mexican-style cheeses. The cheese produced in the implicated plant was frequently contaminated with raw milk. During inspection, 9 out of 80 cheese samples tested were positive for alkaline phosphatase, indicating that the milk was not pasteurized or improperly pasteurized. On several occasions, 10% or more raw milk might have mixed in with pasteurized milk prior to cheese making.

1984 and 1985 two *Salmonella Typhimurium* outbreaks traced back to pasteurized 2% milk produced in an IL plant

(Reference: Ryan, C. A., M. K. Nichels, N. T. Hargrett-Bean, M. E. Potter, T. Endo, L. Mayer, C. W. Langkop, C. Gibson, R. C. McDonald, R. T. Kenney, N. D. Puhr, P. J. McDonnell, R. J. Martin, M. L. Cohen, and P. A. Blake. 1987. Massive Outbreak of Antimicrobial-Resistant Salmonellosis Traced to Pasteurized Milk. *JAMA*. 258:3274.)

The 2% pasteurized milk was likely contaminated by raw milk post-pasteurization. Both the FDA lab and a private lab confirmed that the outbreak strain of *Salmonella* was heat sensitive and would not survive pasteurization. The implicated plant had an unusual setup of its processing line: pasteurization was an early step followed by separation and fat standardization. Investigation at the implicated plant revealed a potential cross-connection between tanks that contained raw milk and pasteurized skim milk.

1993-1994 *Salmonella enteritidis* in pasteurized ice cream in MN, SD

(Reference: Hennessy, T. W., C. W. Hedberg, L. Slutsker, K. E. White, J. M. Besser-Wiek, M. E. Moen, J. Feldman, W. W. Coleman, L. M. Edmonson, K. L. MacDonald, and M. T. Osterholm. 1996. A national outbreak of Salmonella enteritidis infections from ice cream. The Investigation Team. *New England Journal of Medicine*. 334:1281-1286.)

Outbreak investigators concluded that the ice cream premix was most likely contaminated during transport in a tanker trailer that had

previously carried non-pasteurized liquid eggs contaminated with *S. enteritidis*.

1995 *Yersinia enterocolitica* outbreak due to post-pasteurization contamination

(Reference: Ackers, M. L., S. Schoenfeld, J. Markman, M. G. Smith, M. A. Nicholson, W. DeWitt, D. N. Cameron, P. M. Griffin, and L. Slutsker. 2000. An outbreak of Yersinia enterocolitica O:8 infections associated with pasteurized milk. *Journal of Infectious Disease*. 181:1834-1837.)

The outbreak occurred in Vermont and New Hampshire. The implicated milk was likely contaminated post pasteurization when it was filled into milk bottles rinsed by untreated well-water. Well water had high coliform counts, which suggested possible fecal contamination and possible *Y. enterocolitica* contamination by pigs on the dairy farm. *Y. enterocolitica* was isolated from 1 raw milk sample and 1 fecal sample from a pig on the dairy farm.

2000 *Salmonella* Typhimurium outbreak in PA and NJ

(Reference: Olsen, S. J., M. Ying, M. F. Davis, M. Deasy, B. Holland, L. Lampietro, M. Baysinger, F. Sassano, L. D. Polk, B. Gormley, M. J. Hung, K. Pilot, M. Orsini, S. van Duyne, S. Rankin, C. Genese, E. A. Bresnitz, J. Smucker, M. Moll, and J. Sobel. 2004. Multidrug-resistant *Salmonella* Typhimurium infection from milk contaminated after pasteurization. *Emerging Infectious Diseases*. 10:932-935.)

Outbreak investigation indicated that the milk processing plant had several violations of sanitary standards that could have resulted in the contamination of milk after pasteurization. These violations included excess condensation and high humidity in processing areas, leakage of raw milk onto plant floor, and storage of raw milk at > 10°C. Contamination might have originated from *Salmonella*-contaminated raw milk since "*two dairy cow isolates of S. Typhimurium obtained during the outbreak period were outbreak related strains*."

2006 *Campylobacter jejuni* outbreak in CA prison

(Reference: Yuan, J. W., Jay, M. T., Barry, P., Schneider, J., Beam, S., Kanan, R., Mandrell, R., Miller, W., Winslow, D., and Mohle-Boetani, J. 2007. Campylobacteriosis Outbreak Associated with Pasteurized Milk — California, May 2006 . Available at http://www.cdc.gov/eis/downloads/2007.EIS.Conference.pdf[19]. Accessed 11-4-2010.)

During investigation, it was noted that pasteurized milk produced before the outbreak had high bacteria counts. In addition, about 100 different *C. jejuni* strains were isolated on the dairy farm with 3 isolates matching the human illness strain. These observations suggested that either the starting raw milk had very high levels of pathogen contamination from the dairy environment or the milk was contaminated post pasteurization.

2007 *L. monocytogenes* outbreak in MA

(Reference: CDC. 2008. Outbreak of Listeria monocytogenes infections associated with pasteurized milk from a local dairy – Massachusetts, 2007. *Morbidity and Mortality Weekly Report*. 57:1097-1100.)

The pasteurized milk was most likely contaminated post pasteurization. The dairy plant had poor sanitation practices and several environmental samples obtained at the plant were positive for *L. monocytogenes*.

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### Raw milk produced under HACCP does not make it safe to drink.

FDA does not believe that HACCP can ensure raw milk safety. The sanitary procedures described in a food safety plan under HACCP might help to reduce the probability of raw milk contamination but they will not ensure that raw milk is pathogen-free.

As the preceding discussion demonstrates, raw milk does not naturally kill pathogens of concern. Further, testing raw milk for the various pathogens prior to consumption can not be used as an alternative to pasteurization. The potential pathogens present in raw milk can be diverse, variable, and unpredictable. It is simply impossible to test every single batch of raw milk for every single pathogen prior to human consumption. More importantly, the inability of a method to detect pathogens does not indicate the absence of pathogens (Oliver et al., 2009).

There is no visual or sensory indicator for the presence of pathogen. Typical milk quality indicators, such as standard plate counts and somatic cell counts, do not provide information on the presence or absence of pathogens. Seemingly high quality raw milk based on these routine quality indicators can still contain pathogen (Van Kessel et al., 2008). In the Federal Register notification for the final rule to 21 CFR Part 1240.61, FDA made a number of findings including the following:

"*It has not been shown to be feasible to perform routine bacteriological tests on the raw milk itself to determine the presence or absence of all pathogens and thereby ensure that it is free of infectious organisms.*"

HACCP ensures product safety through process control and not by finished product testing. HACCP has been considered possible for chemical and physical hazard controls in farm settings. However, HACCP is not effective or even possible in farm settings for biological hazards, including pathogens (Cullor, 1997; Sperber, 2005). Cullor (1997) indicated that potential biological hazards that may exist on the dairy farms do not have well-known critical control points. Since establishing critical control points is one of the most important aspects of HACCP, without well-known critical control points, HACCP simply does not work for pathogen control for raw milk production on the farm.

Organic Pastures is an example of a raw milk producer with a HACCP plan whose milk has been found to contain pathogens. In 2007, raw cream from Organic Pastures was found to be contaminated with *Listeria monocytogenes* (FDA, 2007). In 2006, raw milk contaminated with *E. coli* O157:H7 from Organic Pastures was implicated in an outbreak that resulted in 6 illnesses and 3 hospitalizations (CDC, 2008). The median age of this outbreak's victims was 8 years (range: 6- 18 years) (CDC, 2008).

**References:**


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- Van Kessel, J. S., J. S. Karns, D. R. Wolfgang, E. Hovingh, B. M. Jayarao, C. P. v. Tassell, and Y. H. Schukken. 2008. Environmental sampling to predict fecal prevalence of *Salmonella* in an intensively monitored dairy herd. *Journal of Food Protection*. 71:1967-1973.


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### Summary

None of the claims made by the raw milk advocates that we have examined for you can withstand scientific scrutiny. Unfortunately, the false "health benefits" claims of raw milk advocates may cause parents to give raw milk to their children and prompt immuno-compromised people, such as pregnant women, the elderly, and hospitalized patients, who want better nutrition, to also start consuming raw milk. It is these very same sub-groups of the population, however, that are most at risk for becoming ill or even dying from foodborne illness as a result of consuming adulterated raw milk.

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### For More Information

- Questions and Answers on Raw Milk [21]
- Consumer Update: Raw Milk May Pose Health Risk [22]
- Food Facts: The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk [23]
- Food Safety and Raw Milk (from CDC) [24]
- Milk, Cheese, and Dairy Products (from FoodSafety.gov) [25]

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2. http://www.bouldercounty.org/find/library/help/epiconsep10.pdf
3. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm206311.htm
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21. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm122062.htm
22. /ForConsumers/ConsumerUpdates/ucm232980.htm
23. /Food/ResourcesForYou/Consumers/ucm079516.htm
24. http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
25. http://www.foodsafety.gov/keep/types/milk/index.html

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14. http://www.health.state.ny.us/press/releases/2010/2010-01-29_campylobactor_contamination_in_raw_milk.htm
15. http://www.nasda.org/File.aspx?id=16298
16. http://www.prnewswire.com/news-releases/pennsylvania-agriculture-department-suspends-raw-milk-sales-permit-of-pasture-maid-creamery-in-lawrence-county-90216057.html
17. http://health.utah.gov/pio/nr/2010/051610-SalmonellaRawMilk-NR.pdf
18. http://www.doh.wa.gov/Publicat/2010_news/10-087.htm
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20. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108992.htm

21. /Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm122062.htm
22. /ForConsumers/ConsumerUpdates/ucm232980.htm
23. /Food/ResourcesForYou/Consumers/ucm079516.htm
24. http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html
25. http://www.foodsafety.gov/keep/types/milk/index.html

# Raw Milk May Pose Health Risk


What's a building block in the food pyramid that's important for building and maintaining bone mass? It's milk.

Whether it's from cows, goats, sheep, or another mammal, milk and milk products are an important source of calcium throughout a person's life.

Most of the milk sold in the United States is pasteurized, a process during which the milk is heated to 161 degrees and kept there for 15 seconds. Pasteurization kills harmful bacteria—including salmonella, E. coli, and listeria—that can contaminate milk before it gets to your table. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommend pasteurization for all milk consumed by people in the United States.

**Pasteurization Reduces Illness**

Pasteurization of milk is an effective means of preventing outbreaks of foodborne illness, including tuberculosis, brucellosis, salmonellosis, scarlet fever, and listeriosis. It was first used in the United States more than 100 years ago and has been widely used for more than a half-century, says John Sheehan, an FDA expert on the safety of dairy products.

*Pasteurization was first used in the United States more than 100 years ago, and it has been widely used for more than a half-century.*

But increasingly, consumers are seeing "raw" milk—and cheeses, yogurts, and other products made from it—in specialty shops, farmers' markets, and stores. That's partly because many Americans have adopted a "back to nature" philosophy about the foods they eat, embracing the idea that locally produced and minimally processed foods are more nutritious.

But in the case of raw milk, FDA says that's not true. Although the heating process slightly affects a few of the vitamins—thiamine, vitamin B6 and folic acid within the B-complex, and vitamin C, the changes are not significant. Meanwhile, there is a risk that milk could be contaminated by environmental factors such as soil or animal feces, animal diseases, or bacteria on an animal's skin.

Consumers are also seeing more raw milk products because of the growth of the artisanal cheese industry, Sheehan says. These cheeses are made by hand using what are considered to be traditional methods—often on the farm where the milk is produced. Some of these cheese makers use pasteurized milk in their products, but others use raw milk that could contain disease-causing bacteria.

Some people believe cheese made from raw milk is better for you, but Sheehan says there is no scientific evidence to support that belief.

In countries where pasteurization of milk is less common, outbreaks of foodborne illness attributed to tainted milk or milk products occur more frequently than they do in the United States. In France, for example, the rate of foodborne illness attributed to milk and milk products was reported to be roughly three times what it is in the U.S., says Sheehan, citing a 2001 study by researcher Marie-Laure De Buyser and other French scientists.

### When in Doubt—Ask!

Federal law prohibits dairies from distributing raw milk across state lines if it has been packaged for consumers. This means raw milk can only be distributed between states if it's going to plants to be pasteurized or used to make aged cheese before being sold to consumers. Experts have long believed that aging cheese for 60 days or longer killed disease-causing bacteria. FDA is now reviewing the scientific basis for that belief.

Each state makes its own laws about selling raw milk within the borders of the state. About half of states allow some form of raw milk to be sold to consumers.

Consumers should be alert when they buy milk or milk products. To avoid raw milk, here are a few things you can do:

- Read the label on milk or milk products before you buy them. Many companies put the word "pasteurized" right on the label—but, Sheehan says, it is not required.
- Ask store employees if specific brands are pasteurized.
- At farm stands or farmers' markets, ask if the milk and cream being sold have been pasteurized. If the market sells yogurt, ice cream, or cheese, ask if they were made with pasteurized milk.

### Symptoms of Foodborne Illness

Not all raw milk and products made from it contain harmful bacteria. But if they do, the bacteria could be especially dangerous to pregnant women, children, the elderly, and people with weakened immune systems. While most healthy people recover from a foodborne illness in a short time, some people may develop symptoms that are chronic, severe, or even life-threatening.

Symptoms of foodborne illness may include:

- vomiting
- diarrhea
- abdominal pain
- fever
- headache
- body aches

If you think you might have become ill from drinking raw milk—or eating yogurt, cheese, or a product made from it—see your health care provider immediately. FDA

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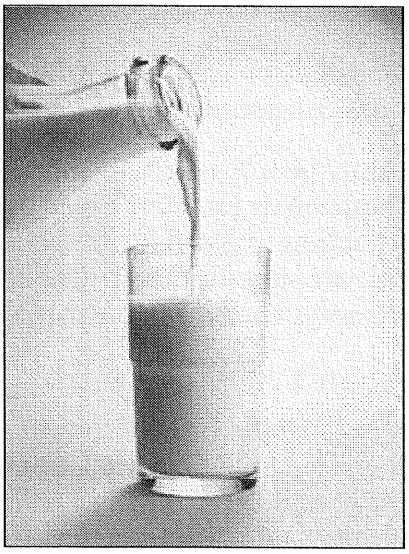
Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

# Raw (Unpasteurized) Milk

**Raw milk can carry harmful germs that can make you very sick or kill you. If you're thinking about drinking raw milk because you believe it has health benefits, consider other options.**

## Trying to decide about raw milk?



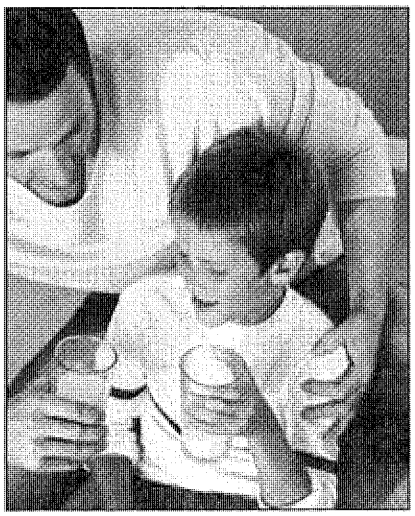
Developing a healthy lifestyle is a process with many decisions and steps. One step you might be thinking about is adding raw milk to your diet. Raw milk is milk that has not been pasteurized to kill harmful germs. Germs include bacteria, viruses, and parasites. It's important to understand the risks of drinking raw milk, especially because you may be hearing claims about the supposed "benefits" of raw milk.

Raw milk contains bacteria, and some of them can be harmful. So, if you're thinking about consuming raw milk because you believe that it is a good source of beneficial bacteria, you need to know that it isn't and you may instead get sick from the harmful bacteria. If you think that certain types of bacteria may be beneficial to your health, consider getting them from foods that don't involve such a high risk. For example, so-called probiotic bacteria are sometimes added to pasteurized fermented foods, such as yogurt and kefir.

Milk and products made from milk need minimal processing, called pasteurization, which can be done by heating the milk briefly (for example, heating it to 161°F for about 20 seconds). When milk is pasteurized, some bacteria remain in it, but the disease-causing ones are killed. Harmful germs usually don't change the look, taste, or smell of milk, so only when milk has been pasteurized can you be confident that these germs are not present. To ensure that milk is safe, processors rapidly cool it after pasteurization, practice sanitary handling, and store milk in clean, closed containers at 45°F or below.

Remember, you can't look at, smell, or taste a bottle of raw milk and tell if it's safe to drink. Make the best decision for the health of your family. If you want to keep milk in your family's diet, protect them by not giving them raw milk. Even healthy adults can get sick from drinking raw milk. If you're thinking about drinking raw milk because you believe it has health benefits, consider other options.

## Who is at greatest risk of getting sick from drinking raw milk?



The risk of getting sick from drinking raw milk is greater for infants and young children, the elderly, pregnant women, and people with weakened immune systems, such as people with cancer, an organ transplant, or HIV/AIDS, than it is for healthy school-aged children and adults. But, it is important to remember that healthy people of any age can get very sick or even die if they drink raw milk contaminated with harmful germs.

## What are the risks associated with drinking raw milk?

Raw milk can carry harmful bacteria and other germs that can make you very sick or kill you. While it is possible to get foodborne illnesses from many different foods, raw milk is one of the riskiest of all.

Getting sick from raw milk can mean many days of diarrhea, stomach cramping, and vomiting. Less commonly, it can mean kidney failure, paralysis, chronic disorders, and even death.

Many people who chose raw milk thinking they would improve their health instead found themselves (or their loved ones) sick in a hospital for several weeks fighting for their lives from infections caused by germs in raw milk. For example, a person can develop severe or even life-threatening diseases, such as Guillain-Barré syndrome, which can cause paralysis, and hemolytic uremic syndrome, which can result in kidney failure and stroke.

## Aren't raw or natural foods better than processed foods?

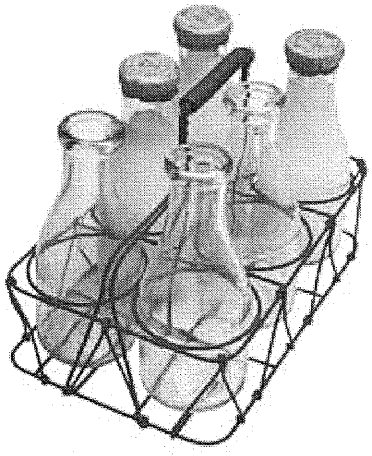
Many people believe that foods with no or minimal processing are better for their health. Many people also believe that small, local farms are better sources of healthy food. However, some types of processing are needed to protect health. For example, consumers process raw meat, poultry, and fish for safety by cooking. Similarly, when milk is pasteurized, it is heated just long enough to kill disease-causing germs. Most nutrients remain after milk is pasteurized. There are many local, small farms that offer pasteurized organic milk and cheese products.

### I've heard that many organic and raw milk producers are creating sanitary and humane conditions for raising animals and producing "safe" raw milk and raw milk products (like cheeses and yogurts). Does this help reduce milk contamination?

Adherence to good hygienic practices during milking can reduce, but not eliminate, the risk of milk contamination. The dairy farm environment is a reservoir for illness-causing germs. No matter what precautions farmers take, and even if their raw milk tests come back negative, they cannot guarantee that their milk, or the products made from their milk, are free of harmful germs.

- Germs such as *Escherichia coli*, *Campylobacter*, and *Salmonella* can contaminate milk during the process of milking dairy animals, including cows, sheep, and goats. Animals that carry these germs usually appear healthy.

## How does milk get contaminated?



Milk contamination may occur from:

- Cow feces coming into direct contact with the milk
- Infection of the cow's udder (mastitis)
- Cow diseases (e.g., bovine tuberculosis)
- Bacteria that live on the skin of cows
- Environment (e.g., feces, dirt, processing equipment)
- Insects, rodents, and other animal vectors
- Humans, for example, by cross-contamination from soiled clothing and boots

Pasteurization is the only way to kill many of the bacteria in milk that can make people very sick.

## Information about raw milk-related outbreaks

States that allow the legal sale of raw milk for human consumption have more raw milk-related outbreaks of illness than states that do not allow raw milk to be sold legally.

Among dairy product-associated outbreaks reported to CDC between 1973 and 2009 in which the investigators reported whether the product was pasteurized or raw, 82% were due to raw milk or cheese. From 1998 through 2009, 93 outbreaks due to consumption of raw milk or raw milk products were reported to CDC. These resulted in 1,837 illnesses, 195 hospitalizations, and 2 deaths. Most of these illnesses were caused by *Escherichia coli*, *Campylobacter*, or *Salmonella*. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; among the 93 raw dairy product outbreaks from 1998 to 2009, 79% involved at least one person younger than 20 years old.

A study released by CDC in February 2012 examined the number of dairy outbreaks in the United States during a 13-year period. Between 1993 and 2006, 60% (73/121) of dairy-related outbreaks reported to CDC were linked to raw milk products. Three-quarters of these outbreaks occurred in states where the sale of raw milk was legal at the time. Experts also found that those sickened in raw milk outbreaks were 13 times more likely to be hospitalized than those who got ill from pasteurized milk during an outbreak.

As a consumer, you can take steps when grocery shopping and at home with all of your dairy products to minimize the risk of getting sick:

1. Only consume pasteurized milk and milk products. Look for the word "pasteurized" on the dairy labels. If in doubt, don't buy it!
2. Keep pasteurized dairy products refrigerated at 40 degrees Fahrenheit or below at home and dispose of any expired products to reduce the risk of illness.
3. If you consume soft, fresh, un-aged cheeses like queso fresco, make sure they are made from pasteurized milk. Aged cheeses made from raw milk are generally okay to eat because germs usually die off during the aging process. However, outbreaks associated with these cheeses have been identified.

Reported outbreaks represent the tip of the iceberg. For every outbreak and every illness reported, many others occur, and most illnesses are not part of recognized outbreaks. Protect yourself and your loved ones. Avoid raw milk, it's just not worth the risk.

## More Information

- Visit CDC's Raw (Unpasteurized) Milk website (/foodsafety/rawmilk/raw-milk-index.html)
- Read CDC the new study: Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws – United States, 1993-2006 [PDF - 268KB] (http://wwwnc.cdc.gov/eid/ahead-of-print/article/18/3/pdfs/11-1370.pdf) (Questions and Answers about the study (/foodsafety/rawmilk/nonpasteurized-outbreaks.html) )
- Watch Real Stories of the Dangers of Raw Milk (/foodsafety/rawmilk/raw-milk-videos.html)
- Listen to "Got Milk? [PODCAST – 5:28 minutes] (http://www2c.cdc.gov/podcasts/player.asp?f=10651) ", to learn about the risks associated with drinking unpasteurized (raw) milk
- Visit FoodSafety.gov's Myths about Raw Milk (http://www.foodsafety.gov/keep/types/milk/index.html) (http://www.cdc.gov/Other/disclaimer.html)
- Visit FDA's The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk (http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079516.htm) (http://www.cdc.gov/Other/disclaimer.html) , FDA Federal Registry: Cheeses and Related Cheese Products (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=133&showFR=1) (http://www.cdc.gov/Other/disclaimer.html)
- Visit Real Raw Milk Facts (http://www.realrawmilkfacts.com) (http://www.cdc.gov/Other/disclaimer.html)
- Got raw milk? Don't Drink It [PDF - 330KB] (/media/matte/2012/02_Raw_Milk_Dontdrink.pdf)

CDC works 24/7 saving lives and protecting people from health threats to have a more secure nation. A US federal agency, CDC helps make the healthy choice the easy choice by putting science and prevention into action. CDC works to help people live longer, healthier and more productive lives.

Page last reviewed: February 28, 2012
Page last updated: February 28, 2012
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Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix M

# ASSOCIATION OF FOOD AND DRUG OFFICIALS

## 2005

**RESOLUTION NUMBER 1**

**Submitted by:** **Association of the Food and Drug Officials of the Southern States**

**Date:** **April 13, 2005**

**Concerning:** **Presenting information and position statements to State Legislative officials considering changing food laws regarding sale of raw milk and raw milk products.**

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**Whereas**, there has been a well documented history of milk borne illnesses throughout the nation associated with the consumption of raw milk and raw milk products; and

**Whereas,** Federal agencies such as FDA and CDC and numerous states have reported recent illnesses and deaths associated with the consumption of raw milk and milk products such as cheeses produced from unpasteurized milk; and

**Whereas,** the FDA continues to report continued importation of significant amounts of cheeses manufactured from raw milk, with laboratory analysis of these cheeses confirming the presence of *Listeria* and various other pathogens; and

**Whereas,** AFDO supports mandatory pasteurization for all milk and milk products intended for direct human consumption except where alternative procedures to pasteurization are provided (i.e. curing of certain cheese varieties) to ensure the safety of finished products; and

**Whereas,** State Public Health and Agriculture Officials are reporting increased activity on the part of State legislatures to amend current laws or pass new laws that will allow for the sale of raw milk and raw milk products; therefore, be it

**Resolved,** that AFDO update the Position Statement on Raw Milk and Milk Products that was revised by the AFDO Board of Directors on June 14, 2003, to include current illness data associated with the sale of raw milk products, as well as position statements of various public health and industry entities; and be it further

**Resolved** that the AFDO Position Statement be sent throughout the nation to State Public Health and Agriculture Officials for presentation to their legislative representatives who may be considering adopting or amending dairy laws that would permit the sale of raw milk and milk products.

# PUBLIC HEALTH VETERINARIAN COALITION COMMITTEE

# AMERICAN ASSOCIATION OF PUBLIC HEALTH VETERINARIANS

## VETERINARY PUBLIC HEALTH POLICY STATEMENTS-2000

### Position Statement on Raw (Unpasteurized) Milk/Products

***Developed by the American Association Of Public Health Veterinarians***

***Background:*** All food products of animal origin consumed in the raw state present a potential health threat to consumers. In addition, *Escherichia coli* 0157:H7, first identified in 1982, is now rapidly emerging as one of the most important foodborne pathogens in North America. Undercooked ground beef is the most frequently reported food vehicle for *E. Coli* 0157:H7, but infections have also been linked to the consumption of raw milk. During 1993, the Oregon State Health Division reported two outbreaks of *E. Coli* 0157:H7 associated with the consumption of raw milk. In one of these outbreaks, an infant was provided a bottle of raw milk and was hospitalized after developing severe hemolytic uremic syndrome (kidney damage). *E. Coli* 0157:H7 was isolated from milking cows at the two implicated dairy herds.

Cattle are considered to be the reservoir of this pathogen. The organism is shed in the feces; and may infect the udder (as has been shown with *Salmonella*). Most often, raw milk becomes contaminated with *E. Coli* 0157:H7 when there is poor hygiene at the diary resulting in fecal contamination of the udder and, subsequently, the milk. Like other pathogens found in raw milk/products, *E. Coli* 0157:H7 is killed by standard pasteurization methods. Although a dairy may strictly adhere to clean procedures in collecting milk, it is impossible to completely eliminate occasional contamination of raw milk by disease-producing organisms carried in bovine feces. Milk can also be intrinsically contaminated if the cow's udder is infected. Pasteurization of milk is the acknowledged, time-honored method to destroy this and other pathogens in milk/products.

Less than 20 states in the United States permit the sale and distribution of packaged raw milk/products intrastate. The FDA banned the interstate shipment of raw milk/products, including certified raw milk, in part because of concerns about contamination with *Salmonella dublin* which it considered a "life-threatening hazard" (FDA Consumer, 1986 Sep; 20(7)). Many pathogens including other *Salmonella* serotypes and *Campylobacter* are well-documented links to the consumption of raw milk/products.

**Key Public Health Issues:**

- Many human pathogens have been documented in raw milk (e.g., *Salmonella, Campylobacter, Yersinia, Listeria, Brucella, E. coli).*
- Consumption of raw milk products has been identified as an important risk factors for *E. Coli* 0157:H7.
- Pasteurization of milk/products prior to sale is not required in all states.

***Final Position Statement:***

The Public Health Veterinarian Coalition Committee recommends that only pasteurized milk/products be consumed or sold.

# H-150.980 Milk and Human Health

Next Policy | Previous Policy
H-150.980 Milk and Human Health

The AMA reaffirms its policy that all milk sold for human consumption should be required to
Reaffirmed by CLRPD Rep. 2, I-95; Reaffirmed: CSA Rep. 8, A-05)

# A VMA Positions on Pasteurization of Milk and Milk Products

Inasmuch as apparently healthy cows and goats can shed in their milk organisms which are pathogenic to human beings and may cause diseases such as brucellosis, Campylobacter enteritis, salmonellosis, and tuberculosis; and, inasmuch as milk handlers may introduce pathogenic agents during the handling of unpasteurized milk (including certified and raw milk), only pasteurized milk and milk products should be sold for human consumption. In those states where the sale of unpasteurized milk is authorized, those products should be labeled "Not Pasteurized and May Contain Organisms that cause Human Disease."

(Approved by the A VMA House of Delegates, 1980)

The AVMA directly and through each of its state and allied associations promotes the passage of state laws requiring pasteurization of all milk to be sold within the state and consumed as fluid milk or to be used in the manufacturer of dairy products.

(Approved by the AVMA House of Delegates, 1993)

# *Cornell University Food Science Department*
# *Position Statement on Raw Milk Sales and Consumption*

We recommend pasteurization of milk intended for consumption by humans. Specifically, we strongly recommend that raw milk not be served to infants, toddlers, or pregnant women, or any person suffering from a chronic disease or a suppressed immune system. In addition, we strongly recommend that raw milk not be provided to the general public at farms or at retail; raw milk consumption could expose these people to unnecessary and/or extremely costly and painful risks for which a milk producer may be held legally responsible. Pasteurization offers protection – both for the consumer and for the producer - from the consequences of foodborne infection by pathogens that can be found in raw milk.

**Health Hazards Associated with Raw Milk Consumption**

Physicians linked consumption of raw milk with the spread of disease early in the 20$^{th}$ century. Raw milk consumption was associated with many serious human diseases, including diphtheria, typhoid, tuberculosis, and brucellosis (1). In fact, in 1938, 25% of all U.S. illnesses resulting from consumption of contaminated food and water were linked back to milk consumption (2). During this era, human illnesses typically resulted from consumption of milk that had been obtained from unhealthy cows under unsanitary conditions. Modern U.S. dairy products are associated with considerably less than 1% of foodborne illnesses that are traced back to food source each year (2). The reduction in numbers of foodborne illnesses associated with milk consumption over the years reflects implementation of: (i) on-farm programs to control animal diseases, including brucellosis, tuberculosis and mastitis; (ii) enhanced farm sanitation practices; (iii) temperature control of milk products from the farm to the consumer (milk must be kept at 45°F or below within 2 hours of milking); and (iv) pasteurization of the majority of commercial dairy products (2).

In addition to the reduction in the number of illnesses associated with dairy product consumption since 1938, the nature of dairy-borne human illnesses has changed, as well. In the past 20 years, illnesses from dairy product consumption have been predominantly associated with *Salmonella enterica, Listeria monocytogenes, Campylobacter jejuni*, and *Escherichia coli* O157:H7 (3), which can be present in milk obtained from healthy animals, typically as a consequence of contamination that occurs during or after milking (e.g., milk contamination from contact with fecal material or inadequately cleaned equipment) (4). In recent years, pathogenic microorganisms have been isolated from bulk tank samples at rates ranging from 0.87% to 10% of total samples collected (5, 6, 7, 8, 9), indicating a measurable probability of encountering pathogenic bacteria in raw milk.

**Examples and prevalence of human foodborne pathogens isolated from raw bulk tank milk** (adapted from Ruegg, P. http://www.uwex.edu/milkquality/PDF/zoo.pdf)

| Pathogen | State or Province | # Tanks Sampled | % Positive Bulk Tanks | Reference |
|---|---|---|---|---|
| *Salmonella* | WI, MI, IL | 678 tanks | 4.70% | 6 |
| | Ontario | 1,721 tanks | 0.17% | 8 |
| | SD, MN | 131 tanks | 6.10% | 5 |
| | TN, VA | 292 tanks | 8.90% | 9 |
| *Listeria* | Ontario | 1,721 tanks | 2.73% | 8 |
| | SD, MN | 131 tanks | 4.60% | 5 |
| | TN, VA | 292 tanks | 4.10% | 9 |
| *E. coli* O157:H7 | Ontario | 1,721 | 0.87% | 8 |
| | WI | 115 tanks | 10.00% | 7 |

**Milk Pasteurization**

The public health objective of milk pasteurization, as defined in the Grade "A" Pasteurized Milk Ordinance (2), is to eliminate all non-spore forming pathogens commonly associated with milk. Pasteurization processes are specifically implemented to reduce the potential risk to consumers of illness due to pathogens that may be present in raw milk. All milk intended for human consumption must be handled according to good agricultural and manufacturing process procedures. As pasteurization is not designed to sterilize milk, it may not eliminate all harmful bacteria if raw milk is heavily contaminated. Therefore, milk intended for human consumption must be obtained from healthy cows and protected from contamination. The temperature and time regime for pasteurization is currently designed to kill *Coxiella burnetii*, an animal pathogen that is the causative agent of Q-fever in humans. *C. burnetti* is currently accepted as the most heat-resistant human pathogen found in milk. Good hygiene practices during milking and subsequent handling of milk are essential to reduce the risk of contamination on the farm and in the milk processing plant. Careful packaging of pasteurized milk in clean, sanitized containers also helps retard spoilage of milk so it lasts longer after it is purchased. Milk that is not properly handled can become re-contaminated after the heat treatment. Rapid cooling after pasteurization, sanitary handling, and storage in a clean, closed container at 40°F or below are also important aspects of ensuring safe milk.

**Many Types of Raw Foods Can be Hazardous for Human Consumption**

Many raw foods may be contaminated with harmful bacteria. Certain raw foods should always be treated as if they are contaminated. For example, ground beef may be contaminated with a number of organisms associated with a cow's gastrointestinal tract, including *E. coli* O157:H7, however proper cooking will kill these organisms. Other foodborne disease outbreaks from *Salmonella* and *Campylobacter* are associated with consumption of undercooked chicken. *Salmonella* infections also have been associated with consumption of raw or undercooked eggs. *Listeria monocytogenes* infections have been attributed to consumption of a number of foods, including improperly cooked

hotdogs. Heat treatments for many foods are commonly accepted practices that not only make the food more palatable, but also, when conducted in accordance with accepted food safety guidelines, reduce the risk of acquiring foodborne infections.

**Examples of Recent Outbreaks Attributed to Raw Milk Consumption**

In recent years, illnesses from raw milk consumption have made national headlines. For example, *E. coli* O157:H7 infections occurred in the states of Oregon and Washington in December 2005. Of 140 people reportedly consuming milk from a farm, 18 became ill. Five patients (aged 1-13 years old) were hospitalized and four of these patients developed Hemolytic Uremic Syndrome (10). In 2006, *E. coli* O157:H7 was responsible for illness in six children from California (11) and two children in Washington (12). Litigation on behalf of two of the children from California has recently been filed (13). In three additional 2006 outbreaks, *Campylobacter jejuni* infections were diagnosed in two people in Ohio (14), five in Colorado (15), and > 50 people following consumption of raw milk cheese in Wisconsin (15). In 2007, illnesses attributed to raw dairy product consumption included a *Salmonella* outbreak that sickened 29 in Pennsylvania (16), a *Campylobacter* outbreak that affected 67 in Kansas (17), and listeriosis infections among four pregnant women in North Carolina, which resulted in three miscarriages and a premature delivery (18). For comprehensive information on foodborne illnesses, please visit the Centers for Disease Control (CDC) website: http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm. To reduce the risk of contracting foodborne illnesses, consumers should avoid raw milk products.

**Cornell University staff members supporting this position statement:**

Robert Ralyea, M.S., Sr. Extension Associate, Food Science Department
(rdr10@cornell.edu)

David P. Brown, M.S., Sr. Extension Associate, Food Science Department
(dpb1@cornell.edu)

Jason R. Huck, M.S., Dairy Operations Manager, Cornell University (jrh63@cornell.edu)

Martin Wiedmann, Dr. med. vet, Ph.D., Associate Professor and Director of Graduate Studies, Field of Food Science and Technology

Kathryn J. Boor, Ph.D., Professor and Food Science Department Chair
(kjb4@cornell.edu)

Contact information:
Food Science Department
Stocking Hall
Cornell University
Ithaca, NY 14853
607-255-7643

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**International Association for Food Protection (IAFP)**
**Position Statement**

# *Milk Pasteurization and the Consumption of Raw Milk*

Prepared by Ronald H. Schmidt[1] and P. Michael Davidson[2]
On behalf of the IAFP Dairy Quality and Safety Professional Development Group (PDG)
and the 3-A Committee on Sanitary Procedures

## Milk Pasteurization

Federal regulation of milk pasteurization and sanitation in dairy processing plants has been in existence in the United States for nearly 100 years (1). This comprehensive program involves application of sanitary procedures throughout production, handling, pasteurization, and distribution. As a result of regulations under the US Public Health Service and a variety of state and local regulatory agencies, the incidence of milk-borne illness in the US has decreased from approximately 25 per cent of all reported foodborne illness outbreaks in 1938 **to less than 1 per cent of reported outbreaks today** (1). Similar trends have been observed internationally with mandatory milk pasteurization having a significant positive impact on public health and safety in many countries.

## Risks of Raw Milk Consumption

Pathogenic or disease-causing microorganisms may be shed into milk even by healthy cows, goats, and sheep (2). Further, milk handling procedures on the dairy farms may introduce pathogenic microorganisms into the milk. Milk is an excellent growth medium and when stored improperly will allow the rapid proliferation of pathogens. A recent survey by Jayarao et al. (3) identified several foodborne pathogenic bacteria, including *Campylobacter jejuni,* Shigatoxin producing *Escherichia coli, Listeria monocytogenes*, *Salmonella* serovars, and *Yersinia enterocolitica* associated with raw milk. This is but one of several studies demonstrating that pathogenic bacteria are common in raw milk (4,5). In addition, unpasteurized milk is a vehicle for transmission of other pathogenic microorganisms (e.g. *Brucella, Mycobacterium*) (6,7). While these pathogens can affect the health of anyone who drinks raw milk, they are especially dangerous to high risk consumers (e.g., pregnant women, children, the elderly, and people with weakened immune systems).

The consumption of raw milk has been associated with numerous foodborne illness cases and outbreaks and has resulted in product recalls (8,9,10). According to the survey report by the National Association of State Departments of Agriculture (NASDA) in

[1]Food Science and Human Nutrition Department, University of Florida, Gainesville, FL
[2]Food Science and Technology Department, University of Tennessee, Knoxville, TN

2004 (11), 29 states have recorded illness outbreaks traceable to raw milk consumption. Further, in
2005-2006, more than 10 outbreaks caused by the consumption of raw milk or raw milk cheese were reported by the Food and Drug Administration (FDA) (12-15).

Pasteurization assures the destruction of pathogenic microorganisms that may be present in raw milk. Since 1987, US FDA regulations (16) have required mandatory pasteurization of packaged milk and milk products for human consumption in interstate commerce. Milk pasteurization as a public health control measure is endorsed by the Centers for Disease Control and Prevention (CDC) (8) and the U. S. Department of Agriculture (USDA) Agricultural Marketing Service (17). In spite of this, the majority of state regulations currently allow raw milk sales with certain limitations and legislative changes have been or are being proposed in many other states to allow raw milk sales.

As a public health control procedure, the milk pasteurization process (or equivalent) has been recognized throughout the world. According to the World Health Organization (WHO) (18): *"Pasteurization of milk is almost universally accepted as an essential public health technology that enjoys the confidence and support of the consuming public"*. In Canada, federal and many provincial regulations prohibit the sale of raw milk (18). However, direct sale of unpasteurized milk to the consumer is allowed in many regions of the world, with certain restrictions and limitations.

A variety of regulatory, educational and public health authorities have issued position statements, fact sheets, and related documents which warn against the risks of raw milk consumption, including:

- American Veterinary Medical Association (AVMA) (1);
- Association of Food & Drug Officials (AFDO) (20);
- Health Canada (21,22);
- NASDA (11);
- National Association of State Public Health Veterinarians (NASPHV) (23);
- National Conference on Interstate Milk Shipments (NCIMS) program (24);
- State regulatory agencies (25,26); and
- University cooperative extension programs (27-30).

In recent years, organizations (31,32) have emerged promoting raw milk consumption and making unsubstantiated and false claims regarding the health benefits achieved by drinking raw milk and the "toxic effects of drinking pasteurized milk". Further, they make unsupported statements that raw milk sales will "save the family farm." These organizations have sought to overturn state regulations prohibiting the sale of raw milk. This movement has had some support from some individual state cooperative extension specialists who are promoting direct farm sales under sustainable and value added agriculture programs.

As the premier professional association for microbiological safety of foods, the International Association for Food Protection (IAFP), the IAFP Dairy Quality and Safety Professional Development Group, and the 3-A Committee on Sanitary Procedures,

[1]Food Science and Human Nutrition Department, University of Florida, Gainesville, FL
[2]Food Science and Technology Department, University of Tennessee, Knoxville, TN

commend the success of the time honored and effective, regulatory program for milk pasteurization and sanitation through the NCIMS (24), a cooperative federal/state regulatory program. We hereby join the numerous other associations and agencies in warning consumers regarding the risk of raw milk consumption. It is overwhelmingly clear from scientific and epidemiological evidence that the risks of raw milk consumption far outweigh any perceived benefits. Therefore, it is the position of IAFP that:

- consumption of unpasteurized milk will lead to increased risk of serious milkborne illness and even death, especially among at risk populations; and
- allowing the sale of unpasteurized milk for direct consumption, as a public health policy, would place would place many consumers at risk and should be prohibited.

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**International Dairy Foods Association**
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

March 23, 2011

The Honorable Raymond J. Lesniak
985 Stuyvesant Avenue
Union, NJ 07083

Dear Chairman Lesniak:

I urge you to oppose A 743, a bill that would allow the sale of raw milk products to consumers in New Jersey. The U.S. Food and Drug Administration has long advised consumers that the consumption of raw milk poses unnecessary health risks and should be avoided.

The International Dairy Foods Association (IDFA), Washington, DC, represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies representing a $110-billion a year industry. IDFA's 220 dairy processing members run more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. IDFA can be found online at www.idfa.org.

The dairy industry has an excellent food safety record with less than 1 percent of all food-borne disease cases associated with pasteurized milk and dairy products, as reported by the Center for Disease Control and Prevention. Unfortunately, this reputation is tainted by the much higher incidence of food related illnesses from raw, unpasteurized milk and other raw milk products. According to the CDCP, 71% (137 of 193 cases) of the reported food borne illnesses from dairy products were attributable to consuming under pasteurized or raw milk, including one death. This is all the more remarkable when you consider that raw milk consumption is a small, but growing portion of total dairy consumption.

Prior to the discovery of pasteurization over a century ago, dairy products were the largest source of food-borne illnesses in this country. Naturally occurring bacteria in raw milk can cause a number of illnesses including tuberculosis, brucellosis, salmonellosis, listeriosis (spontaneous abortions in pregnant women), and food poisoning-like symptoms, some of which have the ability to cause long-term negative health impacts.

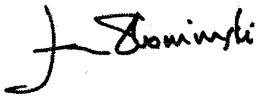
Pasteurization removes the great majority of these pathogens and, combined with refrigeration, has allowed the dairy processing industry to establish an excellent food safety record. Product testing, as required by A 743, is not an adequate substitute and cannot ensure the same level of safety. Increasing the availability of raw milk for direct human consumption will undermine and detract from the overall superior food safety record and safe image of all dairy products.

Although proponents of raw milk claim that nutrients are lost due to pasteurization, there is no meaningful difference in the nutritional values of pasteurized and unpasteurized milk. Claims

that raw milk has medicinal properties that may be disease-curing are also unfounded.

Raw milk sales cause illnesses, and often deaths, in the United States every year. Regulating the sales of raw milk will encourage its consumption when the correct approach is to warn consumers of its inherent dangers. A 743 adopts the wrong approach towards a serious health issue and I urge you again to oppose it.

Sincerely,



Jerry Slominski
Senior Vice President, Legislative Affairs & Economic Policy
International Dairy Foods Association

International Dairy Foods Association

Milk Industry Foundation | National Cheese Institute | International Ice Cream Association



# Consumer Safety & Raw Milk

*January 11, 2012*

## IDFA Commends Actions to Deter Human Consumption of Raw Milk


Two recent actions, one at the state level and another at the federal level, underscored the importance of pasteurization for milk sold to consumers and helped to protect the dairy industry's strong food-safety record.

The New Jersey State Senate's Economic Growth Committee last week removed from consideration a bill that would have legalized the sale of raw milk to consumers in the state. Earlier this week, the White House responded to a public petition, turning down the request to legalize raw milk sales for consumers across the country.

The New Jersey committee was set to hear testimony on a bill, A. 743, which would allow the sale of raw milk to consumers at the farm level. The bill had been passed by the State Assembly in April and was awaiting Senate approval. The committee chairman, Senator Stephen Lesniak (D-Union), pulled the bill from the hearing agenda due to significant opposition, effectively killing the bill for the rest of the legislative session.

IDFA **sent a letter** last March to the committee members and sent a **joint letter** with the National Milk Producers Federation in April to New Jersey Governor Chris Christie and Senate Majority Leader Stephen Sweeney in opposition to the bill.

### White House Response

The White House response reiterated the administration's belief that raw milk for human consumption has potentially dangerous health risks and should not be allowed for sale across interstate lines. The response, written by Doug McKillop, senior policy advisor for rural affairs, stressed that claims of extra nutritional value in raw milk are unfounded and that raw milk has been shown to cause illness.

"This administration believes that food-safety policy should be based on science," McKillop said. "In this case, we support pasteurization to protect the safety of the milk supply because the health risks associated with raw milk are well documented."

**Read the petition and the White House response**.

IDFA has consistently opposed the sale of unpasteurized milk to consumers, because it may contain harmful bacteria that can cause life-threatening illnesses. The Centers for Disease Control and the Food and Drug Administration recommend that no one consume unpasteurized milk, and federal law prohibits the retail sale of unpasteurized milk across state borders.

Raw milk regulations vary by state, however, and some states allow the sale of raw milk to local retail food stores or directly from the farm to consumers within their borders. Other states have considered expanding access to raw milk, and IDFA will continue to monitor and oppose these actions.

"We congratulate the New Jersey State Senate and the White House for looking out for the safety of consumers," said Jerry Slominski, senior vice president of legislative affairs and economic policy. "The Centers for Disease Control and Prevention, the American Medical Association, the American Academy of Pediatrics and other organizations have endorsed the pasteurization of milk and restriction of the sale of products containing raw milk."

For more information, contact Slominski at jslominski@idfa.org or (202) 220-35

**BACK**

International Dairy Foods Association

Milk Industry Foundation | National Cheese Institute | International Ice Cream Association

1250 H Street, NW, Suite 900
Washington, DC 20005
Phone: (202) 737-4332
Fax: (202) 331-7820

# National Environmental Health Association Position Regarding

## *Sale or Distribution of Raw Milk*

**Adopted: January 28, 2008**

*Editor's Note: The NEHA Board of Directors recently adopted this position in opposition to any legislation that would allow the sale or distribution of raw, unpasteurized milk to the consumer. NEHA strongly supports pasteurization before sale to the consumer. In addition, NEHA strongly supports consumer education about the dangers of consuming raw, unpasteurized milk. Below is the full text of the NEHA position.*

The Cornell University Department of Food Safety has stated that "milk is a natural food. It is nutrient-rich: it contributes high-quality protein, essential vitamins and minerals including calcium to the diet" (Scott, 2002). Milk in its raw state contains a number of bacteria, some of which may be pathogenic such as enterotoxigenic *Staphylcoccus aureus, Campylobacter, Escherichia coli, Listeria, Salmonella, Yersinia, Brucella,* and *Mycobacterium tuberculosis* (Headrick et al., 1998). This is the case for all dairy animals, including cows, goats, and sheep. The process of pasteurization has been used for a hundred years to destroy pathogenic bacteria that are present in raw milk (International Association for Food Protection [IAFP], 2008). The Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA) (U.S. Food and Drug Administration, 2006), and the World Health Organization (WHO) (WHO, 2006) endorse the process of pasteurizing milk as a public health control measure.

Milkborne disease has been reduced greatly by the use of pasteurization. Prior to 1938, milkborne illness represented 25 percent of all foodborne illness outbreaks. As a result of efforts by the U.S. Public Health Service and individual states requiring the mandatory use of pasteurization, milkborne illness represents less than 1 percent of foodborne illness outbreaks. Cases of illness caused by the consumption of raw, unpasteurized milk have continued to occur (Headrick et al., 1998). FDA and CDC have noted the following outbreaks:

- December 2007: Three counties in North Carolina reported cases of *Listeria monocytogenes* from the consumption of illegally produced soft Mexican type cheeses made from raw milk (State of North Carolina, 2007).
- 2007: CDC reported 29 cases of *Salmonella typhimurium* infection that were associated with the consumption of raw milk and cheese made from raw milk in York County, Pennsylvania (CDC, 2007b).
- 2007: CDC's *Morbidity and Mortality Weekly Report* for the week of March 2, 2007, noted that from 1998 to May of 2005 CDC identified 45 outbreaks of foodborne illness that implicated unpasteurized milk, or cheese made from unpasteurized milk. They noted: "These outbreaks accounted for 1,007 illnesses, 104 hospitalizations, and two deaths" (CDC, 2007b).
- 2005–2006: The U.S. Food and Drug Administration recorded more than 10 outbreaks caused by the consumption of raw milk or raw milk cheese (FDA, 2007).
- 2004: The National Association of State Departments of Agriculture (NASDA) survey indicated that 29 states have recorded milkborne outbreaks traceable to raw milk consumption (FDA, 2007).
- 2002–2003: Two children were hospitalized in Ohio for infection with *Salmonella enterica* serotype *typhimurium*. These children and 60 other people in Illinois, Indiana, Ohio, and Tennessee developed bloody diarrhea, cramps, fever, chills and vomiting from *S. typhimurium* tracked to consuming raw milk (CDC, 2003).

- 2001: An outbreak of *Campylobacter jejuni* infections from drinking raw or unpasteurized milk occurred in Wisconsin associated with milk procured through a cow-leasing program (CDC, 2002).
- 2000–2001: In North Carolina, 12 adults were infected with *Listeria monocytogenes* linked to homemade, Mexican-style fresh soft cheese produced from contaminated raw milk sold by a local dairy farm. Ten of the 12 victims were pregnant women, and infection with the bacterium resulted in five stillbirths, three premature deliveries, and two infected newborns (CDC, 2001).
- 1998: In Massachusetts, 66 people received injections to protect against potential exposure to rabies after drinking unpasteurized milk from a local dairy. A cow that died at the dairy was found to be infected with rabies. Transmission of the rabies virus through unpasteurized milk, although not the common route of infection, is theoretically possible according the Centers for Disease Control and Prevention (CDC, 1999).

Moreover, the occurrence of outbreaks due to raw milk has been found to correlate with the legal status of raw milk sale within a state. In a review of raw milk–associated outbreaks reported to CDC during 1972–1992, Marcia L. Headrick, D.V.M., M.P.H., and colleagues found that the rate of raw milk–associated outbreaks was higher in states in which the sale of raw milk was legal. The authors concluded that banning the intrastate sale of raw milk could reduce the number of milk-associated outbreaks (Headrick et al., 1998).

Recently, advocates of the consumption of natural food have approached legislators in a number of states to allow the sale of raw milk to the consumer. They have contended that the pasteurization process destroys the nutritional benefits of milk. In some instances they have pushed for the adoption of legislation that would allow individuals to purchase a portion of the production of a milk cow through an arrangement know as "Cow Share."

John Sheehan, Director of the U.S. Food and Drug Administration's Division of Dairy and Egg Safety, stated that research showed that there is no significant difference in the nutritional value of pasteurized and unpasteurized milk. He indicated that the caseins, the major family of milk proteins, is largely unaffected and any modification in whey protein that might occur is barely perceptible (Bren, 2004). Sheehan further stated: "Raw milk is inherently dangerous and should not be consumed. Raw milk continues to be a source of foodborne illness and even a cause of death within the United States.... Pasteurization destroys pathogens and most other vegetative microbes which might be expected and have shown to be present in milk" (Testimony of John F. Sheenan, 2007).

A number of regulatory, educational, and public health organizations have issued position papers regarding the dangers associated with the consumption of raw milk. These include:

- Association of Food & Drug Officials (AFDO),
- American Public Health Association (APHA),
- American Medical Association (AMA),
- American Academy of Pediatrics,
- U.S. Animal Health Association,
- National Association of State Public Health Veterinarians,
- Council of State and Territorial Epidemiologists,
- House of Delegates of the American Veterinary Medical Association,
- U.S. Food & Drug Administration, and
- International Association for Food Protection (IAFP).

The National Environmental Health Association recognizes the nutritional value of milk, and it further recognizes the overwhelming scientific evidence that raw milk can transmit pathogenic bacteria to the consumer. The National Environmental Health Association further recognizes the overwhelming scientific and public health evidence that pasteurization of milk has been proven to be a sound method of preventing milkborne disease. NEHA therefore

- Opposes any legislation that would allow the sale or distribution of raw, unpasteurized milk to the consumer. NEHA further opposes arrangements such as "Cow Shares," "Herd

Sharing," bartering, exchange, or any other action that would allow the consumer to obtain a portion of the production of raw, unpasteurized milk from a bovine, ovine, or caprine animal.

- Supports legislation that requires pasteurization of milk prior to sale or distribution to the consumer.
- Supports efforts to educate the consumer about the dangers inherent in consuming unpasteurized milk or products made from raw milk.

The National Environmental Health Association has long supported preventive measures to protect the safety of food for the public. NEHA acknowledges the importance of milk as source of nutrition and is concerned about the safety of milk and products made from milk. NEHA's position regarding raw milk is consistent with sound, science-based, preventive public health measures.

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## National Mastitis Council, Inc.

## Position Statement on the Consumption of Raw Unpasteurized Milk

The current growth in consumer demand for raw milk reflects a steadily expanding market for a range of locally produced, natural, unprocessed foods. To meet this increased demand, more dairy producers are becoming involved in the sale and/or distribution of raw milk.

Raw milk is milk from cows, sheep, goats and other animals that has not been pasteurized. Pasteurization of raw milk was introduced several years ago to prevent the spread of zoonotic milkborne diseases, especially tuberculosis and brucellosis. Enhanced nutritional qualities, better taste, and health benefits have all been advocated as reasons for consuming raw milk. However, there is a lack of science-based data to substantiate these claims. On the other hand, health risks have been associated with consumption of raw milk. A number of disease outbreaks have been reported in people following consumption of raw milk. For example, 12 documented outbreaks associated with raw milk consumption occurred in the U.S. between 2000 and 2008. From these outbreaks, 435 persons were diagnosed with foodborne bacterial infections traced back to the product, with more than 60 people hospitalized and five deaths including stillbirths due to listeriosis. During this same time period, there were only two documented outbreaks associated with consumption of pasteurized milk products; one involved *Listeria monocytogenes*, the other, *Salmonella* Typhimurium. Post-pasteurization contamination was implicated in both of these outbreaks although the specific mode of contamination was not identified.

Despite numerous studies that demonstrate risks associated with consumption of raw milk, people continue to consume raw milk. Based on recent and historical illnesses associated with consumption of raw milk, several organizations, agencies and associations including the U. S. Food and Drug Administration, the U. S. Centers for Disease Control and Prevention, the American Medical Association, the American Academy of Pediatrics, the American Public Health Association, the American Veterinary Medical Association, the U. S. Animal Health Association, the U. S. Department of Agriculture, the National Environmental Health Association, the International Association for Food Protection, Health Canada, European Food Safety Authority, Food Standards Australia New Zealand, and the World Health Organization all have formal statements regarding the hazards associated with consuming raw milk and advocate that milk be pasteurized.

In the U. S., it is a violation of federal law to sell raw milk for consumer use across state lines and intrastate sale of raw milk is illegal in approximately 20 states. Among states that allow intrastate commerce in raw milk intended for human consumption, regulations and standards vary considerably. In some countries such as Canada, raw milk is not allowed to be sold.

Where raw milk is sold legally, strategies to reduce human health risks are needed. Appropriate regulatory minimum standards should be in place to ensure that labeling, sanitation during milking and levels of microbial contamination are effectively monitored and maintained. Targeted education alerting consumers to the potential foodborne hazards in raw milk (and other dairy products) are also needed. Regulations requiring that unpasteurized milk products meet specific hygiene and microbiological standards have worked effectively in other countries. Development of microbiological standards for raw milk appear to have merit but require methods that can detect a variety of different pathogens and will likely be cost prohibitive. Furthermore, testing of raw milk cannot be used as an effective alternative to pasteurization since the inability of a method to detect a pathogen does not indicate its absence.

A requirement for health warnings to be added and prominently displayed on the labels of raw milk may be a useful mechanism to warn consumers of the inherent risks associated with their consumption. Some U.S. states already require warning labels. However, intensive educational programs are needed to insure that vulnerable populations (the elderly, pregnant women, immunosuppressed people, and children) truly understand the risks that are associated with consumption of these products. From the standpoint of reducing risks at the farm level, development of pre- and post-harvest control measures to minimize fecal contamination of milk is critical to the control of pathogens. Some foodborne pathogens of humans are endemic, commensal organisms in dairy cattle and further research efforts to identify on-farm risk factors related to contamination of raw milk are

needed. It is likely that bacterial contamination could be reduced by improving hygiene during milking, although complete elimination of these risks is not feasible.

Of primary importance is the need to provide educational programs and materials that bring awareness of microbial safety hazards to dairy farmers, dairy workers, milk processors and consumers. Dairy producers supplying raw milk must also be well-informed of the risks and liabilities associated with the raw milk they sell, and their insurers should be informed of the activity. Enhanced educational efforts targeting consumers is essential to protect them from potential hazards associated with the consumption of raw milk. Efforts to educate policy makers, regulators and legislators are also necessary so that appropriate and necessary regulations and microbial standards for raw milk to be sold for human consumption can be established.

**The NMC, along with several other public health organizations, agencies and associations supports consumption of pasteurized milk and discourages the sale and consumption of raw milk. In states where raw milk is legally sold, NMC encourages strategies to reduce human health risks that are inherent in the consumption of these products. Such strategies include development of uniform regulations and safety standards; and consumer and producer education concerning production, sales and consumption of raw milk. Educational programs are needed to insure that vulnerable populations (the elderly, pregnant women, immunosuppressed people, and children) truly understand the risks that are associated with consumption of these products. While these efforts may be able to reduce risks associated with raw milk consumption, the only sure way to prevent raw milk-associated foodborne illness is for consumers to drink milk that has been pasteurized.**

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*The National Mastitis Council, Inc. (NMC) is a professional organization dedicated to the production of high quality milk. The NMC provides a forum for the global exchange of information related to udder health, milking management, milk quality, and milk safety. Founded in 1961, the NMC has members from more than 40 countries representing all segments of the dairy industry. For additional information: NMC, 421 S. Nine Mound Rd., Verona, WI 53593 USA. Phone: (608) 848-4615 Fax: (608) 848-4671. nmc@nmconline.org www.nmconline.org*

NATIONAL MILK PRODUCERS FEDERATION

# News Release

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FOR IMMEDIATE RELEASE
Tuesday, November 1, 2011

Contact: Christopher Galen
(703) 243-6111 ext. 356
E-Mail: CGalen@nmpf.org

**NMPF Urges Food and Drug Administration to Defend Laws Against Raw Milk Sales**
As States Waver in Face of Pressure, Feds Need to Hold Fast in Defense of Food Safety

ARLINGTON, VA -- The nation's top public health organization needs to stand firm in the face of mounting pressures to further legalize the direct sale to consumers of a potentially dangerous product: raw milk, the National Milk Producers Federation (NMPF) said today, as it urged the Food and Drug Administration (FDA) not to waver in the face of pressure tactics from raw milk supporters.

Those supporters were out in force today at the FDA headquarters in Silver Spring, Maryland, urging FDA Commissioner Margaret Hamburg to cease federal efforts to ban the trafficking in raw milk sales across state lines. Current FDA law prohibits the interstate sales of raw milk, although the majority of states allow some form of in-state sales and/or distribution of raw milk.

Raw milk supporters have increased their criticism of the FDA interstate sales restriction "in spite of the clear and compelling documentation that raw milk is a proven means of transmitting serious human pathogens, including *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*, and *Salmonella,*" said NMPF President and CEO Jerry Kozak. "We hope that Commissioner Hamburg looks at the evidence, and doesn't just listen to the noise from those who would weaken public health protections."

While raw milk advocates have made numerous statements touting the benefits of consuming raw milk, these claims mislead consumers and have not been supported by science-based studies, Kozak said.

"Raw milk consumption is inherently dangerous because the product can contain pathogens that are capable of causing foodborne illness," Kozak said. "Pasteurization is one of the most effective food safety tools developed and, when properly conducted, is the only way to ensure that milk is free from disease-causing microorganisms."

-more-

Kozak said it is particularly concerning that a key constituency in the raw milk movement includes mothers who wish to purchase the product to feed to their children. He noted that more than three-quarters of foodborne illness outbreaks associated with raw milk or milk products involve a child.

"Kids are particularly vulnerable to the diseases caused by the pathogens that may be consumed with raw milk. There are numerous cases where long-term illnesses have resulted from the ingestion of raw milk," Kozak said. "The FDA needs to stand on the side of protecting public health, especially the health of minors whose parents may not fully grasp the potential consequences of the hazards they are exposing their kids to."

"Many diseases are not preventable, but where there is a clear and effective prevention against milk-transmitted foodborne illness, why would we allow the myths and untruths to remove that protection?," Kozak asked.

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix N

Appendix N

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People. Saving Money through Prevention.

# Press Release

For Immediate Release: February 21, 2012
Contact :CDC Division of News and Electronic Media (http://www.cdc.gov/media)
(404) 639-3286

## Majority of dairy-related disease outbreaks linked to raw milk

*CDC Report Shows Higher Rates of "Raw" Milk Outbreaks in States Where It's Legal*

The rate of outbreaks caused by unpasteurized milk (often called raw milk) and products made from it was 150 times greater than outbreaks linked to pasteurized milk, according to a study by the Centers for Disease Control and Prevention. The 13-year review also revealed that the states where the sale of raw milk was legal had more than twice the rate of outbreaks as states where it was illegal.

The study, published Feb. 21 in the CDC journal Emerging Infectious Diseases (http://wwwnc.cdc.gov/eid/), reviewed dairy product outbreaks from 1993 to 2006 in all 50 states. The authors compared the amount of milk produced in the United States during the study period (about 2.7 trillion pounds) to the amount that CDC estimates was likely consumed raw (1 percent or 27 billion pounds) to determine the 150 times higher rate for outbreaks caused by raw milk products. Raw milk products include cheese and yogurt.

The study included 121 dairy–related disease outbreaks, which caused 4,413 illnesses, 239 hospitalizations and three deaths. In 60 percent of the outbreaks (73 outbreaks) state health officials determined raw milk products were the cause. Nearly all of the hospitalizations (200 of 239) were in those sickened in the raw milk outbreaks. These dairy-related outbreaks occurred in 30 states, and 75 percent (55 outbreaks) of the raw milk outbreaks occurred in the 21 states where it was legal to sell raw milk products at the time. The study also reported that seven states changed their laws during the study period.

Consumers can't tell if raw milk is safe to drink by looking at, smelling, or tasting it. Even under ideal conditions of cleanliness, collecting milk introduces some bacteria. Unless the milk is pasteurized, these bacteria can multiply and grow in the milk and cause illness. Pasteurization involves heating milk to kill disease-causing bacteria.

"This study shows an association between state laws and the number of outbreaks and illnesses from raw milk products," said Robert Tauxe, M.D., M.P.H., deputy director of CDC's Division of Foodborne, Waterborne and Environmental Diseases (DFWED) (http://www.cdc.gov/media/subtopic/sme/tauxe.html). "Restricting the sale of raw milk products is likely to reduce the number of outbreaks and can help keep people healthier. The states that allow sale of raw milk will probably continue to see outbreaks in the future."

The study also found that the raw milk product outbreaks led to much more severe illnesses, and disproportionately affected people under age 20. In the raw milk outbreaks with known age breakdowns, 60 percent of patients were younger than age 20, compared to 23 percent in outbreaks from pasteurized products. Children are more likely than adults to get seriously ill from the bacteria in raw milk.

"While some people think that raw milk has more health benefits than pasteurized milk, this study shows that raw milk has great risks, especially for children, who experience more severe illnesses if they get sick," said study co-author Barbara Mahon, M.D., M.P.H., deputy chief of CDC's DFWED Enteric Diseases Epidemiology Branch. "Parents who have lived through the experience (http://www.cdc.gov/foodsafety/rawmilk/raw-milk-videos.html) of watching their child fight for their life after drinking raw milk now say that it's just not worth the risk." Among other key findings:

- Thirteen percent of patients in raw milk outbreaks were hospitalized compared to 1 percent in pasteurized milk outbreaks. This may be because raw milk outbreaks were all caused by bacteria, such as E. coli O157, which tend to produce more severe illnesses, according to the study.
- Pasteurized milk and cheese outbreaks were often caused by relatively mild infections like norovirus and Staphylococcus aureus.

To view the study, please visit www.cdc.gov/eid (http://www.cdc.gov/eid) . For more information about raw milk, visit http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html (http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html) .

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (http://www.hhs.gov/)

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Historical Document: February 21, 2012
Content source: Office of the Associate Director for Communication, Division of News and Electronic Media
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# Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993–2006

**Adam J. Langer, Tracy Ayers, Julian Grass, Michael Lynch, Frederick J. Angulo, and Barbara E. Mahon**

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**Release date: February 21, 2012; Expiration date: February 21, 2013**

**Learning Objectives**

Upon completion of this activity, participants will be able to:

- Evaluate the epidemiology of foodborne illness related to the consumption of dairy products
- Analyze the clinical presentation and outcomes of foodborne disease related to the consumption of dairy products
- Distinguish the organism most commonly associated with foodborne illness after consumption of unpasteurized dairy products
- Assess sources of contamination of pasteurized dairy products

**Editor**

**P. Lynne Stockton, VMD, MS, ELS(D),** Technical Writer/Editor, *Emerging Infectious Diseases. Disclosure: P. Lynne Stockton, VMD, MS, ELS(D), has disclosed no relevant financial relationships.*

**CME Author**

**Charles P. Vega, MD,** Health Sciences Clinical Professor; Residency Director, Department of Family Medicine, University of California, Irvine. *Disclosure: Charles P. Vega, MD, has disclosed no relevant financial relationships.*

**Authors**

*Disclosures:* ***Adam J. Langer, DVM, MPH; Tracy Ayers, MS; Julian Grass, MPH; Michael Lynch MPH, MD; Frederick J. Angulo, DVM, PhD;*** *and* ***Barbara E. Mahon, MD, MPH,*** *have disclosed no relevant financial relationships.*

Although pasteurization eliminates pathogens and consumption of nonpasteurized dairy products is uncommon, dairy-associated disease outbreaks continue to occur. To determine the association of outbreaks caused by nonpasteurized dairy products with state laws regarding sale of these products, we reviewed dairy-associated outbreaks during 1993–2006. We found 121 outbreaks for which the product's pasteurization status was known; among these, 73 (60%) involved nonpasteurized products and resulted in 1,571 cases, 202 hospitalizations, and 2 deaths. A total of 55 (75%) outbreaks occurred in 21 states that permitted sale of nonpasteurized products; incidence of nonpasteurized product–associated outbreaks was higher in these states. Nonpasteurized products caused a disproportionate number (≈150× greater/unit of product consumed) of outbreaks and outbreak-associated illnesses and also disproportionately affected persons <20 years of age. States that restricted sale of nonpasteurized products had fewer outbreaks and illnesses; stronger restrictions and enforcement should be considered.

Author affiliation: Centers for Disease Control and Prevention, Atlanta, Georgia, USA

DOI: http://dx.doi.org/10.3201/eid1803.111370

In the United States, milk and other dairy products are dietary staples; the 2010 Dietary Guidelines for Americans recommend that most Americans include dairy products in their diet (*1*). However, numerous pathogens can contaminate dairy products and cause illness and death. Milkborne infections were relatively common before the advent of pasteurization in the late 19th century (*2*), and in the United States today, illness related to consumption of nonpasteurized dairy products remains a public health problem.

In 1948, Michigan enacted the first statewide requirement that dairy products be pasteurized, and many other states soon did the same (*2*). In 1987, the United States Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers (*3*). However, sale of nonpasteurized dairy products within the state where they are produced is regulated by each state, and some states permit sale of these products. Despite the federal ban on the sale of nonpasteurized products in interstate commerce, the broad use of pasteurization by the dairy industry, and the infrequency with which nonpasteurized dairy products are consumed, illnesses and outbreaks associated with consumption of these products continue to occur (*4–23*).

State and local health departments report foodborne disease outbreaks to the Centers for Disease Control and Prevention (CDC) through the Foodborne Disease Outbreak Surveillance System. As a result of efforts to enhance outbreak surveillance starting in 1998, the total number of outbreak reports increased substantially (*24*). A recent comprehensive analysis of foodborne disease outbreaks associated with dairy products (dairy-associated outbreaks) reported to CDC reviewed outbreaks that occurred during 1973–1992 (*4*). We reviewed subsequent dairy-associated outbreaks, reported in the United States during 1993–2006. We characterized the outbreaks and examined their association with state laws regarding sale of nonpasteurized dairy products.

## Methods

To compare the incidence of foodborne outbreaks involving nonpasteurized dairy products among states with differing laws with regard to the sale of these products (i.e., states that permitted their sale vs. states that prohibited their sale), we reviewed reports of foodborne disease outbreaks involving dairy products reported to CDC during 1993–2006. These reports, completed by state and local health departments, typically included the number of cases associated with the outbreak; the age and sex distribution of outbreak-associated case-patients; the number of hospitalizations and deaths; the etiologic agent associated with the outbreak; the type of dairy product implicated (e.g., fluid milk, cheese); and whether the implicated dairy product was marketed, labeled, or otherwise presented to the consumer as pasteurized or nonpasteurized. Hereafter, we refer to these products as pasteurized or nonpasteurized. Thus, any outbreak involving a dairy product that was contaminated after pasteurization or that was intended to be pasteurized but underwent inadequate pasteurization was classified as involving pasteurized product. When possible, we corrected missing or incomplete data by asking the health department that conducted the investigation for more information.

To determine whether the sale of nonpasteurized dairy products was legal at the time of each outbreak, we contacted the 50 state departments of health and agriculture and requested data on whether the state permitted the sale of nonpasteurized dairy products produced in that state for each year from 1993 through 2006. We defined an illegal state-year as a year in which a state prohibited the sale of all nonpasteurized products, and we defined a legal state-year as a year in which a state permitted the sale of nonpasteurized dairy products produced in that state. Data on the estimated population, by state, for each year were obtained from the US Census Bureau. To compare the incidence of outbreak and outbreak-associated cases during illegal state-years to that during legal state-years, we stratified the outbreaks by legal status of the state in which the outbreak occurred at the time of the outbreak and calculated incidence density ratios for reported outbreaks (Poisson model) and for outbreak-associated cases (zero-inflated negative binomial model).

## Results

During 1993–2006, a total of 30 states reported 122 foodborne disease outbreaks caused by contaminated dairy products. Dairy-associated outbreaks occurred in all years except 1996, and outbreaks involving nonpasteurized dairy products occurred in all years except 1994 and 1996. The number of reported dairy-associated outbreaks increased in 1998 after surveillance for foodborne disease outbreaks was enhanced (Figure 1).

Whether the product was pasteurized or nonpasteurized was known for 121 of the 122 outbreaks, and most outbreaks (73 [60%]) involved nonpasteurized dairy products. Of the 121 outbreaks for which product pasteurization status was known, 65 (54%) involved cheese and 56 (46%) involved fluid milk. Of the 65 outbreaks involving cheese, 27 (42%) involved cheese made from nonpasteurized milk. Of the 56 outbreaks involving fluid milk, an even higher percentage (82%) involved nonpasteurized milk.

The 121 outbreaks involving dairy products for which pasteurization status was known resulted in 4,413 reported illnesses. Among these illnesses, 1,571 (36%) resulted from nonpasteurized dairy products. The median number of persons reported ill during outbreaks involving

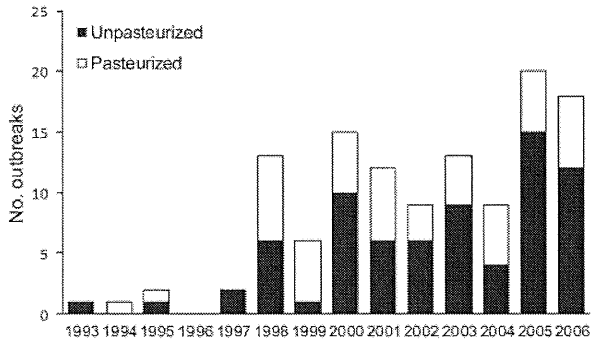


Figure 1. Number of dairy product–associated outbreaks, by year and pasteurization status of product, United States, 1993–2006.

nonpasteurized dairy products was 11 (range 2–202). Outbreaks involving nonpasteurized dairy products resulted in 202 hospitalizations (hospitalization rate 13%). In contrast, outbreaks involving pasteurized dairy products resulted in 37 hospitalizations (hospitalization rate 1%). Two deaths were associated with an outbreak caused by consuming nonpasteurized dairy products, and 1 death was associated with an outbreak caused by a pasteurized product (Table).

Ill persons in outbreaks involving nonpasteurized dairy products were generally younger than those in outbreaks involving pasteurized dairy products. For the 60 outbreaks involving nonpasteurized dairy products for which age of patients was known, 60% of patients were <20 years of age; for the 37 outbreaks involving pasteurized dairy products for which age of patients was known, 23% of patients were <20 years of age ($p<0.001$).

The causative agent was identified for all 73 outbreaks involving nonpasteurized dairy products; all were caused by bacteria. One outbreak was caused by *Campylobacter* spp. and Shiga toxin–producing *Escherichia coli*. Among the remaining 72 outbreaks, 39 (54%) were caused by *Campylobacter* spp., 16 (22%) by *Salmonella* spp., 9 (13%) by Shiga toxin–producing *E. coli*, 3 (4%) by *Brucella* spp., 3 (4%) by *Listeria* spp., and 2 (3%) by *Shigella* spp. Among the 30 outbreaks involving pasteurized dairy products for which the causative agent was reported, 13 (44%) were caused by norovirus, 6 (20%) by *Salmonella* spp., 4 (13%) by *Campylobacter* spp., 3 (10%) by *Staphylococcus aureus*, and 1 (3%) each by *Clostridium perfringens*, *Bacillus cereus*, *Listeria* spp., and *Shigella* spp.

A total of 48 reported outbreaks involved pasteurized dairy products. The source of contamination was reported for 7 (14%) of these outbreaks, of which at least 4 (57%) probably resulted from post-pasteurization contamination by an infected food handler. Failure of the consumer to store the dairy product at an appropriate temperature probably contributed to 3 other outbreaks. Such temperature abuse can enable pathogens (present because they either survived pasteurization in low numbers or were introduced after pasteurization) to multiply to concentrations capable of causing illness.

During the study period, 43 (86%) states did not change their legal status regarding the sale of nonpasteurized dairy products produced in that state. Among these 43 states, selling nonpasteurized dairy products produced in that state was legal in 21 (49%). Of the 7 states that changed their legal status, 3 changed from legal to illegal (Mississippi in 2005, Ohio in 2003, and Wisconsin in 2005), 3 changed from illegal to legal (Arkansas in 2005, Illinois in 2005, and Nevada in 2005), and 1 (Oregon) changed from legal to illegal in 1999 and then back to legal in 2005 (Figure 2).

Among the 700 state-years (14 years × 50 states) included in our analysis of the association of legal sales status and nonpasteurized dairy–associated outbreaks, sale of nonpasteurized dairy products produced in the state was legal for 342 state-years and illegal for 358 state-years. We excluded from analysis 2 outbreaks caused by nonpasteurized dairy products because each occurred in multiple states with differing laws. Of the 71 remaining outbreaks involving nonpasteurized dairy products, 55 (77%) occurred in states where sale of nonpasteurized dairy products produced in that state was legal. Among these 71 outbreaks involving nonpasteurized dairy products, 1,526 persons became ill and 1,112 (73%) of these illnesses occurred in states where it was legal to sell nonpasteurized dairy products. Also among these 71 outbreaks involving nonpasteurized dairy products, 15 occurred in states where sale of nonpasteurized dairy

Table. Characteristics of disease outbreaks after consumption of dairy products, United States, 1993–2006

| Product | Outbreak characteristic, no. | | | |
|---|---|---|---|---|
| | Total | Associated illnesses | Associated hospitalizations | Associated deaths |
| Nonpasteurized | | | | |
| Fluid milk | 46 | 930 | 71 | 0 |
| Cheese | 27 | 641 | 131 | 2 |
| Total | 73 | 1,571 | 202 | 2 |
| Pasteurized | | | | |
| Fluid milk | 10 | 2,098 | 20 | 0 |
| Cheese | 38 | 744 | 17 | 1 |
| Total | 48 | 2,842 | 37 | 1 |
| All dairy | 121 | 4,413 | 239 | 3 |

products was illegal. The source of the nonpasteurized dairy products was reported for 9 of these outbreaks: 7 (78%) were associated with nonpasteurized dairy products obtained directly from the producing dairy farm, 1 was associated with nonpasteurized dairy products obtained under a communal program to purchase shares in dairy cows (i.e., cow shares, a scheme used to circumvent state restrictions on commercial sales of nonpasteurized dairy products) (*11*), and 1 was limited to members of a large extended family who consumed nonpasteurized milk from their own cow.

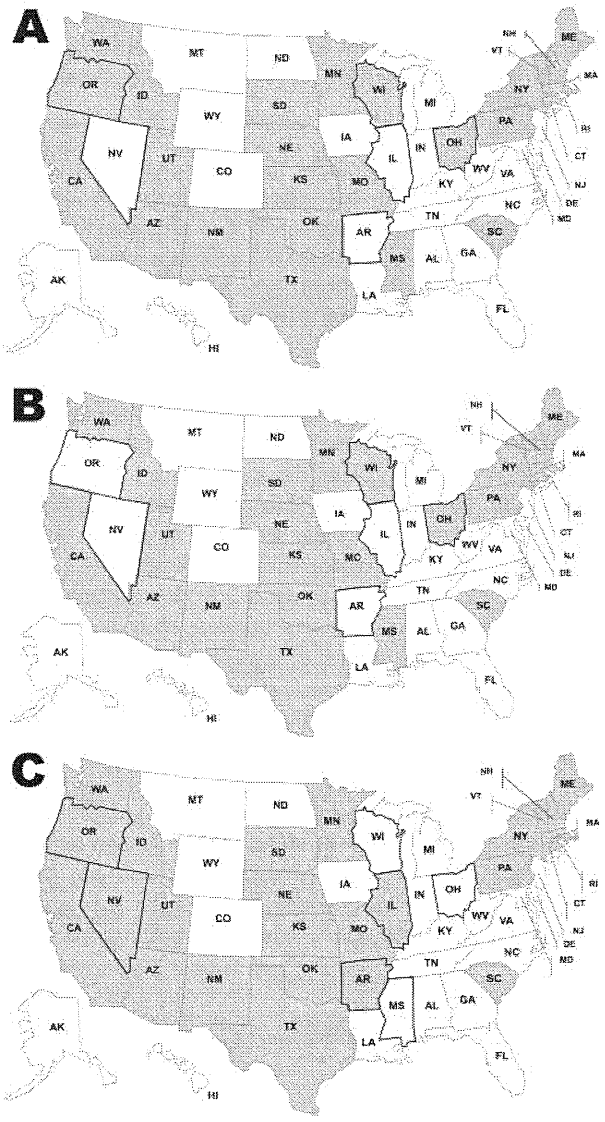


Figure 2. Legal status of nonpasteurized dairy product sale or distribution, by state, United States, for A) 1993, B) 1999, and C) 2006. Gray shading indicates states where nonpasteurized dairy product sale or distribution was permitted. States outlined in black changed legal status during the study period.

Incidence density ratios (IDRs) for nonpasteurized product–associated outbreaks and outbreak-associated cases during legal and illegal state-years varied by the type of dairy product (milk or cheese) and are reported separately. In states where it was legal to sell nonpasteurized dairy products, the rate of outbreaks caused by nonpasteurized fluid milk was >2× as high as in states where it was illegal to sell nonpasteurized dairy products (IDR 2.20, 95% CI 1.14–4.25). The rate of outbreak-associated illnesses caused by nonpasteurized fluid milk was 15% higher in states where it was legal to sell nonpasteurized dairy products, but this result was not statistically significant (IDR 1.15, 95% CI 0.24–5.54). States where it was legal to sell nonpasteurized dairy products had nearly 6× the rate of outbreaks caused by cheese made from nonpasteurized milk (IDR 5.70, 95% CI 1.71–19.05) and nearly 6× the rate of outbreak-associated illnesses (IDR 5.77, 95% CI 0.59–56.31), although the IDR for outbreak-associated illnesses was not statistically significant.

## Discussion

Incidence of outbreaks caused by nonpasteurized dairy products was higher in states that permitted the sale of nonpasteurized dairy products than in states that prohibited such sale. This association was evident for nonpasteurized fluid milk and cheese made from nonpasteurized milk. Although this association did not extend to the rates of outbreak-associated cases, factors other than whether it was legal to sell nonpasteurized dairy products probably affect the number of cases that occur in an outbreak. These factors include the volume and area of distribution of the contaminated product, the pathogen involved, the underlying health status of the exposed persons, and the ability of the responding public health agency to swiftly intervene to terminate the outbreak.

Because consumption of nonpasteurized dairy products is uncommon in the United States, the high incidence of outbreaks and outbreak-associated illness involving nonpasteurized dairy products is remarkable and greatly disproportionate to the incidence involving dairy products that were marketed, labeled, or otherwise presented as pasteurized. In a population-based survey conducted in 1996–1997, only 1.5% of respondents reported having consumed nonpasteurized dairy products in the 7 days before being interviewed; and in the 2003–2004 and 2005–2006 National Health and Nutrition Examination Surveys, only <1% of respondents who drank milk reported that they usually drank nonpasteurized milk (*21,25,26*). Because many of these respondents also reported consuming pasteurized dairy products, the proportion of dairy products consumed nonpasteurized by volume or weight is probably <1%. To illustrate this point, it is useful if we provide a hypothetical weighting of the findings in this study by the

amount of nonpasteurized and pasteurized dairy products consumed. Total milk production in the United States in 2010 was estimated at 193 billion pounds, suggesting that ≈2.7 trillion pounds of milk were consumed during the 14 years from 1993 through 2006 (*27*). If 1% of dairy products were consumed nonpasteurized, then during these 14 years, 73 outbreaks were caused by the 27 billion pounds of nonpasteurized dairy products that were consumed and 48 by the 2,673 billion pounds of pasteurized products that were consumed. Therefore, the incidence of reported outbreaks involving nonpasteurized dairy products was ≈150× greater, per unit of dairy product consumed, than the incidence involving pasteurized products. If, as is probably more likely, <1% of dairy products are consumed nonpasteurized, then the relative risk per unit of nonpasteurized dairy product consumed would be even higher.

After 1998, when surveillance for foodborne outbreaks was enhanced, the number of reported foodborne disease outbreaks caused by dairy products increased, as did the total number of reported foodborne outbreaks. Outbreaks involving nonpasteurized dairy products were all associated with bacterial enteric pathogens, most of which have known animal reservoirs. In contrast, among outbreaks in which a pasteurized dairy product was implicated, the most commonly reported causative agent was norovirus (44% of outbreaks), a pathogen with a human reservoir. These results suggest that outbreaks caused by nonpasteurized dairy products are probably caused by pathogens in the dairy environment, which would be eliminated by proper pasteurization, and that outbreaks caused by pasteurized dairy products are probably caused by contamination of the products at some point after pasteurization.

The objective of pasteurization is to eliminate from fluid milk those pathogens that originate in the dairy environment; however, pasteurization does not protect against contamination that might occur later, such as during food handling. In addition, if pasteurization is not performed properly (for appropriate times and at appropriate temperatures), pathogens might not be eliminated from the milk. Appropriate post-pasteurization food-handling practices can minimize the risk for reintroduction of pathogens into dairy products after pasteurization. In addition, other precautions, such as maintaining the dairy product at an appropriate temperature and disposing of expired products, reduce the risk to the consumer should the product become contaminated after pasteurization. When outbreaks do occur because of contamination of dairy products that are marketed as pasteurized, the source of contamination is typically traced to improper pasteurization, improper storage, or improper handling of the products after marketing (*28–30*). In our study, all outbreaks associated with pasteurized products for which information on the source of contamination was available were attributed to post-pasteurization mishandling.

Among outbreak-associated cases involving nonpasteurized dairy products, 60% involved persons <20 years of age. Public health and regulatory authorities are obligated to protect persons who cannot make fully informed decisions (e.g., children) from potential health hazards. Dietary decisions for younger children, in particular, are often made by caregivers. The American Academy of Pediatrics advises against giving nonpasteurized dairy products to children and recommends that pediatricians counsel caregivers against use of these products (*31*).

Proportionately more persons were hospitalized during outbreaks caused by nonpasteurized (13%) than by pasteurized dairy products (1%). This observation suggests that infections associated with nonpasteurized dairy products might be more severe, and it is consistent with the more frequent identification of bacterial, rather than viral or toxic, causative agents and with the larger proportion of illnesses affecting children.

Limitations of this analysis are primarily associated with the nature of the CDC Foodborne Disease Outbreak Surveillance System. Outbreak reporting by state and local health departments is voluntary, and outbreak reports are not always complete. For this analysis, we obtained missing data whenever possible by contacting the reporting state health department. In addition, the CDC outbreak surveillance database is dynamic; reporting agencies can submit new reports and can change or delete previous reports at any time as new information becomes available. Therefore, the results of this analysis represent data available at 1 point in time and might differ from those published earlier or subsequently.

In summary, foodborne outbreaks involving dairy products continue to be a public health problem in the United States, and this problem is disproportionately attributable to nonpasteurized dairy products. Since the US Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers in 1987, all legal sale and distribution has occurred within states that permit the sale of nonpasteurized dairy products that originated in that state. How much illegal distribution in interstate commerce continues is unknown. The increased risk for outbreaks associated with legal intrastate sale of nonpasteurized dairy products demonstrated in this analysis can be weighed against the purported nutritional or other health benefits attributed to these products. Scientifically credible evidence for the health benefits of nonpasteurized dairy products beyond the benefits of those of otherwise equivalent pasteurized products is lacking (*32*). The risk for outbreaks resulting from cheese made from nonpasteurized milk in states where nonpasteurized

milk sale is legal may be higher for particular groups within those states. For example, in recent years, foodborne outbreaks involving nonpasteurized dairy products have been reported in association with traditional nonpasteurized products marketed to the growing Hispanic community in the United States (*5,33*).

Our analysis shows that legal intrastate sale of nonpasteurized dairy products is associated with a higher risk for dairy-related outbreaks and implies that restricting sale of nonpasteurized dairy products reduces the risk for dairy-related outbreaks within that state. Pasteurization is the most reliable and feasible way to render dairy products safe for consumption. Although warning labels and signs or government-issued permits are prudent where the sale of nonpasteurized dairy products is legal, they have not been shown to be effective and, given the results of this analysis, do not seem to reduce the incidence of outbreaks involving nonpasteurized dairy products to the degree that pasteurization does (*18*). Whether certain types of warnings or more explicit health advisories might be more effective than others is unknown. Public health officials at all levels should continue to develop innovative methods to educate consumers and caregivers about the dangers associated with nonpasteurized dairy products. State officials should consider further restricting or prohibiting the sale or distribution of nonpasteurized dairy products within their states. Federal and state regulators should continue to enforce existing regulations to prevent distribution of nonpasteurized dairy products to consumers. Consumption of nonpasteurized dairy products cannot be considered safe under any circumstances.

## Acknowledgments

We gratefully acknowledge Patricia Griffin and Casey Barton Behravesh for review of the manuscript and the state and local health departments that investigate and report enteric disease outbreaks to CDC.

Dr Langer was a CDC Preventive Medicine Fellow assigned to the Division of Foodborne, Bacterial, and Mycotic Diseases at the time of this study. He is now an epidemiologist with the CDC Division of Tuberculosis Elimination. His research interests include the investigation of infectious disease outbreaks and animal-to-human transmission of infectious agents.

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Address for correspondence: Adam J. Langer, Centers for Disease Control and Prevention, Mailstop E10, 1600 Clifton Road NE, Atlanta, GA 30333 USA; email: alanger@cdc.gov

Indiana State Board of Animal Health

Report on the Sale of Raw Milk

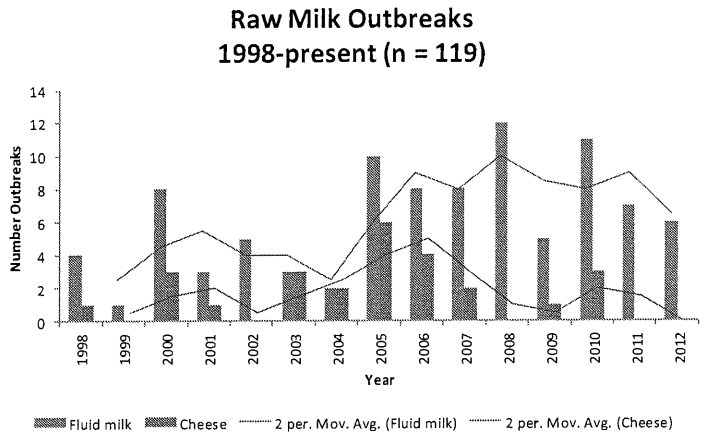
# Appendix O

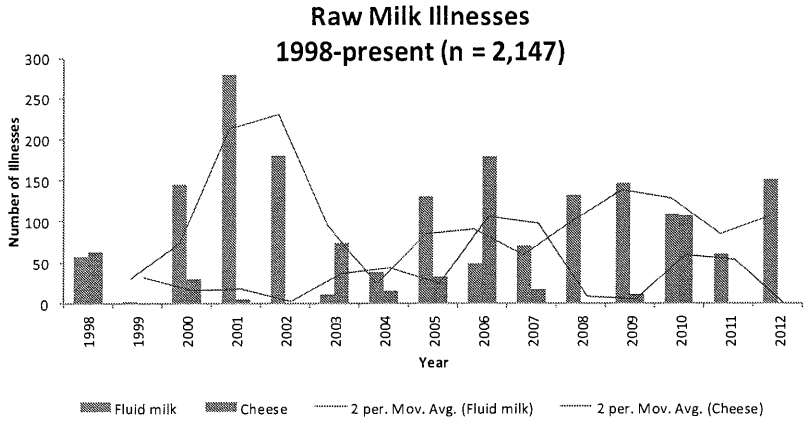
## Outbreaks from Foodborne Pathogens in Unpasteurized (Raw) Milk and Raw Milk Cheeses, United States 1998-present

These tables were compiled by the Real Raw Milk Facts working group through searches of the Centers for Disease Control and Prevention's (CDC) online foodborne disease outbreak database (1998-2009). Because the CDC database has about a two-year lag period, preliminary data was gathered from government and dairy industry press releases, reports, and newsletters to document recent outbreaks (2010-present). Information on farm type and size was taken from the implicated dairy's website, when available.

**SUMMARY**

- 119 total outbreaks
  - 86 fluid milk: 18 cow, 4 goat, 64 unspecified milk type
  - 27 cheese: 2 aged, 3 homemade, 17 Mexican-style queso fresco, 1 goat chevre, 1 curds, 3 unspecified
  - 6 multiple raw dairy products (fluid milk, cheese, and/or colostrum)
- 2,147 total illnesses, 2 deaths
  - 1,514 fluid milk-related illnesses, no deaths: 249 cow, 63 goat, 1,202 unspecified
  - 576 cheese-related illnesses: 46 aged, 80 homemade, 324 Mexican-style queso fresco (2 deaths), 5 goat chevre, 63 curds, 58 unspecified cheese type
  - 57 multiple raw dairy products-related illnesses (fluid milk, cheese, and/or colostrum)






Appendix O

**Table 1. 2010-2012 Data Extracted from Online News Releases and Reports.**

| Year | Month | State | Etiology | No. Ill | Source | Type of Farm | Comments/References |
|---|---|---|---|---|---|---|---|
| 2012 | Jan-Apr | CA | *Campylobacter* sp. | 10 | Raw cow milk, other raw dairy products | Organic Pastures Dairy; grassfed, pastured (~400 milking cows) | Retail (legal); CDFAa 2012 |
| 2012 | Apr | OR | *E. coli* O157:H7 (19 cases)<br>*Campylobacter* (1 case)<br>*Cryptosporidium* (1 case) | 21 | Raw cow milk | Foundation Farm, small 4 cow herdshare | Cowshare (OR law does not specify legality of herdshares); 4 children hospitalized with HUS; 4 children from the farm family sick; OHA 2012 |
| 2012 | Mar-Apr | MO | *E. coli* O157:H7 | 14 | Raw cow milk | Stroupe Farm in Howard County, central Missouri | Farm sales legal; 1 child hospitalized with HUS; MDHSS, 2012 |
| 2012 | Mar | CA | *Campylobacter jejuni* | 9 | Raw cow milk, other dairy products | Claravale Farm, San Benito County; Jersey herd | Retail (legal); CDFAb 2012 |
| 2012 | Jan-Feb | PA/MD/NJ/WV | *Campylobacter jejuni* | 80 | Raw cow milk | The Family Cow dairy in Chambersburg; ~200 milking cows | Retail (legal in PA); customers brought milk to other states; MDHMH 2012 |
| 2012 | Jan | KS | *Campylobacter jejuni* | 18 | Raw goat milk | Unnamed dairy in South Central Kansas | Farm sales (legal); KDA 2012 |
| 2011 | Aug-Nov | WA | *E. coli* O157:H7 | 3 | Raw cow milk | Cozy Vale Creamery and Farm, Tenino; pasture-based micro dairy | Retail sale (legal); WDOH 2011 |
| 2011 | Aug-Oct | CA | *E. coli* O157:H7 | 5 | Raw cow milk | Organic Pastures Dairy; grassfed, pastured (~400 milking cows) | Retail sale (legal); CDFA 2011 |

| Year | Month | State | Etiology | No. Ill | Source | Type of Farm | Comments/References |
|---|---|---|---|---|---|---|---|
| 2011 | Sep | NY | *Campylobacter* sp. | 5 | Raw cow milk | Willow Marsh Farm; all natural grassfed milk with no feed additives or horomones | Farm sale (legal); NYDOH 2011 |
| 2011 | Jul | NC | *Campylobacter* sp. | 8 | Raw cow milk | Tucker Adkins in York County, SC; ~60 milking cows | Retail sale (legal in SC), customers brought milk from SC to NC; FDA 2011 |
| 2011 | May-Jul | AK | *Campylobacter jejuni* | 18 | Raw cow milk | Byers Farm in Matnusk-Susitna (Mat-Su) Valley; ~150 cows | Herdshare (legal, unregulated); AKDOH 2011 |
| 2011 | Jun | WI | *Campylobacter jejuni* | 18 | Raw cow milk | Unnamed Racine County farm; ~250 cows; sells to processor | Parent brought milk to school; DATCP/DHS 2011 |
| 2011 | Jun | MI | *Coxiella burnetii* | 3 | Raw cow milk | Dairy Delight, Livingstone County, MI | Cowshare (legal, unregulated); FSN 2011 |
| 2010-2011 | | UT | *Salmonella* Newport | 62 | Raw milk Mexican style queso fresco cheese | Unnamed Wasatch County dairy | Illegal production and distribution of raw milk cheese by a West Valley man; as many as 2,100 may have been infected since 2009; FDA 2011 |
| 2010 | Dec | MN/OR/ VT/WA | *E. coli* O157:H7 | 8 | Aged raw milk cheese | Sally Jackson Cheeses; small, raw dairy with cows, sheep and goats | Retail sale (legal); FDA 2010 |
| 2010 | Nov | AZ/CA CO/NM/ NV | *E. coli* O157:H7 *Listeria monocytogenes* also found in the cheeses | 38 | Aged raw milk cheese | Bravo Farms Cheese Factory; medium-sized, hormone and antibiotic free dairy | Retail sale (legal); 15 hospitalized with 1 child with HUS; CDC 2010a |
| 2010 | Nov | TX | *Salmonella* sp. | 4 | Raw cow milk | Lavon Farms; medium sized (~200 cows) Guernsey and Jersey raw milk dairy | Farm store (legal); DCDOH 2010 |

| Year | Month | State | Etiology | No. Ill | Source | Type of Farm | Comments/References |
|---|---|---|---|---|---|---|---|
| 2010 | Oct | MN | *Campylobacter; Cryptosporidium* | 7 | Raw cow milk, dairy products | Hartmann Dairy Farm; no pesticides, herbicides, antibiotics or genetically modified grains fed to raw milk dairy cows | Farm sale (legal), farmer also sold through off-farm buyer's club (illegal); MDA/MDH 2010a |
| 2010 | Jun | CO | *Campylobacter jejuni; E.coli* O157:H7 | 30 | Raw goat milk | Billy Goat Dairy; small farm (~54 goats) | Hershare (legal); BCPH 2010 |
| 2010 | May | WA | *E. coli* O157:H7 | 2 | Raw cow milk | Jackie's Jerseys; small, local grassfed | Retail sale (legal); WDOH 2010a |
| 2010 | May | MN | *E. coli* O157:H7 | 8 | Raw cow milk, dairy products | Hartmann Dairy Farm; no pesticides, herbicides, antibiotics or genetically modified grains fed to raw milk dairy cows | Farm sale (legal), farmer also sold through off-farm buyer's club (illegal); MDA/MDH 2010b |
| 2010 | Apr | UT | *Salmonella* Newport | 10 | Raw cow milk | Redmond Heritage Farms; small pasture fed (no grain) | Farm and retail sale (legal); CDC 2010b |
| 2010 | Apr | UT | *Campylobacter* sp. | 15 | Raw cow milk | Ropelato Dairy; medium (~160 cows) raw milk dairy | Retail sale (legal); FSN 2010 |
| 2010 | Mar | PA | *Campylobacter* | 10 | Raw cow milk | Pasture Maid; small, local raw milk dairy | Retail sale (legal); PDA 2010 |
| 2010 | Feb | WA | Shiga toxin-producing *E. coli* | 6 | Raw cow Milk | Jackie's Jerseys; small, local grassfed | Farm and retail sale (legal); WDOH 2010b |
| 2010 | Feb | MI/IL/IN | *Campylobacter* sp. | 12 | Raw cow milk | Forest Grove Dairy; small (~75 Jerseys), grassfed raw milk dairy | Cowshare (legal, unregulated) and multi-state buyer's club (illegal interstate shipment); FDA 2010 |
| 2010 | Jan | NY | *Campylobacter* sp. | 5 | Raw milk | Willow Marsh Farm; small, local pasture based raw milk dairy | Farm store; NYDOH 2010 |
| | | | | | | | |

**Table 2. 1998-2009 data extracted from CDC's Foodborne Outbreak Online Database (FOOD).**

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 2009 | Sep | WA | *E. coli* O157:H7; O121 | 3 | 0 | Raw whole milk | |
| 2009 | Aug | WI | *Campylobacter jejuni* | 52 | 1 | Raw whole milk | |
| 2009 | May | PA | *Campylobacter jejuni* | 2 | 0 | Raw whole milk | |
| 2009 | Mar | UT | *Campylobacter jejuni* | 10 | 0 | Raw milk Mexican-style queso fresco cheese | |
| 2009 | Mar | CO | *Campylobacter jejuni* | 81 | 1 | Raw whole milk | Cowshare; CDPHE 2009 |
| 2009 | Jan | PA | *Campylobacter jejuni* | 9 | 1 | Raw whole milk | |
| 2008 | Nov | ND | *Campylobacter jejuni* | 3 | 0 | Raw milk | |
| 2008 | Aug | MN | *Campylobacter jejuni* | 2 | 2 | Raw milk | |
| 2008 | Aug | PA | *Campylobacter jejuni* | 65 | 1 | Raw milk | |
| 2008 | Aug | MN | *Campylobacter* sp. | 2 | 0 | Raw milk | |
| 2008 | Aug | VT | *E. coli* O157:H7 | 6 | 3 | Raw milk | |
| 2008 | Jun | CT | *E. coli* O157:NM (H-) | 14 | 5 | Raw milk | CTDPH 2008; Guh 2010 |
| 2008 | May | CA | *Campylobacter jejuni* | 16 | 1 | Raw milk | Cowshare |
| 2008 | Apr | MO | *E. coli* O157:H7 | 4 | 2 | Raw goat milk | MDHSS 2008 |
| 2008 | Apr | MA | *Campylobacter jejuni* | 8 | 0 | Raw milk | |
| 2008 | Apr | OH | *Campylobacter jejuni* | 3 | 1 | Raw milk | |
| 2008 | Apr | UT | *Campylobacter jejuni* | 4 | 0 | Raw milk | |
| 2008 | Mar | ID | *Campylobacter coli* | 5 | | Raw milk | |
| 2007 | Dec | WA | *Campylobacter jejuni* | 18 | 0 | Raw milk | |
| 2007 | Nov | CA | *Campylobacter jejuni* | 11 | 0 | Raw milk/colostrum | Retail sale; CDPH 2008a |
| 2007 | Oct | KS | *Campylobacter jejuni* | 16 | 0 | Raw milk and cheese | Donation to fair by local dairy; CDC 2009 |
| 2007 | Sep | PA | *Campylobacter jejuni* | 4 | 0 | Raw milk | |
| 2007 | Jul | GA | *Campylobacter jejuni* | 8 | 0 | Raw milk | |

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 2007 | Jun | PA | *Salmonella* Typhimurium | 13 | 1 | Raw milk cheese | On-farm sale; CDC 2007b |
| 2007 | Apr | SC | *Campylobacter jejuni; Salmonella* Give | 11 | 4 | Raw milk | |
| 2007 | Apr | NY | *Campylobacter* sp. | 2 | 1 | Raw milk | |
| 2007 | Mar | CA | *Brucella* sp. | 3 | 1 | Raw milk Mexican-style queso fresco cheese | |
| 2006 | Nov | ID | *E. coli* O157:H7 | 4 | 0 | Raw whole milk | |
| 2006 | Sep | CA | *E. coli* O157:H7 | 6 | 3 | Raw milk/colostrum | Retail sale; CDC 2008a |
| 2006 | Sep | CO | *Campylobacter* sp. | 5 | 4 | Raw whole milk | |
| 2006 | Sep | WA | *E. coli* O157:H7 | 2 | 1 | Raw whole milk | Retail sale; WDOH 2006 |
| 2006 | Aug | PA | *Salmonella* Typhimurium | 20 | 2 | Raw milk Mexican-style queso fresco cheese | |
| 2006 | Aug | KS | *Brucella* sp | 5 | 3 | Raw milk goat/chevre cheese | |
| 2006 | May | WI | *Campylobacter jejuni* | 58 | 2 | Homemade raw milk cheese | |
| 2006 | May | VA | *Campylobacter jejuni* | 9 | 0 | Raw milk | |
| 2006 | Mar | IL | *Salmonella* Meleagridis; Newport | 96 | 36 | Raw milk Mexican-style queso fresco cheese | CDC 2008 |
| 2006 | Feb | NY | *Campylobacter* sp. | 2 | 0 | Raw whole milk | |
| 2006 | Jan | IL | *Campylobacter jejuni* | 18 | 0 | Raw whole milk | |
| 2006 | Jan | OH | *Campylobacter* sp. | 3 | 1 | Raw whole milk | |
| 2005 | Dec | CO | *Campylobacter jejuni* | 22 | 0 | Raw whole milk | |
| 2005 | Nov | Multistate | *E. coli* O157:H7 | 18 | 5 | Raw whole milk | Cowshare; CDC 2007a; Denny 2008 |
| 2005 | Nov | CA | *Shigella* sp. | 2 | | Raw milk Mexican-style queso fresco cheese | |
| 2005 | Nov | CO | *Campylobacter jejuni* | 5 | 0 | Raw whole milk | Cowshare |
| 2005 | Sep | CA | *Salmonella* Group B | 12 | 2 | Raw milk Mexican-style queso fresco cheese | |

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 2005 | Sep | CA | *Salmonella* sp. | 2 | | Raw milk Mexican-style queso fresco cheese | |
| 2005 | Sep | CA | *Salmonella* Typhimurium | 3 | | Raw milk Mexican-style queso fresco cheese | |
| 2005 | Sep | UT | *Campylobacter jejuni* | 11 | 0 | Raw whole milk | |
| 2005 | Sep | AZ | *Campylobacter jejuni* | 13 | 1 | Raw whole milk | |
| 2005 | Jul | WY | *Campylobacter jejuni* | 11 | 2 | Raw whole milk | |
| 2005 | Jun | TX | *Listeria monocytogenes* | 12 | 12 | Raw milk Mexican-style queso fresco cheese | |
| 2005 | May | KS | *Campylobacter jejuni* | 4 | 0 | Raw whole milk | |
| 2005 | May | IA | *Campylobacter jejuni* | 33 | 0 | Raw whole milk | |
| 2005 | Apr | OK | *Campylobacter jejuni* | 11 | 3 | Raw goat milk | |
| 2005 | Mar | WY | *Campylobacter jejuni* | 3 | 0 | Raw milk | |
| 2005 | Feb | TX | *Brucella* sp. | 2 | 2 | Raw milk Mexican-style queso fresco cheese | |
| 2004 | Nov | CA | *Salmonella* Typhimurium | 12 | 1 | Raw milk Mexican-style queso fresco cheese | 1 death |
| 2004 | Jul | WY | *Campylobacter* sp. | 6 | 1 | Raw whole milk | |
| 2004 | May | WA | *E. coli* O157:H7 | 3 | 2 | Raw milk Mexican-style queso fresco cheese | Restaurant |
| 2004 | Feb | IA | *Campylobacter jejuni* | 32 | 0 | Raw whole milk | |
| 2003 | Oct | MI | *Campylobacter jejuni* | 6 | 0 | Raw milk | Church/temple |
| 2003 | Oct | CA | *Campylobacter jejuni* | 11 | 0 | Raw milk Mexican-style queso fresco cheese | |
| 2003 | Aug | CA | *Salmonella* Typhimurium | 50 | 7 | Raw milk Mexican-style queso fresco cheese | |
| 2003 | May | WA | *Campylobacter jejuni; E.coli* O157:H7 | 3 | 0 | Raw milk | |
| 2003 | Apr | VT | *Campylobacter jejuni* | 18 | 0 | Raw milk cheese | |
| 2003 | Mar | WI | *Campylobacter jejuni* | 2 | 0 | Raw milk | |

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 2003 | Feb | TX | *Listeria monocytogenes* | 12 | 12 | Raw milk Mexican-style queso fresco cheese | 1 death |
| 2002 | Nov | OH | *Salmonella* Typhimurium | 107 | 6 | Raw milk | Dairy-restaurant; CDC 2003; Mazurek 2004 |
| 2002 | Sep | CA | *Campylobacter* sp. | 12 | 0 | Raw milk | |
| 2002 | Apr | KS | *Campylobacter jejuni* | 46 | 1 | Raw milk | |
| 2002 | Jan | UT | *Campylobacter jejuni* | 13 | 0 | Raw whole milk | High school athletic team dinner; Peterson 2003 |
| 2002 | Jan | WA | *Campylobacter jejuni* | 2 | 0 | Raw whole milk | |
| 2001 | Nov | NC | *E. coli* O157:H7 | 202 | 11 | Raw milk | School |
| 2001 | Nov | WI | *Campylobacter jejuni* | 75 | 0 | Raw whole milk | Cowshare; CDC 2002 |
| 2001 | Jul | CA | *Brucella* sp | 4 | | Homemade raw milk cheese | |
| 2001 | Apr | Multistate | *Salmonella* Newport | 27 | 12 | Raw milk cheese | |
| 2001 | Mar | MN | *Campylobacter jejuni* | 4 | 0 | Raw whole milk | |
| 2000 | Sep | NY | *Campylobacter jejuni* | 39 | | Raw whole milk | Fair/festival |
| 2000 | Nov | NC | *Listeria monocytogenes* | 12 | | Raw milk Mexican-style queso fresco cheese | CDC 2001; MacDonald 2005 |
| 2000 | Jun | ID | *Campylobacter jejuni* | 42 | 1 | Raw milk | Camp |
| 2000 | Jun | OK | *Campylobacter jejuni* | 11 | 1 | Raw milk | |
| 2000 | Jun | MN | *Campylobacter* sp. | 8 | 1 | Raw milk | |
| 2000 | May | WI | *Campylobacter jejuni* | 19 | 0 | Raw milk | |
| 2000 | Apr | Multistate | *Campylobacter jejuni* | 18 | 0 | Homemade raw milk cheese | |
| 2000 | Feb | OK | *Campylobacter jejuni* | 21 | 2 | Raw milk | |
| 2000 | Feb | TX | *Campylobacter* sp. | 2 | | Raw milk | |
| 2000 | Feb | ID | *Campylobacter jejuni* | 4 | 0 | Raw whole milk | |
| 1999 | Jun | WA | Campylobacter sp. | 2 | | Raw milk | |
| 1998 | Oct | MA | *Salmonella* Typhimurium | 47 | 2 | Raw milk | |

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 1998 | Jul | NY | Campylobacter sp. | 3 | | Raw milk | |
| 1998 | Jul | SD | *Campylobacter jejuni* | 6 | 1 | Raw milk | |
| 1998 | Jul | ME | *E. coli* O157:H7 | 2 | 2 | Raw milk | |
| 1998 | Jun | WI | *E. coli* O157:H7 | 63 | 24 | Raw milk cheese curds | CDC 2000 |

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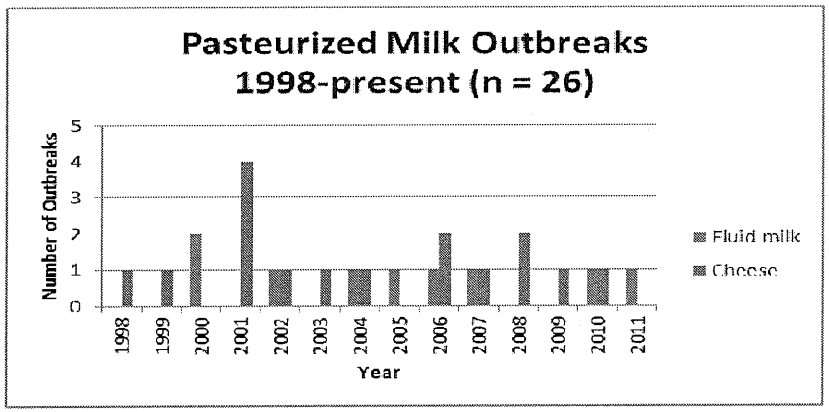
## Outbreaks from Foodborne Pathogens in Pasteurized Milk and Pasteurized Milk Cheeses, United States 1998-present

These tables were compiled by the Real Raw Milk Facts working group through searches of the Centers for Disease Control and Prevention's (CDC) online foodborne disease outbreak database (1998-2009). Because the CDC database has about a two-year lag period, preliminary data was gathered from government and dairy industry press releases, reports, and newsletters to document recent outbreaks (2010-present). Information on farm type and size was taken from the implicated dairy's website, when available.

**SUMMARY**

- 26 total outbreaks
  - 9 fluid milk
  - 16 cheese: 14 non-Mexican style; 2 Mexican style queso fresco
  - 1 powdered milk
- 2,786 total illnesses, 4 deaths
  - 2,200 fluid milk-related illnesses (3 deaths)
  - 550 cheese-related illnesses: 537 non-Mexican style (1 death), 13 Mexican style queso fresco
  - 36 powdered milk-related illnesses



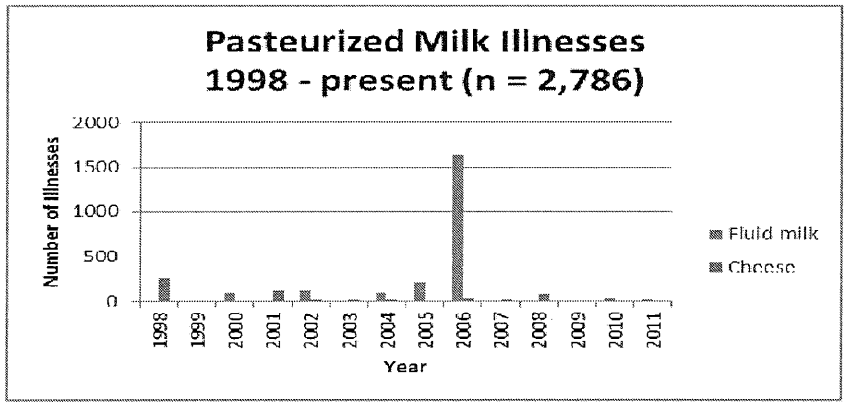



**Table 1. 2010-2012 Data Extracted from Online News Releases and Reports.**

| Year | Month | State | Etiology | No. Ill | Source | Type of Farm | Comments/References |
|---|---|---|---|---|---|---|---|
| 2011 | Mar-Aug | PA | *Yersinia enterocolitica* | 16 | Pasteur-ized cow milk | Brunton Dairy, small family farm (~100 cows); on-farm pasteurization, bottling and home delivery | Retail (legal); CDC 2011 |
| 2010 | Aug | OR | *Salmonella* Braenderup | 23 | Pasteur-ized cow milk and cream | Umpqua Dairy Farm in Roseburg, OR; outbreak resulted from external contamination of sealed containers, not the milk itself | Retail (legal); 2 hospitalizations; OHA 2010 |
| 2010 | Feb | WA | *Listeria monocytogenes* | 5 | Pateur-ized Mexican style queso fresco cheese | Queseria Bendita brand (unspecified milk source) | Retail (legal); FDA 2010 |

**Table 2. 1998-2009 data extracted from CDC's Foodborne Outbreak Online Database (FOOD).**

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 2009 | Nov | WA | *Listeria monocytogenes* | 2 | 2 | Cheese | |
| 2008 | Oct | Multistate | *Listeria monocytogenes* | 8 | 4 | Pasteurized Mexican style queso fresco cheese | |
| 2008 | Apr | NJ | *Salmonella* Java | 70 | 0 | Pasteurized cheddar cheese | |

| Year | Month | State | Etiology | No. Ill | No. hospit-alized | Source | Comments/references |
|---|---|---|---|---|---|---|---|
| 2007 | Aug | Multistate | *Salmonella* Montevideo | 20 | 9 | Pasteurized shredded cheese | |
| 2007 | Jun | MA | *Listeria monocytogenes* | 5 | 3 | Pasteurized milk | 3 deaths; local farm and processor, home delivery; CDC 2008 |
| 2006 | Dec | CT | Norovirus | 11 | 0 | Pasteurized swiss cheese | |
| 2006 | Aug | OR | *Listeria monocytogenes* | 3 | 2 | Pasteurized cheese | 1 death |
| 2006 | May | CA | *Campylobacter jejuni* | 1644 | 7 | Pasteurized milk | Prison/jail; milk not distributed to the public; Jay 2007 |
| 2006 | May | MI | *Staphylococcus aureus* | 36 | 0 | Powdered milk | Prison/jail; milk not distributed to the public |
| 2005 | Sep | CO | *Campylobacter jejuni* | 200 | 1 | Pasteurized 1% milk | Prison/jail; milk not distributed to the public; Haubert 2006 |
| 2004 | Dec | WA | Norovirus | 14 | 0 | Pasteurized cheese | Restaurant |
| 2004 | Jun | CA | *Salmonella* Newport | 100 | 5 | Pasteurized milk | |
| 2003 | Nov | CA | Norovirus | 13 | 0 | Pasteurized cheddar cheese | |
| 2002 | Aug | WY | *Salmonella* Typhimurium | 116 | 4 | Pasteurized 2% milk | School |
| 2002 | Apr | IN | Norovirus | 25 | 0 | Pasteurized cheese | Restaurant |
| 2001 | Dec | FL | Norovirus | 34 | 0 | Pasteurized cheese | Restaurant |
| 2001 | Aug | CT | *Salmonella* Newport | 4 | 1 | Pasteurized cheese | |
| 2001 | Apr | FL | *Staphylococcus aureus* | 3 | 0 | Pasteurized cheese | Restaurant |
| 2001 | Jan | OH | Norovirus | 73 | 0 | Pasteurized swiss cheese | |
| 2000 | Aug | PA | *Campylobacter jejuni* | 3 | 1 | Pasteurized milk | |
| 2000* | Mar-Apr | PA/NJ | *Salmonella* Typhimurium | 93 | 6 | Pasteurized milk | Olsen 2004 |
| 1999 | Jul | MN | Norovirus | 7 | 0 | Pasteurized cheese | |
| 1998 | Sep | MD | Norovirus | 258 | 4 | Pasteurized cheese | |

*not listed in FOOD.

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Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix P

**CDC Cherry Picks Data to Make Case Against Raw Milk - Weston A Price Foundation**

Written by Kimberly Hartke
Wednesday, February 22 2012 12:52 - Last Updated Thursday, February 23 2012 11:04

The Weston A. Price Foundation
For Immediate Release

Contact: Kimberly Hartke, Publicist
703-860-2711, 703-675-5557

# CDC CHERRY PICKS DATA TO MAKE CASE AGAINST RAW MILK

## Agency ignores data that shows dangers of pasteurized milk

Watch Harvard Raw Milk Debate

WASHINGTON, DC, February 22, 2012. In a press release issued yesterday, authors affiliated with the Centers for Disease Control claim that the rate of outbreaks caused by unpasteurized milk and products made from it was 150 times greater than outbreaks linked to pasteurized milk." The authors based this conclusion on an analysis of reports submitted to the CDC from 1993 to 2006.

According to the Weston A. Price Foundation, the CDC has manipulated and cherry picked this data to make raw milk look dangerous and to dismiss the same dangers associated with pasteurized milk.

"What consumers need to realize, first of all," said Sally Fallon Morell, president of the Weston A. Price Foundation, "is that the incidence of foodborne illnesses from dairy products, whether pasteurized or not, is extremely low. For the 14-year period that the authors examined, there was an average of 315 illnesses a year from all dairy products for which the pasteurization status was known. Of those, there was an average of 112 illnesses each year attributed to all raw dairy products and 203 associated with pasteurized dairy products.

"In comparison, there are almost 24,000 foodborne illnesses reported each year on average. Whether pasteurized or not, dairy products are simply not a high risk product."

Because the incidence of illness from dairy products is so low, the authors' choice of the time period for the study affected the results significantly, yet their decision to stop the analysis with the year 2006 was not explained. The CDC's data shows that there were significant outbreaks of foodborne illness linked to pasteurized dairy products the very next year, in 2007: 135 people became ill from pasteurized cheese contaminated with *e. coli*, and three people *died* from pasteurized milk contaminated with listeria (wwwn.cdc.gov/foodborneoutbreaks/Default.aspx).

Outbreaks from pasteurized dairy were also a significant problem in the 1980s. In 1985, there were over 16,000 confirmed cases of Salmonella infection that were traced back to pasteurized

milk from a single dairy. Surveys estimated that the actual number of people who became ill in that outbreak were over 168,000, "making this the largest outbreak of salmonellosis ever identified in the United States" at that time, according to an article in *the Journal of the American Medical Association.*

According to Fallon Morell "In the context of the very low numbers of illnesses attributed to dairy in general, the authors' decision to cut the time frame short, as compared to the available CDC data, is troubling and adds to questions about the bias in this publication."

According to Fallon Morell, the CDC's authors continue to obscure their study by failing to document the actual information they are using. They rely on reports, many of which are preliminary. Of the references related to dairy outbreaks, five are from outbreaks in other countries, several did not involve any illness, seven are about cheese-related incidents, and of the forty-six outbreaks they count, only five describe any investigations.

Perhaps most troubling is the authors' decision to focus on outbreaks rather than illnesses. An "outbreak" of foodborne illness can consist of two people with minor stomachaches to thousands of people with bloody diarrhea. In addressing the risk posed for individuals who consume a food, the logical data to examine is the number of illnesses, not the number of outbreaks.

"The authors acknowledge that the number of foodborne illnesses from raw dairy products (as opposed to outbreaks) were not significantly different in states where raw milk is legal to sell compared with states where it is illegal to sell," notes Judith McGeary of the Farm and Ranch Freedom Alliance. *"In other words, had the authors looked at actual risk of illness, instead of the artificially defined "outbreaks," there would have been no significant results to report."*

This does not end the list of flaws with the study, however. The link between the outbreaks and the legal status of raw dairy mixed an entire category of diverse products. Illnesses from suitcase style raw cheese or *queso fresco* were lumped together with illnesses attributed to fluid raw milk, a much less risky product. In the majority of states where the sale of raw fluid milk is allowed, the sale of *queso fresco* is still illegal. The authors had all of the data on which products were legal and which products allegedly caused the illnesses, yet chose not to use that data.

Similarly, to create the claimed numbers for how much riskier raw dairy products are, the authors relied on old data on raw milk consumption rates, rather than using the CDC's own food survey from 2006-2007. The newer data showed that about 3 percent of the population consumes raw milk—over nine million people--yet the authors chose instead to make conclusions based on the assumption that only 1 percent of the dairy products in the country are consumed raw.

The authors also ignored relevant data on the populations of each state. For example, the three most populous states in the country (California, Texas, and New York) all allow for legal sales of raw milk; the larger number of people in these states would logically lead to larger numbers of illnesses than in low-population states such as Montana and Wyoming and has nothing to do

with the fact that raw milk is illegal in those states.

"It would hardly be surprising to see some sort of increase in foodborne illnesses related to a food where that food is legal," said McGeary. "If we banned ground beef, we'd see fewer illnesses related to ground beef products. Yet this new study fails to prove even that common-sense proposition, even as it claims to prove a great deal more. What the data really shows is that raw dairy products cause very few illnesses each year, even though the CDC data indicates that over 9 million people consume it."

*The Weston A. Price Foundation is a 501C3 nutrition education foundation with the mission of disseminating accurate, science-based information on diet and health. Named after nutrition pioneer Weston A. Price, DDS, author of Nutrition and Physical Degeneration, the Washington, DC-based Foundation publishes a quarterly journal for its 13,000 members, supports 500 local chapters worldwide and hosts a yearly conference. The Foundation headquarters phone number is (202) 363-4394,* www.westonaprice.org, info@westonaprice.org.

Contact: Kimberly Hartke, Publicist, The Weston A. Price Foundation
press@westonaprice.org
703-860-2711, 703-675-5557

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Report on the Sale of Raw Milk

# Appendix Q

Appendix Q

# Raw or Undercooked Animal-Source Protein in Cat and Dog Diets

*(Approved by the AVMA Executive Board April 2012; approved by the AVMA House of Delegates July 2012)*

The AVMA discourages the feeding to cats and dogs of any animal-source protein that has not first been subjected to a process to eliminate pathogens because of the risk of illness to cats and dogs as well as humans. Cooking or pasteurization through the application of heat until the protein reaches an internal temperature adequate to destroy pathogenic organisms has been the traditional method used to eliminate pathogens in animal-source protein, although the AVMA recognizes that newer technologies and other methods such as irradiation are constantly being developed and implemented.

Animal-source proteins of concern include beef, pork, poultry, fish, and other meat from domesticated or wild animals as wel as milk* and eggs. Several studies[1–6] reported in peer-reviewed scientific journals have demonstrated that raw or undercooked animal-source protein may be contaminated with a variety of pathogenic organisms, including Salmonella spp, Campylobacter spp, Clostridium spp, Escherichia coli, Listeria monocytogenes, and enterotoxigenic Staphylococcus aureus. Cats and dogs may develop foodborne illness after being fed animal-source protein contaminated with these organisms if adequate steps are not taken to eliminate pathogens; secondary transmission of these pathogens to humans (eg, pet owners) has also been reported.[1,4] Cats and dogs can develop subclinical infections with these organisms but still pose a risk to livestock, other nonhuman animals, and humans, especially children, older persons, and immunocompromised individuals.

To mitigate public health risks associated with feeding inadequately treated animal- source protein to cats and dogs, the AVMA recommends the following:

- Avoid feeding inadequately treated animal-source protein to cats and dogs
- Restrict cats' and dogs' access to carrion and animal carcasses (eg, while hunting)
- Provide fresh, clean, nutritionally balanced and complete commercially prepared or home-cooked food to cats and dogs, and dispose of uneaten food at least daily
- Practice personal hygiene (eg, handwashing) before and after feeding cats and dogs, providing treats, cleaning pet dishes, and disposing of uneaten food

* The recommendation not to feed unpasteurized milk to animals does not preclude the feeding of unpasteurized same-species milk to unweaned juvenile animals.

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*Frequently Asked Questions About*

# Raw Pet Foods and the AVMA's Policy

*(August 28, 2012)*

In August 2012, the AVMA House of Delegates approved a new policy on raw or undercooked animal-source protein in dog and cat diets. Below are answers to the questions we've received about this issue.

**Q: What is the AVMA's policy on raw diets?**
**A:** The Raw or Undercooked Animal-Source Protein in Dog and Cat Diets policy, approved by the AVMA House of Delegates in August 2012, is available on our website..

**Q: Does the AVMA policy apply to all raw food fed to pets, or only a certain type?**
**A:** It only addresses raw or undercooked animal-source protein, which includes meat or products from chickens (including eggs), turkeys, cows, pigs, sheep, fish, deer, buffalo, or other animal sources. It also includes raw, unpasteurized eggs and milk. And more specifically, it addresses the need for eliminating pathogens from these diets if they are to be fed to pets.

**Q: How did the AVMA policy come about?**
**A:** The Delta Society (now Pet Partners) contacted our Animal Welfare Division and inquired as to whether or not the AVMA had a policy addressing raw feeding, primarily due to concerns about therapy animals being fed raw diets. At the time, we did not have a policy on the subject. Pet Partners did not request that AVMA develop a policy, and did not suggest a specific policy. The Animal Welfare Division staff contacted the AVMA Council on Public Health and Regulatory Veterinary Medicine (CPHRVM) and notified them of the inquiry. The CPHRVM discussed the matter and felt that the AVMA should have a science-based policy addressing the public health risks of raw food.

For a list of the scientific literature the CPHRVM reviewed when developing this policy, see the reference list.

**Q: Do other veterinary or public health groups have policies or statements about raw diets for pets?**
**A:** Yes. The U.S. Food and Drug Administration Center for Veterinary Medicine (FDA-CVM) makes the following statement on its website:

> *FDA does not believe raw meat foods for animals are consistent with the goal of protecting the public from significant health risks, particularly when such products are brought into the home*

*and/or used to feed domestic pets; however, we understand that some people prefer to feed these types of diets to their pets.*

The U.S. Centers for Disease Control and Prevention (CDC) make the following statement on their website:

> *Raw diets, especially raw meat diets, are not recommended because of the risk for salmonellosis and other infections that can affect pets and their owners.*

In addition, the CDC provided the following statement to the AVMA when the policy was being considered:

> *CDC recommends against feeding raw food to dogs and cats because of the risk of illness to the pet as well as to people living in the household.* ***Do not feed your pet a raw diet. Here is why:***
>
> - *Raw diets consist of foods such as meat, poultry, milk, and eggs that have not been cooked or treated to remove harmful germs.*
> - *These food items can carry harmful bacteria including Salmonella and Campylobacter.*

The American College of Veterinary Nutritionists (ACVN), in a FAQ document on its website, makes the following statement:

> *Raw diets, both home-prepared and commercial, have become more popular. Advocates of raw diets claim benefits ranging from improved longevity to superior oral or general health and even disease resolution (especially gastrointestinal disease). Often the benefits of providing natural enzymes and other substances that may be altered or destroyed by cooking are also cited. However, proof for these purported benefits is currently restricted to testimonials, and no published peer-reviewed studies exist to support claims made by raw diet advocates. No studies have examined differences in animals fed raw animal products to those fed any other type of diet (kibble, canned, or home cooked) with the exception of looking at the effects on digestibility. Typically raw meats (but not other uncooked foods like grains or starches) are slightly more digestible than cooked meat.*
>
> *There are risks and concerns associated with the feeding of raw diets. One of these is the risk of nutritional imbalances, which is a reality for both home-prepared and commercial raw meat diets. Another important risk is related to bacterial or parasitic contamination. Of course, food poisoning is also a major concern for people, and the public health aspects of feeding raw foods to pets cannot be overlooked. Safe and proper handling of raw foods is crucial for reducing the risk, but safety cannot be guaranteed. At this time, the vast majority of purported benefits of feeding raw foods remain unproven, while the risks and consequences have been documented. It is best to discuss the choice of feeding raw foods with your veterinarian so that an informed decision can be made with regard to your pet's diet.*

The American Animal Hospital Association (AAHA) approved a policy in August 2012 that discourages feeding raw meat to pets. The National Association of State Public Health Veterinarians (NASPHV) and American Association of Feline Practitioners (AAFP) both endorsed the AAHA statement. The policy was developed independently of the AVMA's position, but was shared with AVMA prior to posting on the website.

**Q: What influence did the pet food industry have on the AVMA's policy?**
**A:** None. Neither commercial nor raw diet manufacturers were contacted during development of this policy because it was based on public health risk, and not on nutritional comparisons, health benefits, or economic factors. None of the pet food companies were aware that a policy was being developed.

**Q: What is your response to allegations that the AVMA is "in the pockets" of the pet food industry?**
**A:** These allegations are false. We are a science-based organization, and this policy is based on scientific research. Veterinarians are pet owners too. We love our animals and have the experience and training to make educated decisions about what to feed our own pets. Veterinarians choose and recommend diets based on what is best for the animal – e.g., it is medically appropriate and nutritionally balanced to meet that pet's need. Many veterinarians feed commercial diets, and veterinarians are free to make their own choices when it comes to feeding their pets.

Contrary to the internet rumors that have been propagated, none of our Executive Board or House of Delegates members are employed by pet food companies. AVMA Convention Sponsorship provides financial support for programs and activities that are designed to enhance the attendees' overall experience through unique educational programs, networking events and entertainment options. AVMA Convention Sponsorship provides visibility and engagement with attendees for the sponsor, as well as an opportunity to support important educational initiatives. AVMA Convention attendees are invited to attend and participate in sponsored events without any obligation to promote, purchase or sell the sponsor's product or services.

The development of AVMA policy is independent of sponsorship. This is critically important to us because we are expected to be objective, science-based experts on animal health and welfare topics. Sponsorship is necessary to allow us to provide experiences for our members, but we do not allow sponsorships or sponsors to drive AVMA policy.

Veterinarians are independent thinkers, and are free to promote and sell the products they feel will serve their patients' and clients' needs. We encourage you to have an open discussion with your veterinarian about your pet's nutritional needs, and work with them to find the optimal diet for your pet.

**Q: Why does the policy only address raw protein diets, and not other foods?**
**A:** The Council on Public Health and Regulatory Veterinary Medicine (CPHRVM) felt that the science supported a policy that specifically addressed the public health risks associated with raw/undercooked animal-source protein that hasn't been adequately treated to remove pathogens. At a future meeting, the CPHRVM will discuss the pet food recalls and the hazards associated with commercial pet foods to see if a policy is needed. If the CPHRVM or another council or committee determines that other policies addressing pet foods are indicated, they will be developed separately.

Note that with this policy we aren't encouraging commercial diets, we're encouraging "commercially prepared or home-cooked food" (as stated in the policy). As long as it isn't raw or undercooked and doesn't contain pathogens, we're not concerned with what it is or where it came from. Regardless of what you feed your pet, the diet should be free of pathogens that can sicken you, your pet and your family. Just like you, we also want pets' diets to be nutritionally

balanced. We support the FDA's efforts to ensure that pet foods and treats of all types are safe and healthy for pets.

**Q: What are raw diets?**
**A:** Raw diets usually contain some or all of the following: muscle meat from animals (often still on the bone); bones (whole or ground); organ meats (e.g., liver, kidney); raw eggs; raw vegetables and/or fruit; and possibly some dairy products, such as unpasteurized yogurt or milk. As the name implies, the food is not cooked prior to feeding.

**Q: What are the benefits of raw diets, and how do they compare with commercially processed kibble diets?**
**A:** There are many anecdotal reports of benefits associated with feeding raw food – including easier weight management; reduced dental disease; healthier coat and skin; elimination of allergies; improved overall health and immunity; and more – but there is no scientific evidence to support these claims. Raw food advocates also contend that the diet more closely resembles what dogs' and cats' ancestors ate, but this does not account for the evolutionary, biological and dietary changes that have accompanied domestication to produce the pet dogs and cats that currently share our lives. According to the Pet Food Institute raw pet foods comprise approximately less than 1% of the pet food market.

Commercially processed canned or kibble foods are formulated to meet dogs' and cats' nutritional needs for proteins, fats, carbohydrates, vitamins and minerals. They are convenient, cost less than raw or homemade diets, and are readily available in most grocery stores, pet stores and "big box" stores. These pet foods comprise the majority of the pet food market. Commercial foods are nutritionally balanced and they undergo a process of quality control/ inspection that is meant to catch any contaminants or pathogens before they affect pets or people.

At this time, there are no scientific studies comparing the health benefits of raw and commercially prepared foods. The decision to feed one diet or another is a personal decision made by the pet owner.

**Q: What are the risks of raw diets, and how do they compare with commercially processed kibble diets?**
**A:** It's common knowledge that raw meat is likely to be contaminated with bacteria; it's not sterile by any means. Even USDA-inspected, "human grade" meat is not free of bacterial contamination. Some of the commonly-known pathogens that can be present in meat include *Salmonella*, *E. coli*, and *Campylobacter*. Other pathogens that may contaminate raw meat include *Toxoplasma gondii* (the parasite that causes toxoplasmosis), *Cryptosporidium*, *Echinococcus*, *Clostridium*, *Neospora and Sarcocystis*.[1-4] The same applies to raw meat fed to pets. If the raw food isn't adequately treated to eliminate pathogens, you could be feeding your pet potentially harmful pathogens that could cause illness in your pets and/or your family.

The biggest difference is that raw meat is cooked (which kills the bacteria) before it is fed to your family, but the meat is not cooked prior to being fed to a raw-fed pet. When you feed meat to your family, precautions should be taken to store, handle and prepare the meat in order to prevent foodborne illness. Therefore, your family's risk of infection with these bacteria is low when the

appropriate precautions are taken, but the risk of your pet being exposed to and infected with the bacteria is higher because the food isn't cooked to kill the bacteria.
Scientific studies have confirmed that pets fed raw diets contaminated with *Salmonella* can become *Salmonella* carriers; this means that they don't develop any illness, but the *Salmonella* bacteria are shed in the pet's feces (stool) and can contaminate the environment and potentially infect people with the bacteria. For example:

- *Salmonella* has caused illness in dogs fed raw diets.[5]
- *Salmonella* has been found in the stool of sled dogs and racing greyhounds fed raw diets.[6-8]
- An outbreak of *Salmonella* associated with raw feeding caused illness in 27 puppies from 8 litters at a Greyhound breeding facility. Ten of the affected puppies (37%) died. Salmonella was cultured from the raw diet and the environment. Salmonella was cultured from 57 of 61 (93%) stool samples.[9]
- *Salmonella* organisms were isolated from 8 of 10 samples (80%) of homemade raw diets. The bacteria were also found in the stool of 3 of 10 dogs fed homemade raw diets, but in none that were fed commercial diets. While 3/10 may seem like a low number, actual number infected may be significantly higher. It is well known that *Salmonella* is shed intermittently, therefore others may have been infected but not shedding at the time the stool samples were tested.[10]
- Five of 7 dogs shed *Salmonella* after consuming a raw diet, and the type of *Salmonella* was identical to that cultured from the raw food. Healthy dogs became infected with *Salmonella* after a single meal.[11]
- *Salmonella* was recovered from the stool of 6 of 42 dogs (14.3%) fed raw meat, versus 0 of 49 dogs that were not on raw meat diets.[12]
- *Salmonella* cultured from the gut and lungs of two cats that died from salmonellosis was identical to the *Salmonella* cultured from the raw diet they were fed.[13]

In a 1999 study,[14] indoor-only cats fed raw meat in addition to a home-cooked or commercial diet were significantly more likely (19.1% vs. 2.2%) to be positive for antibodies to *Toxoplasma gondii* (indicating exposure and infection); outdoor cats fed raw meat were almost twice as likely to test positive for antibodies to *T. gondii* (30.3% vs 18.4%) than those fed only home-cooked or commercial diets. Another study in 2008 determined that cats fed raw or undercooked viscera (organs) or meat were more than twice as likely (53.5% vs 22.9%) to be antibody-positive for *T. gondii*.[15]

In addition, some raw diets may not be nutritionally balanced for pets. This can result in deficiencies or imbalances, particularly of vitamins and minerals, that can be harmful.[16] This can be particularly problematic in puppies and kittens, because calcium/phosphorus imbalances can lead to bone deformities and growth problems. If you choose to feed raw foods, consult with a veterinarian or veterinary nutritionist to develop a diet that meets your pet's nutritional needs. The high protein levels in raw meat-based diets can be harmful to pets with liver or kidney disease.

Bones or bone fragments in some raw diets can result in intestinal obstruction or perforation, gastroenteritis and fractured teeth.[16]

*Salmonella* has been cultured from raw diets in several studies,[16-18] underscoring the need to adequately treat the diets to eliminate pathogens. In contrast, commercially prepared diets – kibble or canned – are considered adulterated and unfit for consumption if they test positive for bacteria. *Salmonella* infections have certainly been associated with commercially prepared kibble diets, but there have been no studies to determine the relative risks associated with raw vs. kibble diets. Keep

in mind that raw pet foods account for about 1% of the total pet food market, which makes accurate risk comparisons difficult.

**Q: Have cases of human illness been associated with raw food diets?**
**A:** To date, there have been no reports of human illness associated with raw food diets. This doesn't necessarily mean that they don't occur; it could mean that illnesses have occurred but the link to the pet's raw diet wasn't made. In addition, if the pet is eating the same food the humans are eating (but raw instead of cooked), tracing the origin back to the pet's raw food could be very difficult.

Keep in mind, too, that most cases of foodborne illness are never reported because they are usually mild and untreated. However, if someone from a high-risk group (very young, old, and/or immunocompromised) is exposed, the resulting illness is more severe and could even be fatal.

**Q: Have cases of human illness been associated with commercially processed kibble diets?**
**A:** Yes, there have been cases of human salmonellosis associated with commercially prepared diets.

- From 2006-2008, there was a multistate outbreak of *Salmonella enterica* serotype Schwarzengrund infections in humans. A total of 79 cases from 21 states were reported. The source of infection was identified as dry dog food produced at a manufacturing plant in Pennsylvania. This investigation was the first to identify contaminated dry dog food as a source of human *Salmonella* infections
- In spring 2012, an outbreak of *Salmonella* Infantis was traced to a Diamond Foods production facility in Gaston, SC. A total of 49 individuals (47 individuals in 20 states and two individuals in Canada) were infected with the outbreak strain. Seventeen brands representing >30,000 tons of dry dog and cat food produced at the facility were recalled as a result of the outbreak.

There have also been human illnesses associated with "natural" animal by-product pet treats, such as pig ears and dehydrated/dried beef and fish.

- In 1999, contaminated pig ear pet treats were confirmed as the source of an outbreak of human *S.* Infantis in several provinces in Canada.[19]
- In 2002, contaminated pet treats imported from Texas were associated with human *S.* Newport infections in Calgary, Alberta.[20]
- In 2004-2005, contact with *Salmonella*-contaminated pet treats of beef and seafood origin resulted in nine culture-confirmed human *Salmonella* Thompson infections in western Canada and the state of Washington. This was the first outbreak associated with pet treats in the United States.

**Q: Why haven't raw foods been recalled due to Salmonella or other bacteria?**
**A:** Bacteria are expected to be present in raw meat, so the presence of *Salmonella* or other bacteria in raw diets does not trigger the same regulatory process that applies to commercially made canned or kibble pet foods.

That said, we are aware of a recall of raw food. In May 2011, Primal Pet Foods recalled their Feline Chicken & Salmon formula due to contamination with *Salmonella*.

**Q: Why have processed diets been recalled due to *Salmonella* or other bacteria?**
**A:** With the exceptions of the recalls associated with the 2006-2008 and 2012 outbreaks, all other *Salmonella*-related recalls of commercially produced pet foods were associated with the detection of *Salmonella* on routine surveillance testing of products. In the majority of these recalls, no pet or human illnesses were reported.

Unlike with raw pet foods, the detection of *Salmonella* or other bacteria in a commercially processed pet food triggers a cascade of events at the state and federal level that lead to a voluntary recall by the pet food manufacturer. The pet food is considered adulterated and not fit for distribution or sale.

In October 2011, the FDA issued a Nationwide Assignment to Collect and Analyze Samples of Pet Foods, Pet Treats, and Supplements for Pets from Interstate Commerce in the United States for Salmonella. The objectives of the assignment are to 1) determine the prevalence of *Salmonella* in samples collected from a limited number of pet foods, pet treats, and supplements for pets; 2) determine the serotype, genetic fingerprint, and antimicrobial susceptibilities of each *Salmonella* found in samples collected from pet foods, pet treats, and supplements for pets under this assignment; 3) ensure that *Salmonella*-contaminated pet foods, pet treats, and supplements for pets are removed from interstate commerce; and, 4) collect investigational samples for research purposes and for providing surveillance information on microbes other than *Salmonella* in pet foods, pet treats, and supplements for pets.

A review of surveillance testing of samples collected from pet foods and pet treats demonstrated a significant reduction in *Salmonella* from 12.4% (2002) to 6.1% (2009). *Salmonella* prevalence in pet foods declined from 13.0% (2002) to 9.8% (2009).[21] These results certainly indicate progress, but additional progress is desired to eliminate pathogens in all pet food products.

**Q: If animals fed raw diets can shed *Salmonella* in their stool, why haven't there been reports of human illness associated with raw pet diets?**
**A:** Knowing that these pets can shed *Salmonella* in their stool, there's no denying the risk of infection if the food isn't adequately treated to eliminate pathogens. Individual cases of human illness are difficult to identify and trace back. Since salmonellosis is typically a foodborne illness and often does not require medical attention, physicians will most likely attribute the illness to the most recent foodborne outbreak. Therefore, they may not think to inquire about exposure to raw pet food or pets fed raw diets when initially investigating individual cases of illness, and the connection is missed. Furthermore, reports of human illness associated with anything, be it pet turtles or peanut butter, are only reported if they occur as part of an outbreak so that government authorities can trace the illness back to its source. With the exception of commercially produced raw diets, there is not a single consistent product to trace the illness back to in the event of an outbreak. Another compounding factor is that pet owners feeding raw may be taking additional precautions when handling the raw food, reducing their personal risk of illness (but that doesn't reduce the risk to others due to the shedding of bacteria in their pet's stool or other environmental contamination) .

It's also possible that the pet owners have developed some degree of immunity to infection with the bacteria; the potential for owners of raw-fed pets to be carriers of *Salmonella* has not, to our knowledge, been investigated.

**Q: Are there certain groups of people or pets that are more prone to the risks of infection associated with any type of food?**
**A:** Young children, elderly people, and immunocompromised individuals (chemotherapy, immune disease, etc.) are at higher risk of infection and illness if exposed to bacteria.
One of the important concerns that drove the development of this policy is the concern that therapy animals fed raw diets and taken into hospitals, nursing homes or other healthcare facilities could

serve as sources of infection to patients whose immune system may already be compromised by illness.

Pets that are more prone to risks of infection include those with cancer; pets receiving chemotherapy or other immunosuppressive therapies; very old or very young pets; and those with immune diseases.

**Q: Are raw pet food diets subject to different regulations than commercially processed kibble diets?**
**A:** Raw pet foods are produced with little to no regulatory oversight by the state or federal governments. The FDA publishes Guidance for Industry on the Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores, but the guidance is voluntary and not legally enforceable by the FDA. This guidance recommends that raw food producers adhere to many of the same regulations which processed food manufacturers are legally required to follow. We commend those raw food manufacturers who voluntarily adhere to these guidelines and have put controls in place to ensure that their products are free of pathogens. Commercially processed foods are subject to a number of state and federal regulations, including the federal Food, Drug and Cosmetic Act, which charges the FDA with ensuring that human and animal foods are safe and properly labeled. For more information on the FDA's regulation of pet foods, visit their site. The FDA also incorporates the Nutrition Labeling and Education Act in 1990, which regulates the permission of health claims on human food, into its regulation of pet foods.

State regulatory offices also play a vital role in regulating commercial pet food. The 2012 Diamond Foods-origin recall originated when the Michigan Department of Agriculture and Rural Development reported detecting *Salmonella* from an intact package of Diamond Naturals Lamb and Rice Formula for Adult Dogs, collected during regular retail surveillance.

**Q: Why are you warning people of the risks of raw pet food diets, when there have been confirmed cases of human illness from commercially processed kibble diets?**
**A:** This policy isn't a comparison of pet foods. Neither is it a condemnation of raw foods – it is a caution against feeding raw foods that aren't adequately treated to eliminate pathogens. It was developed in response to a recognized risk associated with raw foods and the scientific support that pets fed raw diets are at risk of becoming *Salmonella* carriers and could potentially infect people, particularly those that are most susceptible to infection (the very young, very old, and immunocompromised).

Note that with this policy we aren't encouraging commercial diets, we're encouraging "commercially prepared or home-cooked food" (as stated in the policy). What's important is that the food isn't raw or undercooked and doesn't contain pathogens, Regardless of what you feed your pet, the diet should be free of pathogens that can sicken you, your pet and your family. Just like you, we also want pets' diets to be nutritionally balanced. We support the FDA's efforts to ensure that pet foods and treats of all types are safe and healthy for pets.

Please also be aware that we have made efforts to communicate the risks associated with commercially produced dry food and treats. We have a FAQ document about *Salmonella* and dry pet foods and treats, and our AVMARecallWatch Twitter feed is dedicated to notifying followers about pet food and product recalls.

**Q: Are there raw foods that would be acceptable under the AVMA policy?**
**A:** The primary concern we have about raw animal-source proteins is the bacterial contamination issue. Cooking, pasteurization, irradiation or other methods that successfully eliminate pathogens would render the food products safer and minimize the public health risk and be acceptable.

**Q: Is the AVMA developing, or going to develop, additional policies that address the health risks of pet foods in general?**
**A:** AVMA policy is developed by volunteer AVMA members serving on councils, committees or other entities. Therefore, it is up to those groups to determine the need for and develop new policies. The CPHRVM will discuss the possible development of a policy addressing the public health risks associated with pet foods and treats.
The AVMA, CDC and FDA recommend precautions be taken when feeding any type of pet food or treat.

**Q: If I choose to feed raw food to my pet, what precautions should I take to protect my family?**
**A:** First, be aware of the risks and know that despite your best efforts to clean the surfaces and environment, your pet's stool could remain a potential source of infection. Always practice good food hygiene and sanitation.

- If avoiding commercial foods is your goal, consider cooking the raw food before feeding it to your pet.
- If purchasing commercial raw diets, select products that have been adequately treated to eliminate pathogens.
- Do not purchase the product if the container is damaged.
- Keep the product frozen until ready to use, and promptly refrigerate or discard any leftovers.
- Keep the raw meat intended for your pet(s) separate from that intended for your family, to avoid any cross-contamination. Do not handle raw meat intended for your pet in the same area(s) or use the same utensils or equipment used for preparing food for your family.
- Never allow cooked foods to come into contact with raw meat unless they are subsequently cooked at temperatures that will kill bacteria.
- Wash vegetables and fruit prior to feeding.
- Wash your hands thoroughly after handling raw food.
- Regularly sanitize pet dishes, surfaces, cutting boards and utensils.
- Rigorously control insects and other pests that may be attracted to the raw meat and could spread contamination.

**Q: How would I know if my pet becomes infected with *Salmonella* from its food?**
**A:** There are many sources of *Salmonella*. Because the organism can persist in the environment for weeks, even after thorough cleaning, the exact source of your animal's illness (if it is the food) may be long gone. Animals with salmonellosis may show some or all of the following signs:

- Lethargy
- Decreased appetite
- Fever
- Vomiting
- Excess salivation (in cats)
- Diarrhea (may contain blood or mucus)

Also be aware that pets may be infected with *Salmonella* but may not appear to be sick. *Salmonella* bacteria can be shed in your pet's stool for 4 to 6 weeks, and possibly longer, after infection. If you suspect your pet is ill, contact your veterinarian.

If your pet is infected with *Salmonella* and is shedding the bacteria in their stool, it's also possible for people to become infected by contact with their infected pet's fur, mouth, or feet – as well as anything that can come in contact with your pet's stool. You can find *Salmonella* essentially anywhere the animal has been. *Salmonella* can survive for weeks or even years given the right environmental conditions (temperature, pH, humidity).

**Q: How would I know if my pet is a *Salmonella* carrier?**
**A:** *Salmonella* is usually detected by culturing your pet's stool, but it can be difficult to detect because they don't consistently shed the bacteria in their stool. They intermittently shed the bacteria, but are more likely to do so when stressed. It has been widely reported that infected dogs can shed *Salmonella* in their stool for 6 or more weeks.[4] Several stool samples may be necessary to find the bacteria.

**Q: If my pet is identified as a *Salmonella* carrier, what do I do?**
**A:** Consult with your veterinarian regarding your pet's health and the possible treatment of your pet. If it's confirmed that your pet is a *Salmonella* carrier, take extra precautions to protect yourself and your family.

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Indiana State Board of Animal Health

Report on the Sale of Raw Milk

# Appendix R

NEWS RELEASE

FOR IMMEDIATE RELEASE
July 19, 2011

Contact: Bob Ehart
(202) 296-9680

**NASDA RELEASES RAW MILK SURVEY**

***Washington, D.C.*** – The National Association of State Departments of Agriculture (NASDA) has released updated results from a Raw Milk Survey.

NASDA conducted a Raw Milk Survey, in cooperation with the National Association of Dairy Regulatory Officials (NADRO), to gather current information about the regulation and sale of raw milk in the United States. Raw milk is defined as milk that has not been pasteurized. The Center for Disease Control (CDC) strongly discourages consumption of raw milk as pathogens from raw milk can result in kidney failure, paralysis and fatality, in some cases.

This survey is NASDA's third collection of data since 2004. In 2008, 50 states participated in the survey and 30 states allowed raw milk sales. NASDA's new data reflects no change in the number of states permitting unpasteurized milk sales both on the farm and in retail markets. The 2011 data shows the same 30 states allowing raw milk sales. Likewise, the same 20 states still prohibit the sale of raw milk to consumers. Five states have adopted stricter quality standards to regulate the sale of raw milk since the 2008 survey.

Of the 30 states where raw milk sales are allowed in some form, 13 states restrict legal sales to occur only on the farm where the milk is produced. The survey shows that 12 other states allow the sale of raw milk at retail stores separate from the farm. The remaining five states restrict the availability of raw milk to special markets or have compound regulations.

NASDA represents the commissioners, secretaries, and directors of the state departments of agriculture in all 50 states and four territories. The information for this survey was received from the NADRO members in each state.

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The National Association of State Departments of Agriculture (NASDA)
1156 15th Street, N.W., Suite 1020
Washington, D.C. 20005
(202) 296-9680
www.nasda.org
President: Leonard Blackham - Commissioner, Utah Department of Agriculture and Food

**Summary of results:**

Of the 50 respondents, 30 states authorize the legal sale of raw milk, in some specified manner, for direct human consumption. The remaining 20 states prohibit the sale of raw milk to consumers. The following data represents the 30 states that allow raw milk sales in some form.

**Sales of raw milk restricted to the farm:**

- 13 states restrict legal sales to occur only on the farm where the milk is produced (AR, IL, KS, KY, MA, MN, MS, NE, NY, OK, RI, TX, WI)
    - Four of these states (MN, WI, OK, IL) further restrict sales to only incidental occurrences (i.e., occasional; not as regular course of business; no advertising)
    - Kansas allows sales directly to the consumer on the farm with minimal on-farm advertising.
    - Four states (AR, KY, MS, RI) restrict sales to goat milk only, with two states (KY, RI) also requiring a prescription from a physician
        - AR allows 100 gallons of raw, liquid goat milk to be sold from the farm each month.
- 5 states have a coliform standard for milk sold only on-farm (ID, MA, NY, OR, TX)

**Sales of raw milk at retail stores separate from farm:**

- 12 states allow the sale of raw milk at retail stores separate from the farm (AZ, CA, CT, ID, ME, NH, NM, NV, PA, SC, UT, WA)
    - One of the 12 (UT), requires the store to be owned by the producer, even though it can be located off of the farm.
    - Another state (SC) allows the sale of raw milk both on and off the farm and at farmers' markets if a permit is obtained. Further, farmers must provide retail stores with a warning plaque to be displayed in front of the raw milk.
- Of these 12 states, all 12 have a total coliform standard.
    - 9 states have a coliform standard of $\leq$ 10/mL (AZ, CA, ME, NH, NV, PA, SC, UT, WA)
    - 1 state has a coliform standard of $\leq$ 25/mL (ID)
    - 2 states have a coliform standard of $\leq$ 50/mL (CT, NM)

**Sales of raw milk at farmers' markets and states with compound regulations:**

- 5 states have unique regulations that do not fit in either of the categories above. (CO, MO, OR, SD, VT)
    - One state (OR) allows on-farm sales of raw cow's milk only from farms with no more than two producing cows, nine producing sheep and/or 9 producing goats; Only goat milk is allowed at retail off farm.
    - Of the five states, one state (CO) prohibits all sales of raw milk; however, raw milk may be legally obtained through "share" operations.
    - Another state (VT), allows raw milk to be sold on the farm and if farmers comply with further standards they are also allowed deliver to retail stores. Raw milk sales are prohibited at farmers' markets and advertising is not restricted.
    - Two states (SD, MO,) allow farmers to deliver to farmers' market but not to stores.
    - Of these five states, 4 have minimum standard requirements (MO, OR, SD, VT)
    - 1 state has a coliform standard of $\leq$ 10/mL (VT, OR)
    - 1 state has a coliform standard of $\leq$ 100/mL (MO)
    - 1 state requires the same standards for raw milk as pasteurized milk (SD)

**The Sale of Raw Milk is prohibited in 20 States:** (AL, AK, DE, FL, GA, HI, IN, IA, LA, MD, MI, MT, NJ, NC, ND, OH, TN, VA, WV, WY)

States that have added quality standards for raw milk since 2008 are highlighted in red

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1156 15th Street, N.W., Suite 1020
Washington, D.C. 20005
(202) 296-9680
www.nasda.org
President: Leonard Blackham - Commissioner, Utah Department of Agriculture and Food

**2011 Survey Questions:**

1. Is the sale of raw milk for direct human consumption legal in your state?
2. Do your state laws or regulations expressly prohibit animal share raw milk operations?
3. Do your state laws or regulations authorize raw milk sales only on the farm?
4. Are raw milk sales at retail stores or markets, separate from the farm, legal in your state?
5. Does your state have any microbial standards for raw milk sold to the consumer? If yes, please specify.
6. Is sampling for compliance with the above standard(s) conducted at the farm bulk tank, or at the final package/bottle?
7. Are there any county or local government bans on raw milk sales in your state?
8. Approximately how many producers of milk to be sold raw are operating in your state?
9. What has changed regarding the regulation of raw milk since the 2008 survey?

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1156 15th Street, N.W., Suite 1020
Washington, D.C. 20005
(202) 296-9680
www.nasda.org
President: Leonard Blackham - Commissioner, Utah Department of Agriculture and Food

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Report on the Sale of Raw Milk

# Appendix S

# Appendix S

# State Regulation of Raw Milk

# (11-1-2012)

**Twenty states prohibit the sale of raw milk: AL, AK, DE, FL, GA, HI, IN, IA, LA, MD, MI, MT, NJ, NC, ND, OH, TN, VA, WV, WY**

**Thirty states authorize the legal sale of raw milk in some manner: AR, AZ, CA, CO, CT, ID, IL, KS, KY, MA, ME, MN, MO, MS, NH, NE, NM, NV, NY, OK, OR, PA, RI, SC, SD, TX, UT, VT, WA, WI**

**The methods states use to authorize and regulate raw milk sales to consumers varies widely from state to state. The Indiana State Board of Animal Health compiled the following list of concepts that states utilize to address the distribution of raw milk to consumers.**

- **Method of sales / distribution**
  - **Sales of raw milk restricted to the farm where the product was produced (18):**
    - Arkansas (goats' milk only, limit of 100 gallons per month)
    - Colorado (cow and goat shares, boarding and milking contract, only)
    - Illinois (incidental sales only)
    - Kansas
    - Kentucky (goat milk with a written prescription only)
    - Massachusetts (on the farm where produced)
    - Minnesota (incidental sales of milk, cream and skim milk only)
    - Mississippi (goats' milk only)
    - Missouri (on-farm sales and delivery to consumers)
    - Nebraska (at the farm directly to consumers)
    - New York (on the dairy farm where produced directly to consumer)
    - Oklahoma (incidental sales directly to consumers)
    - Oregon (On-farm sales of cow milk allowed if 3 or fewer cows. Retail sales of goat and sheep milk allowed.)
    - Rhode Island (goat milk with written prescription only)
    - South Dakota (at the farm and direct delivery from farmer to consumer)
    - Texas (only at the point of production, i.e., at the farm)
    - Vermont ("sold only from the farm on which it was produced" but also a limited delivery option)
    - Wisconsin (incidental sales on the farm where the milk is produced only)
  - **Sales of raw milk permitted in retail stores separate from the farm (12):**
    - Arizona
    - California
    - Connecticut

- Idaho
- Maine
- New Hampshire
- New Mexico
- Nevada
- Pennsylvania
- South Carolina
- Utah (Only if store is owned by producer of raw milk)
- Washington

- **Cow/Herd shares. Boarding agreements. Custom milking and bottling.**
  - Colorado (cows and goats only) (legal bill of sale and boarding contract) – must be received directly from the farm where the animals are located.
  - Idaho (no more than 7 cows, 15 sheep or 15 goats)
  - Massachusetts (Official regulation interpretation 2010-1 requires cow share or herd share operations to have a raw milk retail sale permit)
  - New York (considered a sale that must have a sales permit – court decision)
  - Ohio (court decision allows)
  - Tennessee (2009 statute allows the owner or "partial owner" of a hoofed mammal to use milk from the animal for personal use)
  - Utah (cow-share programs specifically prohibited without raw milk for retail permit)
  - Washington (considered a sale)
  - Wisconsin (law allows distribution of raw milk to an individual with a bona fide ownership interest in a licensed dairy farm)
  - Wyoming (2012 rule change will allow raw milk purchases if the person owns a share of the animal that produced the milk)
- **Resale, further distribution and service to the public specifically prohibited**
  Most states prohibit redistribution and service to the public through restaurants, hotels, hospitals and other institutions, requiring sales to be "direct to the consumer". The following are examples (not a complete list of states with this restriction):
  - Arizona – raw milk and raw milk products may not be sold to or used by restaurants, soda fountains or other similar establishments.
  - Colorado - cow / herd share law prohibits retail sale and further distribution.
  - Connecticut – raw milk and raw milk products may not be served in hotels, restaurants, cafeterias, hospitals, schools, or any other public meeting place.
  - Idaho – sales prohibited in a restaurant or other food establishment but allowed in a retail store if correct permit is obtained. Milk from a herd share may not be sold at a food establishment, grocery store or farmers market.
  - Nebraska (not for resale)
  - New Hampshire (sales to stores and "bona fide boarding houses" allowed)
  - Utah (sold to consumers for household use and not for resale)

- Vermont ("sold directly from the producer to the end user and shall not be resold")
- Washington (may not be sold to or used by restaurants or institutions)
- Wisconsin (Sales other than incidental sales to the consumer on the farm are prohibited.)

- **Distribution/transportation.**
  - Idaho (herd share milk and milk products may only be received directly from the producing farm by share owners)
  - Missouri (Home delivery sales)
  - New Hampshire (Home delivery sales)
  - South Dakota (Home delivery sales)
  - Vermont (Home delivery allowed for people who have purchased milk in advance by a one-time payment or through a subscription. Must be delivered directly to the consumer's home.)
  - Washington (Retail sales, including farmers markets, allowed and home delivery.)
- **Restrictions on volume (number of cows, gallons of milk) and types of raw products**
  - Arizona (milk, cream, cottage cheese, buttermilk, butter, kefir and other cheeses allowed)
  - Arkansas (Goat milk only. Not more than an average of 100 gallons per month)
  - Connecticut (Raw milk and raw milk cheese only. No limit but different standards for farmers with daily production greater than 250 pounds of milk)
  - Idaho (Cow, goat and sheep. Allows raw milk products. 2 permits available, a "small herd permit" for farms with not more than 7 lactating cows, 7 lactating sheep or 7 lactating goats)
  - Kansas (Cow and goat milk. Butter and cheese produced on the farm specifically allowed)
  - Kentucky (Goat milk by physician's prescription only)
  - Massachusetts (Cow and goat milk only)
  - Minnesota (Cow, goat and sheep milk, cream, and skim milk only)
  - Mississippi (Goat milk only. No more than 9 producing goats)
  - Missouri (Cow and goat milk and cream only)
  - Nebraska (Milk and cream only)
  - Nevada (Cow and goat milk and milk products)
  - New Hampshire (Cow, goat and sheep milk or cream and raw milk yogurt only. Cheese must be aged)
  - New Mexico (Cow and goat milk, cream, flavored milk and half and half)
  - New York (Milk only)
  - Oklahoma (Incidental sales only. Goat milk limited to monthly average sales of 100 gallons or less)
  - Oregon (Small farms exempt from regulation if they have not more than 3 lactating cows, 9 sheep or 9 goats and sell on the farm only)

        - Pennsylvania (Milk and cheese only)
        - Rhode Island (Goat milk with prescription only)
        - South Dakota (Cow and goat milk, farm and direct deliver to consumer only)
        - Texas (Milk only)
        - Vermont (Two tiered system: Tier one 50 quarts or less and Tier 2 51 quarts to 160 quarts. A cap of 160 quarts (40 gallons) for any farm in any one day)
        - Washington (fluid whole milk, hand skimmed cream and milk that has been hand skimmed only. May not use a separator, homogenizer or any mechanical device to separate raw cream. No flavored milk or milk products allowed).
- **Packaging/Labeling**
    - **Filling and Capping of containers. Container construction and sourcing.**
        - Connecticut (Producers with a daily production of 250 lbs or less may hand cap containers. Producers with a daily production of 250 lbs or more must cap mechanically)
        - Illinois (customers must provide their own containers)
        - Massachusetts (mechanical capping, but may hand cap if meet specific requirements. Containers from approved sources must be provided by the dairy)
        - Minnesota (customers must provide their own containers)
        - Missouri (machine filling and capping required)
        - New Hampshire (up to 1,000 lbs per day may hand cap then must mechanically cap. Consumer provided containers allowed)
        - New Mexico (approved mechanical filler and capper required)
        - Pennsylvania (off-farm sales require separate room with mechanical fill and cap. On-farm sales may use milk room with easily cleanable equipment, customers may fill their own containers)
        - South Carolina (Must be bottled, packaged and sealed at the same location where produced. Filling and capping must be by approved mechanical equipment but may be done in the milkhouse)
        - Vermont (Must be bottled by the farmer. May use customers containers if the farmer cleans the container)
        - Washington (mechanical encouraged but hand capping allowed with regulation)
    - **Labeling, unpasteurized milk warning label required**
        - Arizona
        - California
        - Colorado (prominent warning label required. No statement claiming endorsement by the state may be published. Information about farm standards, herd health, and test results for animals and products is released to consumer.)
        - Connecticut
        - Idaho (Small herd raw milk permit holders selling only at the farm do not need State approval of labels).
        - Kansas

        - Maine
        - Massachusetts
        - Missouri
        - Nevada
        - New Hampshire (Warning label required. Label not required if consumer provides container at the farm but sign with warning required)
        - New Mexico (label and sign at retail required)
        - Oregon (label and may not be sold next to pasteurized)
        - Pennsylvania (Label required if permit holder provides container. Customer provided and filled containers require a sign at the fill location)
        - South Carolina
        - South Dakota
        - Texas (animal feed label)
        - Utah
        - Vermont
        - Washington (warning label and warning signs next to the milk. Pull date required)
    - **Advertising**
        - Arkansas (all advertising is prohibited)
        - Illinois (all advertising is prohibited)
        - Kansas (only advertising allowed is with a sign posted on the farm clearly labeling the product as "raw" milk)
        - Massachusetts (sign must be posted where raw milk is sold, stating "Raw milk is not pasteurized. Pasteurization destroys organisms that may be harmful to human health."
        - Minnesota (all advertising is prohibited)
        - Mississippi (advertising is prohibited)
        - Nebraska (advertising is prohibited)
        - New York (must post sign at sale of milk stating "Notice: Raw milk sold here. Raw milk does not provide the protection of pasteurization."
        - Oklahoma (only permitted to advertise for goats' milk sales)
        - Oregon (advertising for on farm sales is not permitted)
        - South Carolina (advertising is legal)
- **Storage/Handling**
    - **Cooling temperatures of milk and refrigeration of bottled milk**
        - Connecticut (≤ 40˚F within 3 hours of completion of milking. Must be maintained until delivered to consumer)
        - Idaho (≤ 45˚F within two hours after milking)
        - Kansas (≤ 45˚F within one hour after milking and maintained during distribution)
        - Kentucky (≤ 45˚F within two hours after milking – goat milk)
        - Massachusetts (≤ 40˚F within 2 hours after milking and until delivered to the consumer. May not hold milk more than 48 hours before selling)

- Nevada (≤ 45˚F immediately after being drawn from the cow or goat and maintained until delivered to the consumer)
- New Hampshire (≤ 45˚F immediately after being drawn from the cow or goat. Bottled milk maintained at ≤ 40˚F until delivered to the consumer. Required sell by date no more than 5 days from bottling)
- New Mexico (32-45˚F within 2 hours after milking and until delivered to the consumer)
- New York (≤ 45˚F within 2 hours after milking)
- Pennsylvania (≤ 40˚F within 2 hours after milking. Sell by date not to exceed 17 days from production)
- South Carolina (≤ 50˚F within four hours or less after first milking, and to ≤ 45˚F within two hours after the completion of milking. Bottled milk maintained at ≤40˚F)
- South Dakota (≤ 45˚F within two hours after milking)
- Texas (≤ 45˚F within two hours after milking)
- Utah (≤ 50˚F within one hour of the first milking, and ≤ 41˚F within 2 hours after the completion of milking)
- Vermont (≤ 40˚F within 2 hours after milking and maintained at ≤40˚F)
- Washington (≤ 40˚F within 2 hours after milking)

- **Permitting/Registration**
  - **Farm permit. Milk plant permit. (Grade A, Manufacturing, or other permit)**
    - Arizona
    - California (Market Milk/Grade A Permit)
    - Colorado cow / herd share operations (registration)
    - Connecticut (Retail Raw Milk Producer permit, Retail Raw Milk Cheese Manufacturer permit)
    - Idaho (Grade A permit for dairy farms and dairy plants selling raw milk/products. A small farm permit and herd share registration available with different requirements)
    - Kansas (only on-farm sales do not need a permit) Kansas (dairy manufacturing license required if selling cream or butter)
    - Kentucky
    - Maine (Do not need permit if sales are on the farm and they do not advertise)
    - Missouri (Grade A retail raw milk permit for on-farm sales and delivery)
    - Massachusetts (Grade A permit plus additional requirements)
    - Nevada (County milk commission and State Dairy Commission permit)
    - New Hampshire (Grade A permit. No permit required if sales of less than twenty quarts of milk per day)
    - New Mexico (Grade A permit)
    - New York
    - Oklahoma (need manufacturing plant permit to sell more than incidental sales)
    - Oregon (Grade A permit)

        - Pennsylvania
        - South Carolina (Grade A permit)
        - South Dakota (Grade A permit)
        - Texas (Grade A permit)
        - Utah (Grade A standards)
        - Vermont (register)
        - Washington (Grade A)
    - **Inspection (All states requiring permits include inspection. The following have specific provisions concerning the frequency of inspection for raw milk sellers)**
        - Idaho (at least once every 3 months)
        - Missouri (at least once every 6 months)
        - Nevada (farms at least every 6 months and plants at least every 3 months)
        - New Hampshire (unless milk is not sold to a milk plant)
        - New Mexico (at least twice every 6 months)
        - South Carolina (at least once every 3 months)
        - Texas (at least 2 times every 6 months)
        - Utah (no less than 4 times per year)
        - Vermont (annually)
- **Farm Standards: Equipment, Sanitation**
    - **Milking equipment approval by state (In addition to the below list, any state requiring a Grade A permit require Grade A equipment standards)**
        - Arizona, Connecticut, Idaho, Kansas, Kentucky, Massachusetts, Missouri, Nevada, New Hampshire, New Mexico, Oregon, South Carolina, South Dakota, Utah, Vermont, Washington
    - **Approved water supply specifically required. (In addition to the below list, any state requiring a Grade A permit require water supply approval)**
        - Kansas; Kentucky; Massachusetts; Missouri; Nevada; New Mexico; Pennsylvania; South Dakota; Vermont
    - **Equipment cleaning and sanitizing.**
        - Most states with permits require cleaning and sanitizing of bulk tanks regularly (such as each 24 – 48 hours after use) and equipment after each use.
- **Testing/Standards**
    - **Milk quality and microbial standards**
        - Somatic cell count ≤ 750,000/mL (cows' milk)
            - Connecticut
            - Massachusetts
            - New Hampshire
            - New York
            - Pennsylvania
            - South Dakota
            - Texas

        - Washington
- Somatic cell count ≤ 1,000,000/mL (cows' milk and goats' milk)
    - Nevada
    - New Mexico
- Somatic cell count ≤ 1,000,000/mL (goats' milk)
    - Kentucky
    - New Hampshire
    - Texas
    - Washington
- Somatic cell count ≤ 1,500,000/mL (goats' milk)
    - Oregon
    - Pennsylvania
- Cows' milk contains ≤ 500,000 somatic cells/mL, goats'/sheeps' milk contains ≤ 750,000 somatic cells/mL
    - Idaho
- Cows' milk contains ≤ 500,000 somatic cells/mL, goats' milk contains ≤ 1,000,000 somatic cells/mL
    - South Carolina
- Cows' milk contains ≤ 350,000 somatic cells/mL, goats' milk contains ≤ 1,000,000 somatic cells/mL
    - Utah
- Cows' milk contains ≤ 225,000 somatic cells/mL, goats' milk contains ≤ 500,000 somatic cells/mL
    - Vermont
- Bacteria count ≤ 100,000/mL
    - Kansas
- Bacteria count ≤ 30,000/mL
    - New York
    - Connecticut
- Bacteria count ≤ 20,000/mL
    - Kentucky (goats milk)
    - Massachusetts
    - New Hampshire
    - New Mexico
    - Oregon
    - Pennsylvania
    - Texas
    - Utah
    - Washington
- Bacteria count ≤ 15,000/mL
    - Idaho

        - Vermont
    - Bacteria count ≤ 10,000/mL
        - South Carolina
    - Bacteria count ≤ 1,000 colonies/mL
        - Connecticut (thermoduric bacteria count – lab pasteurized count)
    - Coliform standard of ≤ 10/mL
        - Arizona, California, Kentucky (goat), Maine, Massachusetts, New Hampshire, Nevada, Oregon, Pennsylvania, South Carolina, Texas, Utah, Vermont, Washington
    - Coliform standard of ≤ 20/mL
        - New York
    - Coliform standard of ≤ 25/mL
        - Idaho
    - Coliform standard of ≤ 50/mL
        - Connecticut (standard of 150 /mL for raw milk cheese)
        - New Mexico
    - Coliform standard of ≤ 100/mL
        - Missouri
    - No detectable human pathogens (Inherent in general authority in most if not all states, explicit direction for raw milk in the following:)
        - Connecticut
        - Kentucky
        - Nevada (Salmonella)
        - New York (Must enroll in the "Quality Milk Promotion Services" milk sampling program for pathogenic bacteria)
        - Pennsylvania (Salmonella, Listeria monocytogenese, Compylobacter, E. Coli 0157:H7)
        - South Carolina (E. Coli 0157:H7, Solmonella, Listeria monocytogenese, Compylobacter)
        - Texas
        - Utah (Listeria monocytogenese, Salmonella typhimurium; Salmonella dublin; Campylobacter jejuni; and E. Coli 0157)
        - Washington (Compylobacter, E. coli 0157:H7 and Shigatoxin E.coli, Listeria monocytogenese and Salmonella)
- **Frequency of testing standards.**
    - Monthly
        - Connecticut, Massachusetts, Nevada, New Hampshire, New Mexico, New York, South Dakota, Utah, Washington
    - Once each month and for may test for pathogens every two months
        - Kentucky
    - Twice per month

        - Pennsylvania, Vermont
    - Four times in separate months in a six month period
        - Idaho
    - Every 6 months
        - South Carolina
    - Utah: For retail sales, “each batch of milk” is tested for standard plate count and coliform count from a sample taken at the retail store.
  - **Drug residue testing.**
    - Almost all states require testing and follow a no tolerance rule.
- **Animal health requirements.**
  - **Animal Health testing requirements**
    - California
    - Connecticut (herds tested annually for brucellosis and tuberculosis. Milk ring test for brucellosis for the herd monthly. All results reported to the Commissioner. Veterinarian relationship required. Each herd must be enrolled in the Connecticut Plan for Eradication of Mastitis)
    - Idaho (Sheep and goats tested annually for brucellosis. Cows must be brucellosis ring test negative. All animals from tuberculosis accredited herd or annual herd tested negative for TB. Cow shares must give results to owners)
    - Kansas (Herds must meet specific law requirements)
    - Massachusetts (Grade A standard)
    - Missouri (Annual whole herd test for tuberculosis and brucellosis)
    - Nevada (Annual whole herd test for tuberculosis. Brucellosis ring test at least every 90 days. Annual whole herd test for salmonella)
    - New Mexico (Annual whole herd test for tuberculosis. Brucellosis ring test of herd.)
    - New York (Brucellosis milk ring test required for cows and goats)
    - Oregon (Annual whole herd test for brucellosis and tuberculosis)
    - Pennsylvania (Annual veterinary exam required. Annual whole herd blood test for brucellosis or brucellosis milk ring test every 6 months. Annual whole herd test for tuberculosis)
    - South Carolina (Annual whole herd test for brucellosis and tuberculosis)
    - Utah (Each animal evaluated by a veterinarian prior to inclusion in a raw milk supply and every 6 months thereafter. Each animal tested once each year for tuberculosis and brucellosis. Bulk milk tank tested quarterly using the brucellosis ring test)
    - Vermont (Each animal must be identified. Each animal must be evaluated by a veterinarian once each year. Each animal tested before entering the milking string and once each year for tuberculosis and brucellosis. All animals vaccinated for rabies)

        - Washington (Each animal must be tested for tuberculosis, brucellosis and Q fever prior to entering the milking string and annually thereafter).
- **Pet Food Sales**
        - Colorado (must treat raw milk for nonhuman consumption with approved dye)
        - Texas (treat raw milk with dye and include label on container)
        - Washington (raw milk for pet food must be labeled “not for human consumption” and be “decharacterized with harmless food coloring”)
- **Liability insurance required to cover illness.**
    - None
- **Other:**

Connecticut - towns can regulate the sale of raw milk

Kentucky-“the producer shall keep on file records stating volume of unpasteurized goat milk sold and date of sales to each person having submitted a written recommendation statement”

South Carolina – Recall plan required

Vermont-Require the farmer to offer the consumer to take a tour of the farm and any area associated with the milk production.

# Warning label language

The following are examples of existing state requirements that specify exact language for warning labels on raw milk and milk products sold to consumers:

- "raw milk: not pasteurized and may contain organisms injurious to your health." Arizona (A.R.S. § 3-606)
- "Not Pasteurized" Colorado. (Colo. Rev. Stat. § 25-5.5-117)
- "Raw milk is not pasteurized, pasteurization destroys organisms that may be harmful to human health." Connecticut. (Conn. Agencies Regs. § 22-133-132.)
- "ungraded raw milk". Kansas (Kan. Stat. Ann. § 65-771(cc))
- "not pasteurized" or "unpasteurized"; plus "raw" must be in front of the product name. Idaho (IDAPA 02.04.13.011 (2011))
- "Unpasteurized dairy products may contain disease causing organisms. Persons at highest risk of disease from these organisms include newborns and infants, the elderly, pregnant women and those with illnesses or other conditions that weaken their immunity." Nevada State Dairy Commission, Proposed Regulation R082-11, February 8, 2012.
- "Raw Cow's Milk", "Raw Goat's Milk" or "Raw Sheep's Milk" and "Raw milk is not pasteurized. Pasteurization destroys organisms that may be harmful to human health". New Hampshire. (N.H. Admin. Rules, Mil 301.03 (2012))
- "raw" and "raw milk is not pasteurized and may contain organizma that cause human disease". New Mexico (21.34.2 NMAC 2012)
- "This product has not been pasteurized, may contain disease producing organisms". Oregon (Or. Admin. R. 603-024-0543)
- "Raw milk has not been processed to remove pathogens that can cause illness. The consumption of raw milk may significantly increase the risk of foodborne illness in persons who consume it – particularly with respect to certain highly-susceptible populations such as preschool-age children, older adults, pregnant women, persons experiencing illness, and other people with weakened immune systems". Pennsylvania.
- "raw milk" South Dakota (S. Dakota Codified Laws § 39-6-3)
- "raw milk". Utah (Utah Code Ann. § 4-3-14(2)(e)). Retail sales require a sign above the display case stating "Raw Unpasteurized Milk" and labels that state "Raw milk, no matter how carefully produced, may be unsafe." (Utah Code Ann. § 4-3-14(3))
- Vermont: "Unpasteurized (Raw) Milk. Not pasteurized. Keep Refrigerated." and "This product has not been pasteurized and therefore may contain harmful bacteria that can cause illness particularly in children, the elderly, and persons with weakened immune systems and in pregnant women can cause illness, miscarriage or fetal death, or death of a newborn." Both statements must also be posted prominently on the farm where the product is sold. Vt. Stat. Ann. Tit. 6, § 2777(d).
- Washington: "WARNING: This product has not been pasteurized and may contain harmful bacteria. Pregnant women, children, and the elderly and persons with lowered resistance to disease have the highest risk for harm from use of this product". WAC 16-101-800