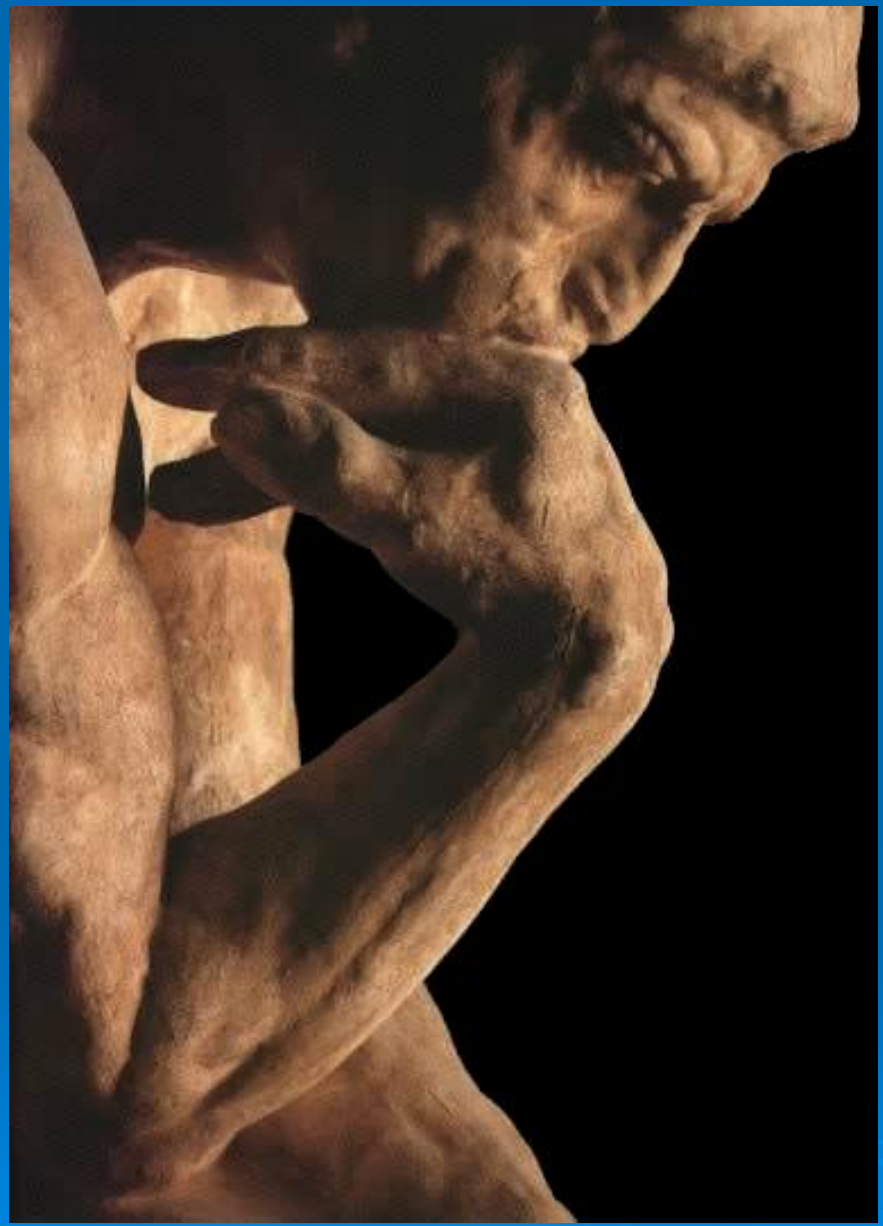
# On The Safety of Raw Milk (with a word about pasteurization)

Presented to 2005 NCIMS

**Cindy Leonard, M.S.**

USFDA/CFSAN
Division of Dairy and Egg Safety

Author: John F. Sheehan, B.Sc. (Dy.), J.D.

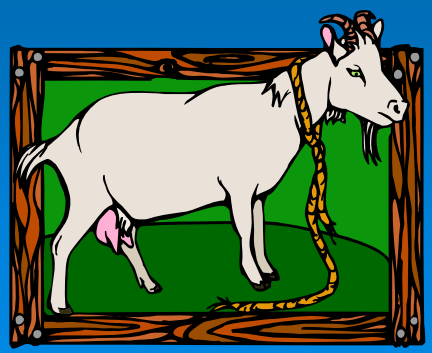
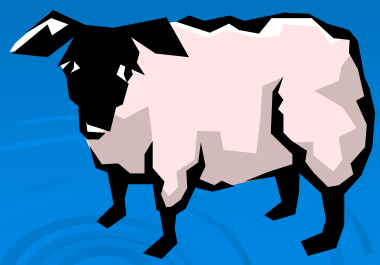


“Through ignorance of what is good and bad, the life of men is greatly perplexed” Cicero, in De Finibus Bonorum et Malorum (I, 13)

# Is raw milk safe to consume?

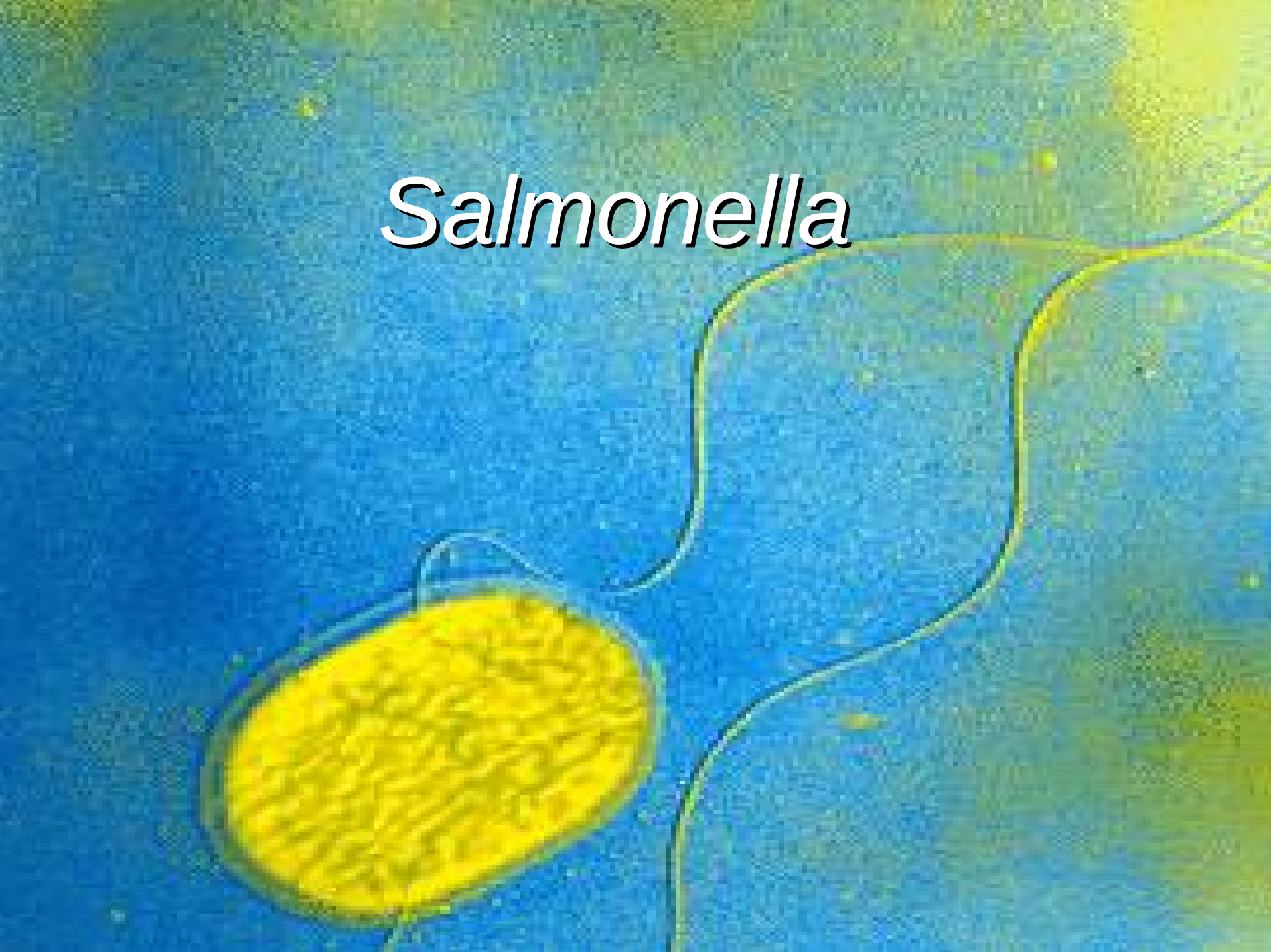
- No. Raw milk is ***inherently*** dangerous. Raw milk may contain a whole host of pathogens, including :
  - ***Enterotoxigenic Staphylococcus aureus***
  - ***Campylobacter jejuni***
  - ***Salmonella species***
  - ***E. coli (EHEC) (ETEC)***
  - ***Listeria monocytogenes***
  - ***Mycobacterium tuberculosis***
  - ***Mycobacterium bovis***
  - ***Brucella species (abortus –cattle) (melitensis-goats)***
  - ***Coxiella burnetii***
  - ***Yersinia enterocolitica***
- This listing is not meant to be exhaustive.

- Incidence rates reported in the literature for each of the pathogens are variable.
- As one might expect, there are variations in incidence rates between countries and even within regions of countries.
- There are also variations in incidence rates reported for the three main commercial milks (bovine, ovine and caprine).


# Outbreaks

- The CDC reports that from 1998 to present there were 39 outbreaks in which unpasteurized milk or cheese made from unpasteurized milk were implicated.
- These outbreaks occurred in 22 states and two of them were multi-state outbreaks. An estimated 831 illnesses, 66 hospitalizations and 1 death were associated with these outbreaks.
- Not all outbreaks are recognized.
- Even when they are, not all are reported to CDC.
- Virtually impossible to capture all of the incidents of individual illness which might occur


Salmonella

# *SALMONELLA* OUTBREAK

- Between 2002-2003 there was a multistate outbreak of *Salmonella typhimurium* infections which were ultimately associated with the consumption of raw milk.
- 62 people were infected, including 40 customers Patients were from Illinois, Indiana, Ohio and Tennessee.
- Of 32 food samples tested, five were positive for *S. typhimurium*, including three raw skim milk samples, one raw milk butter sample and one raw cream sample.
- Upon investigation, only the consumption of raw milk was associated significantly with the illnesses.

- The dairy involved in this outbreak had been in operation since 1958 and it was the only firm in Ohio lawfully selling raw milk. The dairy has since voluntarily relinquished its license to sell raw milk. MMWR Weekly July 4, 2003 52(26) 613-615.

- If you encounter a raw milk vendor who tells you that his milk is safe because he/she has never had a pathogen determined to be present in their raw milk or their raw milk has never been involved in a foodborne outbreak, ask them if they are familiar with this story.

- The fact that they haven't yet found any pathogens present in their raw milk doesn't necessarily mean that such are not present. Much depends on the sampling and analytical methodologies used and they might not be looking for a relatively complete spectrum of pathogens when they test their milk.

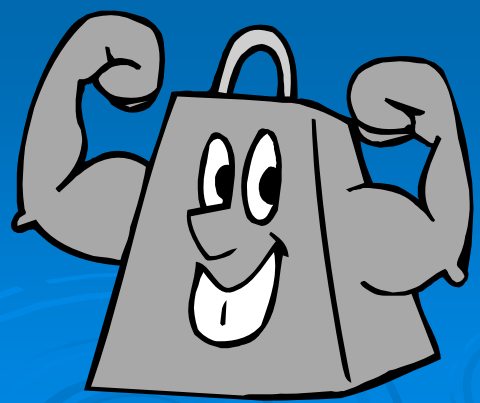
- 'Never Had it' doesn't mean 'Never Will'.

In California, in the 1970’s and 1980’s, the consumption of raw milk and the incidence of *Salmonella dublin* infections was reported upon by several groups of authors.

# Werner et al (1979)

- Reported that between 1971-1975, the mean annual incidence of *Salmonella dublin* infections in California increased more than five fold.
- Investigations of the cases showed an association with raw milk exposure in 44 out of the 113 cases. Of those 44, 35 had used milk from a single dairy.
- 89 of the 113 were hospitalized. 22 of them died.
- *S. dublin* was confirmed to be present in the milk from the dairy, prompting the issuance of a pasteurization order.

- The authors of this report concluded that the public's increasing desire for a "health food" such as raw milk is alleged to be, should be tempered with an appreciation of it's attendant risk to health. Werner et al. Br. Med. J. 1979 (Jul) 28:2 (6184) 238-241



- Almost half of the patients had serious underlying non-infectious diseases, such as leukemias and lymphomas.
- With such patients, the immune system is often compromised as a result of the treatments which they are receiving.
- The combination of a deadly pathogen and an immunocompromised patient is obviously not a good one.
- Unfortunately, raw milk is oftentimes marketed as being a “health food” and some raw milk vendors, when comparing their product to a pasteurized milk, ascribe to it all sorts of curative properties, which are as yet largely unsubstantiated in the scientific literature.

# Taylor et al (1982)

- Reported on *S. dublin* infections in the United States between 1979-1980. They indicated that when exposure to cattle, beef or dairy products was examined, cases differed significantly from controls only by a more frequent consumption of raw milk.

- Taylor et al.  J. Infect. Dis. 1982 Sep; 146(3) 322-7

# What's been happening lately?

- Interestingly enough, Cody et al (1999) reported on two outbreaks of multi-drug resistant *Salmonella typhimurium* DT104 infections linked to raw milk cheeses in Northern California.
- The first outbreak peaked in February of 1997 and the second in April of that year. 110 patients were confirmed. The cause was ultimately determined to be Mexican-style fresh cheese made from raw milk and sold by street vendors.
- Cody et al. JAMA 1999 May 19:281(19):1805-10

- So, if you encounter a raw milk vendor who indicates that California has never had a problem with raw milk safety, ask if they have ever heard of any the above.

# Villar et al (1999)

- Reported on more *S. typhimurium* DT104 infections which occurred in neighboring Washington State during 1997.
- In early 1997, Yakima County health officials noticed a five-fold increase in Salmonellosis among the county's Hispanic residents.
- Between January and May 1997, 54 culture-confirmed cases were reported.

# Villar et al (1999)

- The median age was four (4) years old
- 91% of the patients were Hispanic.
- 17 of the 22 patients enrolled in the case-control study reported eating Mexican – style soft cheese in the seven days prior to the onset of illness.

- The cheese produced and eaten by 2 unrelated patients was made from milk traced to the same local dairy farm.
- Milk samples from the farm yielded the same *S. typhimurium* DT104.
- The incidence of *S. typhimurium* infections in Yakima County returned to the pre-1992 levels following interventions based on these findings.

- The authors concluded that continued efforts were needed to discourage the consumption of raw milk products and to promote healthier alternatives.

- Villar et al. JAMA 1999 May 19; 281(19)1811-6

# Abuela Project

- One of the interventions subsequently implemented in Washington State was the Abuela Project, in which a pasteurized milk queso fresco recipe which produce a cheese with taste and texture acceptable to the Hispanic community was developed.

- 225 people attended safe cheese workshops and the authors report that six months later the workshop participants' acceptance of the new recipe was excellent and that positive behavior changes were maintained.

- For more on the Abuela project, see: Bell et al. Am J. Public Health 1999 Sep; 89 (9) 1421-4.

# Reed and Grivetti (2000)

- JDS 83:2988-2991 mentioned both the California and Washington ST DT104 1997 outbreaks in their article entitled: “Controlling on-farm inventories of bulk tank raw milk – an opportunity to protect public health.”

- The authors reported that “ the most significant source of raw milk (for illegal cheese manufacture) comes from the bulk tanks of licensed dairies”.


*E. Coli* O157:H7

# Keene et al. (1997)

- reported on a prolonged outbreak of *E. coli* O157:H7 which was caused by consumption of raw milk sold at Oregon grocery stores.
- It began in December of 1992 and did not end until June of 1994.
- When the culprit dairy was determined, it was discovered that only 4 of the 132 animals in the herd were initially positive for *E. coli* O157:H7.
- Despite public warnings, new labeling requirements and increased monitoring of the culprit dairy, retail sales and dairy-associated illnesses continued until June of 1994.

- The authors concluded that without restrictions on distribution, *E. coli* O157:H7 outbreaks caused by raw milk consumption can continue indefinitely, with infections occurring intermittently and unpredictably.

- Keene et al. J. Infect. Dis. 1997 Sep. 176 (3) 815-8

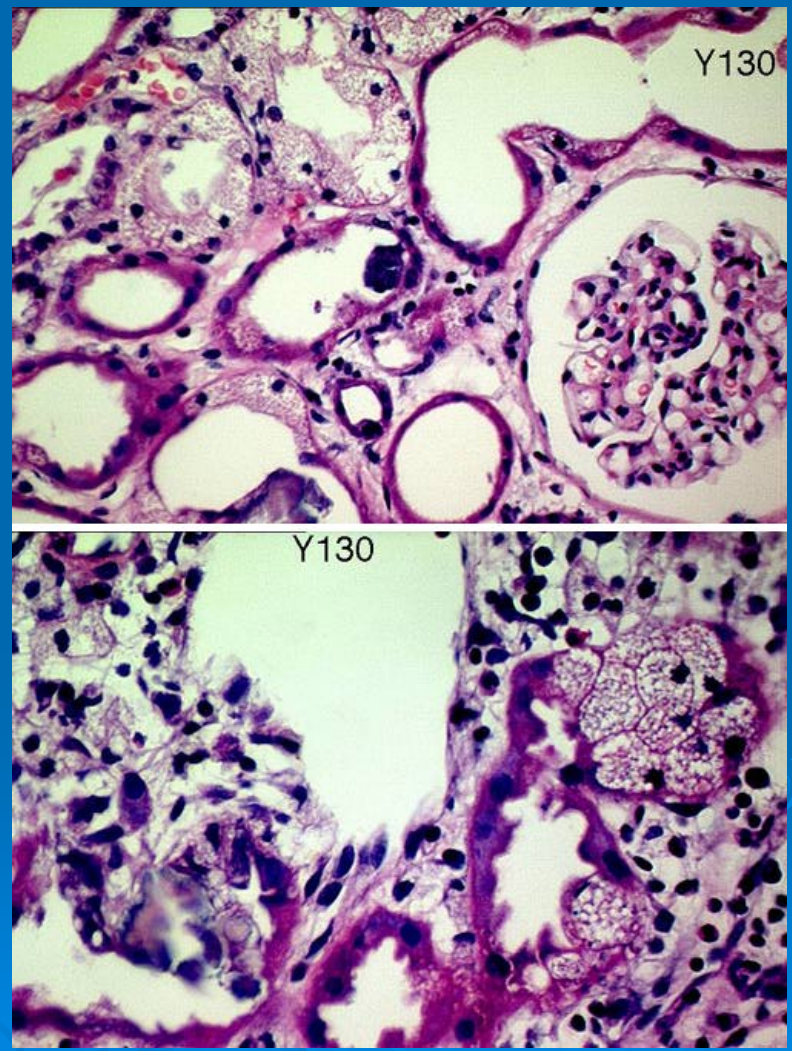
# Proctor and Davis (2002)

- Reported on *E. coli* O157:H7 infections in Wisconsin between 1992-1999. (The disease only became reportable in Wisconsin in April of 2000.)
- Between 1992-1999 there were 1333 cases reported in Wisconsin.
- The highest age-specific mean annual incidence, 13.2 cases per 100,000 population, occurred in children aged 3-5 years old.
- Among case patient identifiable exposures, consumption of raw milk/milk products was among the top three causes most frequently noted, at 7% of cases.
- Proctor and Davis WMJ 2000 Aug; 99(5) 32-7.

# HUS

- One of the complications that can arise as a result of infection with *E.coli* O157:H7 is hemolytic uremic syndrome (HUS), which can have devastating consequences upon victims, (such as acute renal failure), especially where they are very young.

- HUS has been associated with the consumption of raw milk domestically. See Martin et al.  Lancet 1986; 8514:1043

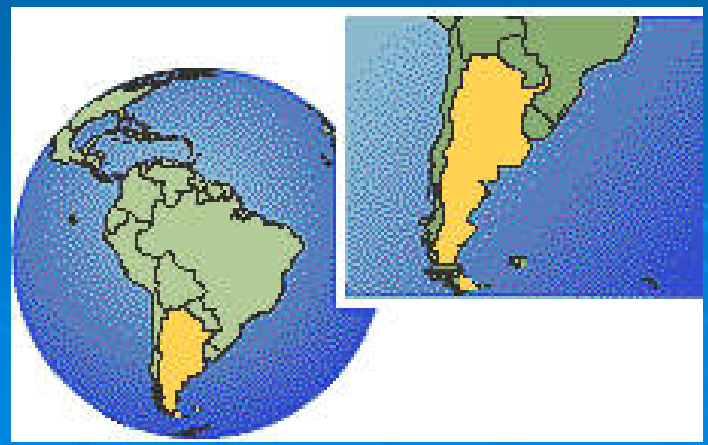


# Rivero et al (2004)

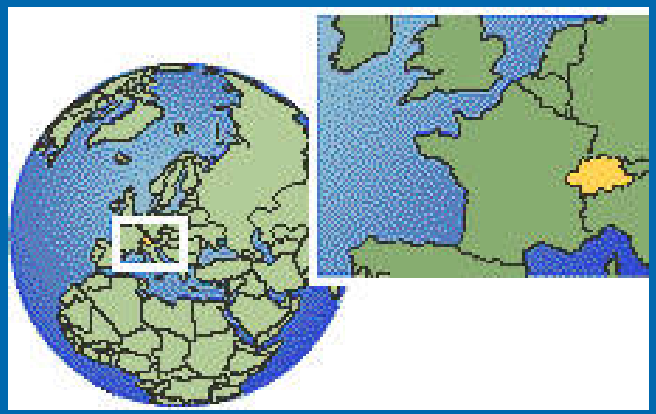
- In Argentina, where HUS is the most common cause of acute renal failure and the second highest cause of chronic renal failure and renal transplantation in children, it is reported that infections are a consequence of the consumption of undercooked meat, raw milk and other contaminated food and water.

- Argentina has the highest incidence of HUS in the world, reporting 420 new cases annually and an incidence of 12.2 cases per 100,000 children in the age group 0-5 years

- Rivero et al Medicina (B.Aires) 2004:64(4):352-6



# Kernland et al (1997)



- Reported on the causes of HUS in childhood in Switzerland.

- **Infection with Shiga-toxin-producing *E. coli* or *Shigella dysenteriae* type I were cited as playing a major role in the pathogenesis of HUS in childhood.**

- **Among the causes was the consumption of raw milk, which resulted in the authors concluding that pasteurization of raw milk is likely to have a positive influence on the incidence of HUS.**

- **Kernland et al. Schweiz Med Wochenschr 1997;127:1229–33.**

# Allerberger et al (2001)

- Reported on two children in Austria who contracted *E. coli* O157:H7 infection and subsequently developed HUS. The authors concluded that “it is prudent to remind them (parents and teachers) that children should not be given unpasteurized milk”.

- Eurosurveillance Vol.6 No.10, October, 2001.

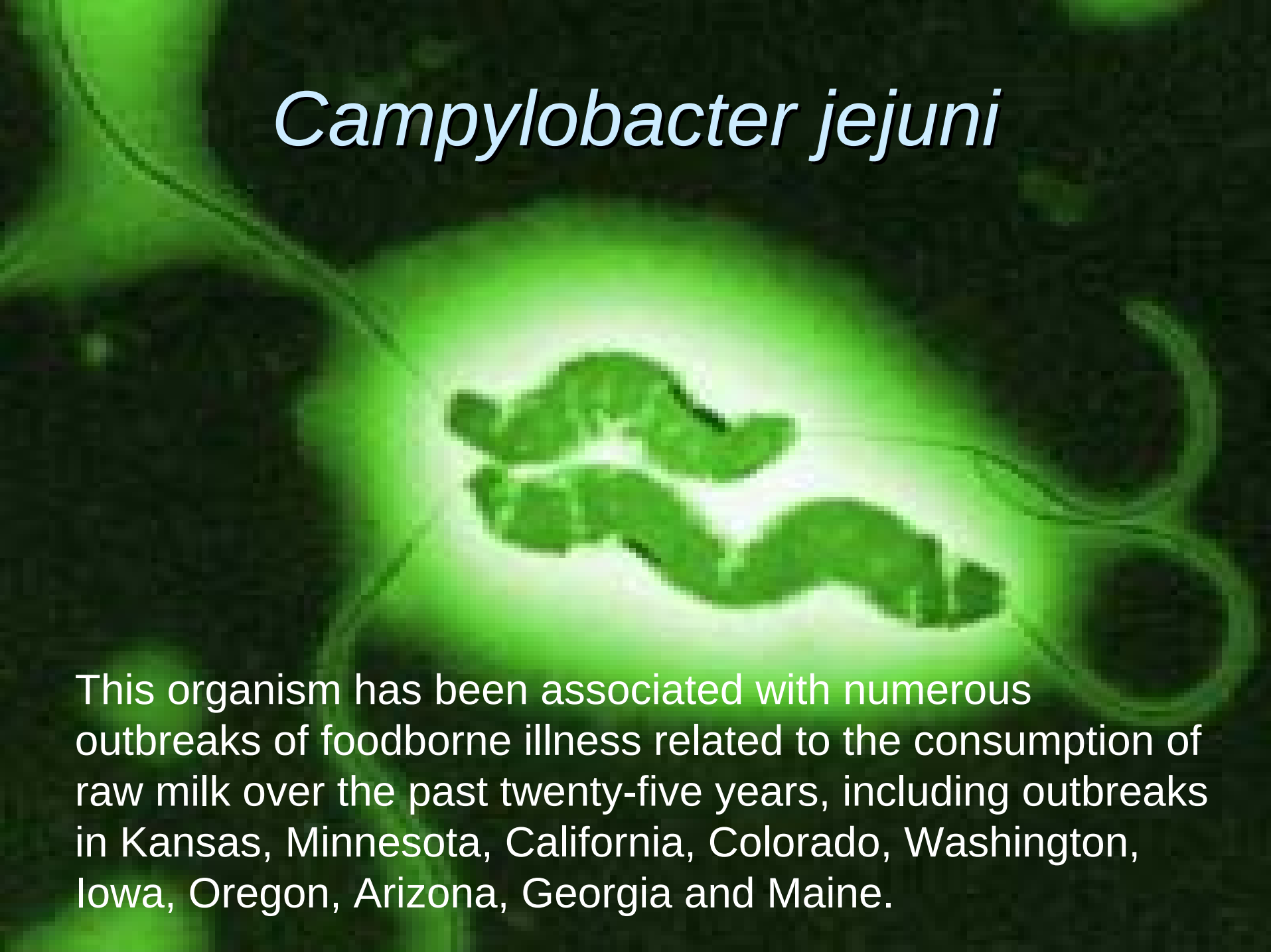
# Children

- Children fall victim to foodborne illness producing such devastating and oftentimes life-changing consequences as HUS.
- If children knew that raw milk might make them very ill, cause them to lose their kidneys or even kill them, would they choose to drink it?

**Regret can be avoided.**

- Children trust us to protect them, keep them safe, yet children are often fed raw milk by parents who believe it to be a healthy choice.
- Continue educational efforts with respect to the hazards associated with consumption of raw milk.
- Continue to urge parents to make only the safest and healthiest choices for their children.

# *Campylobacter jejuni*



This organism has been associated with numerous outbreaks of foodborne illness related to the consumption of raw milk over the past twenty-five years, including outbreaks in Kansas, Minnesota, California, Colorado, Washington, Iowa, Oregon, Arizona, Georgia and Maine.

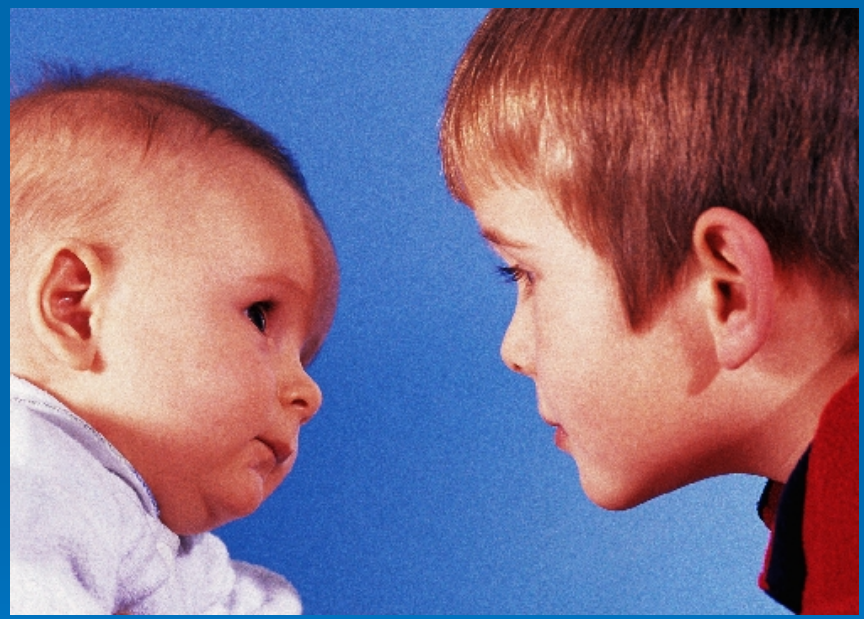
# Schmid et al (1987)

- Reported on their study of *C. jejuni* infections in one Iowa city (Dubuque) over a twelve-month period.
- Culture-confirmed positives were obtained from 53 people. 46 of those participated in the case-control study performed. 21 of the 46 cases occurred in children less than 10 years of age. The age-specific attack rate was highest for children aged one to four years.
- 15 of the 46 had consumed raw milk in the week before the onset of illness.
- 12 of the 15 who had consumed milk were less than 10.

- The authors concluded that: “Eliminating the consumption of raw milk will depend on educational efforts”.

- Schmid et al. J. Infect. Dis. 156, 1 July, 1987

- It is not just the very young that can fall victim to *C. jejuni* infection through the consumption of raw milk.



# Blaser and Williams (1987)

- Documented how after a retreat to an Oregon farm, 19 of 31 college students developed an acute gastrointestinal illness.
- *C. jejuni* infection was recognized in all of the students that were ill and caused asymptomatic infections with three others.
- 22 of 25 students who had consumed raw milk for the first time became infected. This compared with 0 of the 2 students who did not drink the raw milk.
- The quantity of raw milk consumed was directly related to the occurrence and severity of illness.
- Blaser and Williams JAMA 1987 Jan2 1, 257(1) 43-6.


Listeria monocytogenes

# *Listeria monocytogenes* Outbreaks

- *Listeria monocytogenes* (Lm) has been responsible for several outbreaks of foodborne illness domestically.
- Each year approximately 2500 people become seriously ill due to Lm infections.
- Nearly 500 of these die from their infection.
- Listeriosis only accounts for about 0.02% of illnesses due to foodborne disease, but it causes 27.6% of all deaths due to foodborne infection.

# Linnan et al (1988)

- Large outbreak occurred in 1985 in Los Angeles County. 93 cases occurred in pregnant women or their offspring. There were 48 deaths.
- Commercially manufactured Mexican-style cheese made from either a raw milk or a pasteurized milk which was adulterated with raw milk was ultimately determined to be the cause of the illnesses.
- Linnan et al NEJM 1988; 319:823-828.

# MacDonald et al (2005)

- Mexican-style cheeses made and sold unlawfully have also caused outbreaks of foodborne listeriosis. In 2000, there was an outbreak of listeriosis among Hispanic persons living in Winston-Salem area of North Carolina, as reported by Mac Donald et al.

- 13 patients were identified. 11 case patients were pregnant and infection with Lm resulted in 5 stillbirths, 3 premature deaths and 3 infected newborns.

- The authors concluded that the outbreak was caused by the “consumption of non-commercial, homemade, Mexican-style cheese produced from contaminated raw milk sold to unlicensed cheese makers by a local dairy”.

- The authors also concluded that “A combination of outreach and enforcement should be directed at store owners, vendors and dairy farmers, including education about disease risks and vigorous enforcement of laws and regulations governing the production and sale of milk and cheese”.

- MacDonald et al. CID 2005:40 (1 March) 677.

**We couldn’t agree more.**

# Pasteurization

- Pasteurization will destroy all of the pathogens that we have mentioned thus far.
- But what else does pasteurization do?
- FDA has become aware of much erroneous information presently circulating about the impact that minimum legal pasteurization conditions have upon milk.

# Myth No. 1

"Raw milk kills pathogens"

**No, it doesn't.**

- Allusion to the fact that milk does contain certain indigenous enzymes to which antimicrobial properties have been ascribed and to the fact that certain strains of bacteria which might be present in any given milk might be able to produce anti-bacterial compounds known as bacteriocins.

# Myth No. 2(a)

"Lactoferrin (bLf) is an enzyme-based pathogen killer."

- It is not an enzyme.
- It is believed to have dual roles, the one being a facilitator of iron absorption and the other a bacteriostatic role.

# Myth No. 2(b)

"Pasteurization inactivates lactoferrin."

**No, it doesn't.**

- The thermal behavior of lactoferrin is dependent upon the iron status of the protein.
- Paulsson et al (1993) JDS 76:3711-3720 determined that "unheated and pasteurized bLf preparations showed similar antibacterial properties and caused an effective metabolic inhibition with a moderate bacteriostasis".
- They also stated that "pasteurization seems to be the method of choice (when making a lactoferrin product) because it did not alter either the bacterial interactive capacity or the antibacterial activity of bLf".

- Tomita et al  Biochem. Cell Biol. 2002;80(1):109-112, discussing both lactoferrin and lactoferricin, discuss how a pasteurization process was developed for lactoferrin in order to apply active lactoferrin usage to various products.

# Myth No.3

"Pasteurization inactivates enzymes that kill pathogens, including lactoferrin, xanthine oxidase, lactoperoxidase, lysozyme and nisin."

**No, it doesn't.**

- Xanthine oxidase (XO) does not kill pathogens and is not destroyed by pasteurization.
- XO is thought to play a role in human nutrition and health and is a major component of the milk fat globule membrane (MFGM).
- XO has survived a laboratory heating of milk to 75C x 15s, which exceeds minimum HTST conditions.
- Griffiths J. Food Prot. 49 696-705 (1986).

# More on XO

- Another myth : “Homogenization alters XO by making it smaller (somehow). The XO can then access the bloodstream to interact with arterial walls, triggering the deposition of cholesterol and causing atherosclerosis.”
- In 1971, Oster postulated that individuals who drink homogenized milk are prone to atherosclerosis because XO causes a depletion of plasmalogen in cell membranes.
- Additional research and epidemiological studies, including one by the American Heart Association, led to the conclusion twenty years ago that XO was not associated with atherosclerosis.
- Homogenization is simply a process whereby a relatively uniform globule size is mechanically imparted to the fat phase in milk.

- Lactoperoxidase is an integral part of the lactoperoxidase system (lactoperoxidase/thiocyanate/hydrogen peroxide).
- System does have antimicrobial effects.
- In those developing countries where it is difficult to cool milk, the system is utilized by the addition of added thiocyanante and hydrogen peroxide.
- Lactoperoxidase is a very heat stable enzyme. It is not destroyed by minimum pasteurization conditions.
- It is, however, very sensitive to heat at 80C regardless of holding time.

- Lysozyme, in conjunction with lactoferrin, does have a bactericidal effect.
- Lysozyme is not completely destroyed by pasteurization
- In excess of 70% of bovine milk lysozyme will survive normal HTST conditions (Griffiths, 1986).

- Nisin is not an enzyme, but a type of bacteriocin.
- Bacteriocins are proteinaceous toxins produced by bacteria.
- Nisin belongs to a class of bacteriocins known as lantibiotics.
- Nisin binds to a cell membrane precursor lipid component and disrupts cell membrane formation.
- Raw milk will contain inappreciable levels of nisin.

# Myth No.4

"Pasteurized milk causes lactose intolerance."

**No, it doesn't.**

- Lactose intolerance is an inborn error of metabolism.
- All milks, raw or pasteurized, will contain lactose.
- Pasteurization does not change the concentration of lactose.
- A person who is lactose intolerant has a reduced ability to synthesize beta-galactosidase (lactase)
- Might be expected to experience the symptoms of lactose intolerance when consuming either a raw or pasteurized milk.

# Myth No. 5

"Pasteurization destroys lactase and thus causes lactose intolerance."

- Milk does not contain indigenous beta-galactosidase, insofar as we have been able to determine.
- Any beta-galactosidase which might be present in milk would likely be that produced by bacteria.

# Myth No. 6

"Pasteurized milk causes allergic reactions."

- The milk proteins which cause allergic reactions (including lactoferrin) in dairy-sensitive people are present in both raw milk and pasteurized milk.

# Myth No.7

“ Pasteurized milk is the number one allergic food in this country.”

- Peanuts are the leading cause of severe allergic reactions, followed by nuts, shellfish, fish and eggs.

# Myth No. 8

"Pasteurized milk….. has been associated with …arthritis."

- FDA was unable to locate any literature in support of this proposition.
- We did find one reference associating ingestion of ***RAW*** milk with a case of septic arthritis of the hip joint.

- See Campbell et al. J. Clin. Pathology 1993 (Nov) 46 (11) 1057-1058
- Reactive arthritis can occur after Salmonella infections

# Myth No. 9

" The pasteurization process turns casein into a very dangerous molecule that can further precipitate the brain injury (referring to autism)."

- FDA was unable to find any support for this statement.
- The statement is very non-specific.
- Do not know which casein species nor do we know the name of the "dangerous molecule".
- Caseins are largely unaffected by pasteurization.
- Farrell and Douglas (1983) showed that there was little difference in the soluble casein found in raw milk (78.8%) and pasteurized milk (74.8%) (Kiel. Milchwirtsch. Forschungsber. 35;345-356).

# Myth No. 10

"Pasteurization destroys Vitamin C."

**No, it doesn't.**

- Literature reports indicate losses of between 0-10% of the Vitamin C in milk upon pasteurization.
- Milk is not considered to be a significant source of Vitamin C

# Myth No. 11

**"Pasteurization turns the sugar of milk, known as lactose, into beta lactose, which is far more soluble and therefore readily absorbed in the system, with the result that the child soon becomes hungry again."**

- **Allusion to the B-anhydride form of lactose**
- **The alpha-monohydrate form is the stable solid form of lactose, since, in the presence of water and at temperatures below 93.5C, all other forms change to the monohydrate. The monohydrate has an initial solubility of only 7g/100g water at 20C.**
- **The Beta-anhydride form of lactose is formed when crystallization takes place from aqueous solutions at temperatures above 93.5C. The B-form is considerably more soluble than the a-form, having an initial solubility of 50g/100g water at 20C.**
- **Given all of the above, it should be clear that minimum pasteurization conditions will not turn the a-monohydrate into the b-anhydride.**

# Myth no.12

" Pasteurization makes insoluble the major part of the calcium contained in raw milk. This frequently leads to rickets, bad teeth or nervous troubles."

- FDA was unable to locate literature associating pasteurization of milk with either rickets, bad teeth or nervous troubles.
- When human milk was pasteurized, there were no obvious differences in the absorption of nitrogen or the absorption and retention of calcium, phosphorous and sodium when compared to either raw milk or even a boiled milk and all three types were fed to very low birth weight preterm infants.
- Williamson et al. Arch. Dis. Child 1978 Jul (53) 7:555-563

- Literature indicates essentially no differences in calcium levels for both raw and pasteurized cow and goat's milk.
  Lopez et al. JDS 68:1878-1886
- Generally understood that calcium is present in milk at about 1200mg/l.
- Only 34% of the calcium in milk is soluble; 66% of it is present in colloidal form – bound either to phosphate or citrate.
- Perhaps author is referring to a shift in the equilibrium between soluble and colloidal phases which will occur with temperature changes
- Often, temperature-induced changes in the equilibrium are reversible.
- The majority of calcium in milk is already in the colloidal as opposed to soluble phase.

# Myth No. 13

" Pasteurization destroys 20 % of the iodine present in milk, causes constipation and generally takes from milk it's most vital qualities."

- Pasteurization does not "take from milk it's most vital qualities". Far from it. Minimum pasteurization conditions provide safety to milk without appreciably altering it's nutritional value.
- Iodine: Literature indicates that neither cream removal nor pasteurization nor spray-drying of milk affected the concentration of either natural or iodophor-derived iodine.
- Even when milk was boiled, only 0.02% of iodine was lost.
- Wheeler et al. JDS 1983 Feb 66(2) 187-195.

- With regard to the constipation claim, it appears that statement may be based on research which appeared in the NEJM between 1998 and 1999.
- That research dealt with cow's milk and chronic constipation in children.
- The claimant simply extrapolated that research to the population at large, which is, of course, inappropriate.
- The literature that we have seen does not indicate a belief that pasteurization of milk is considered to be causative of constipation, rather a sensitivity to cow's milk protein is believed to be the problem

# Myth No. 14

" Pasteurization destroys Vitamins A, D, E and F, sometimes by as much as 60…. And other water-soluble vitamins by as much as 38 -80%. "

- We think that the claimant here must mean to say Vitamin K and not F.
- Pasteurization of milk does not cause appreciable loss of Vitamin A or any other fat-soluble vitamin.
- See Heat-Induced Changes in Milk, 2nd ed. P.F. Fox, ed. (1995) IDF
- With respect to the other water-solubles in milk, suffice it to say that milk is a good source of thiamine, folate, B-12 and riboflavin and that pasteurization will result in anywhere from zero to 10 percent reduction for each of them.

# Conclusion

- Many negatives are being assigned to the pasteurization of milk. Little, if any of it, is substantiable by the literature currently available.

- We hope that this information will have been helpful to you and we would encourage you to feel free to use the information provided here today as may be necessary.

- This 2005 convening of the NCIMS has a real opportunity to positively impact public health protection nationwide by acting to adopt proposal no. 135, which operates to preclude the sale of raw milk to the unlawful manufacturers of raw milk cheeses.

- We urge that you lend it your support.

“Drinking raw milk or eating raw milk products is like playing Russian roulette with your health.” John F. Sheehan in FDA Consumer Sept/Oct. 2004

USFDA/CFSAN/OPDF/DDES
HFS-367
5100 Paint Branch Parkway
College Park, MD 20740
(301)436-2367

Author: John Sheehan, B.Sc. (Dy.), J.D., Director, DDES
John.Sheehan@fda.hhs.gov

Presenter: Cynthia (Cindy) Leonard, M.S. Dairy Science, Consumer Safety Officer Cynthia.Leonard@fda.hhs.gov

# Questions?