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Raw Milk Misconceptions and the Danger of Raw Milk Consumption

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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 10^7cfu/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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R. Lauener, and C. Braun-Fahrlaender. 2007. Inverse association of farm milk consumption with asthma and allergy in rural and suburban populations across Europe. *Clinical and Experimental Allergy*. 37:661-670.

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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 10^6-10^7cfu/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 the 27 year 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 occurred during 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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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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- 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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