The following are comments and clarifications to a letter from Ted Elkins, Deputy Director, Office of Food Protection and Consumer Health Services, sent to citizens who submitted comments to oppose the Notice of Proposed Action to amend Regulation .06 under COMAR 10.15.06. Production, Processing, Transportation, Storage and Distribution of Milk.

Mr. Elkin’s statements are in green; our rebuttals are in black.

To summarize, Mr. Elkin has made a series of statements unsupported by references and scientific studies. He has ignored many relevant findings concerning the safety and health benefits of raw milk and the increasing evidence of disease caused by pasteurized milk. He has not reported on evidence of bias in reports on alleged problems with raw milk and has withheld discussion of the numerous incidents of food-borne illness in many commonly consumed foods, thus perpetuating the double standard that uninformed health officials have applied to raw milk. The citizens of Maryland deserve accurate information, not unsubstantiated boilerplate allegations.

“The State of Maryland and other federal and state health agencies have documented a long history of the risks to human health associated with the consumption of raw milk. Clinical and epidemiological studies from the Food and Drug Administration (FDA), state health agencies, and others have established a direct causal link between gastrointestinal disease and the consumption of raw milk.”

While several incidents of food-borne illness in recent years have been attributed to the consumption of raw milk, no positive correlation in these cases was established and government reports on these cases show strong evidence of bias. For example, in 1983, a reported outbreak of Campylobacter in raw milk led to the passage of anti-raw milk legislation in the state of Georgia. However, extensive testing failed to find Campylobacter or any other pathogens in any milk products from the dairy. All safety measures had been followed faithfully. In spite of this lack of evidence, the author of the official report concluded: “The only means available to ensure the public’s health would be proper pasteurization before consumption.” (American Journal of Epidemiology, 1983 Vol 114, No 4). Ironically, just 4 years later, a massive outbreak of over 16,000 culture-confirmed cases of antimicrobial-resistant Salmonella typhimurium was traced to pasteurized milk from one dairy in Georgia (JAMA 1987 Dec 11;258(22):3269-74). Yet health officials still allow the sale of pasteurized milk in Georgia.

Another example concerns a November 2001 outbreak of Campylobacter in Wisconsin, which local health officials and the Centers for Disease Control blamed on raw milk from a cow-share program in Sawyer County. According to an official report, posted on the CDC website, 70-75 persons became ill from Campylobacter infection during the 12 weeks following November 10, 2001. However, independent investigators determined that the number of afflicted was over 800. Only 24 of 385 cow-share owners became ill. Most had consumed hamburger at a local restaurant. There was no illness in the remaining 361 cow-share owners and most of those who became ill did not consume raw milk. Health workers at local hospitals showed a clear evidence of bias by testing only those who said they had consumed raw milk; others who reported in sick but had not drunk raw milk were sent home without investigation. Most importantly, independent lab tests found no Campylobacter in the raw milk (www.realmilk.com).
outbreak is one that health officials almost always emphasize when arguing against the consumption of raw milk; yet the evidence of the case points to the fact that raw milk was not the cause of the outbreak.

“The microbial flora of raw milk may include human pathogens present on the cow’s udder and teats.”

Standard sanitary procedures can completely eliminate the presence of human pathogens in human milk. Organic Pastures Dairy in California produces raw milk for retail sales. The dairy and the state have conducted routinely tests for several years and have never found a human pathogen in the raw milk they produce (www.organicpastures.com).

The intrinsic safety of raw milk stands in sharp contrast to the dangers inherent in other foods. For example, a 1978 survey found Salmonella in many “health food” products, including soy flour, soy protein powder and soy milk powder. The authors of the report concluded that “The occurrence of this pathogen in three types of soybean products should warrant further investigation of soybean derivatives as potentially significant sources of Salmonella (Applied and Environmental Microbiology, Mar 1979, pp 559-566).

While raw milk often gets the blame for food-borne illnesses, Campylobacter is best known for contaminating meats. For example, a study carried out during 1999-2000 found that 70.7 percent of chicken and 14.5 percent of turkey samples from Washington, DC grocery stores was infected with Campylobacter. (Zhao C, et al. Applied and Environmental Microbiology, 2001:67(12):5431-5436). Maryland law does not require pasteurization of chicken and turkey, which is highly likely to contain human pathogens, yet has taken steps to deny access to raw milk, which seldom if ever contains human pathogens.

If the goal of the state of Maryland is to eliminate our exposure to human pathogens, perhaps health department officials should take steps to ban the use of coins and cookware. E. Coli has been shown to survive on coins for 7-11 days at room temperature; Salmonella enteritidis can survive 1-9 days on pennies, nickels, dimes and quarters; and Salmonella enteritidis can also survive on glass and Teflon for up to 17 days (Jiang and Doyle. Journal of Food Protection 1999;62(7):805-7).

The truth is that humans are exposed to pathogens on a daily basis—on surfaces, in our water and in the food we eat. To single out raw milk as a source of pathogens shows extreme bias against the only food that is intrinsically safe and that furthermore contains many components that support our immunity to pathogens.

“Further, the intrinsic properties of milk, including its pH and nutrient content, make it an excellent medium for the survival and growth of pathogenic bacteria.”

This statement reveals the complete ignorance of over 40 years of science indicating that raw milk does not support the survival and growth of pathogenic bacteria. Milk contains numerous components that fight against pathogens and strengthen the immune system. These include:

- **Lactoperoxidase**, an enzyme that uses small amounts of H2O2 and free radicals to seek out and destroy bad bacteria. It is found in all mammalian secretions, such as breast milk, tears and saliva. Lactoperoxidase levels are much higher in the milk of animals than humans. For example, lactoperoxidase levels are 10 times higher in goat milk than in human breast milk. So effective is lactoperoxidase in fighting pathogens that other countries are looking into using lactoperoxidase instead of pasteurization to ensure safety of commercial milk (British Journal of Nutrition (2000), 84, Suppl. 1. S19-S25; Indian Journal Exp Biology Vol. 36, August 1998, pp 808-810; 1991 JDairy Sci 74:783-787; Life Sciences, Vol 66, No 23, pp 2433-2439, 2000)

- **Lactoferrin**, an enzyme that steals iron away from pathogens and carries it through the gut wall into the blood stream and also stimulates the immune system. Lactoferrin also ensures complete assimilation of iron by the infant.
- **Polysaccharides**, special sugars that encourage the growth of good bacteria in the gut; protect the gut wall.

- **Medium-Chain Fatty Acids**, special types of fats that disrupt cell walls of bad bacteria; levels are so high in goat milk that the test for the presence of antibiotics had to be changed.

- **Enzymes** that disrupt bacterial cell walls.

- **Antibodies** that bind to foreign microbes and prevent them from migrating outside the gut; initiate immune response (*British Journal of Nutrition* (2000) 84. Suppl. 1, S3-S10, S11-S17).

- **White blood cells** that produce antibodies against specific bacteria, producing immunity for life in the infant.

- **B-lymphocytes**, compounds that kill foreign bacteria and call in other parts of the immune system.

- **Macrophages**, components that engulf foreign proteins and bacteria.

- **Neutrophils**, which kill infected cells; mobilize other parts of the immune system.

- **T-lymphocytes**, components that multiply if bad bacteria are present, while producing immune-strengthening compounds.

- **Lysosyme**, which kills bad bacteria by digesting their cell walls.

- **Hormones & growth factors**, which stimulate the maturation of gut cells thereby preventing “leaky” gut.

- **Mucins**, which adhere to bad bacteria and viruses, preventing those organisms from attaching to the mucosa and causing disease.

- **Oligosaccharides**, special types of sugars which protect other protective components from being destroyed by stomach acids and enzymes; they bind to bacteria and prevent them from attaching to the gut lining and have other functions just being discovered.

- **B12 binding protein**, a component that reduces the levels of vitamin B12 in the colon, which harmful bacteria need for growth. This compound also ensures complete assimilation of B12 by the infant.

- **Bifidus factor** is a complex of good bacteria which promotes growth of *Lactobacillum bifidis*, a helpful bacteria in baby's gut, which helps crowd out dangerous germs.


Most of these components are completely inactivated by pasteurization (*Scientific American*, December 1995; *The Lancet*, Nov 17, 1984), making pasteurized milk highly susceptible to contamination. Mr. Elkin’s statement, that “the intrinsic properties of milk, including its pH and nutrient content, make it an excellent medium for the survival and growth of pathogenic bacteria,” applies only to pasteurized milk, not to raw milk.

It is of interest to note that until recently, the medical profession claimed that breast milk was sterile. Research conducted over the last 20 years indicates that breast milk contains pathogens, often at very

Maryland health officials do not require breastfeeding mothers to pasteurize their milk before giving it to their babies; yet these same officials discourage mothers who are unable to breastfeed from giving their infants the most appropriate and immune-building substitute—raw milk from another mammal such as a cow or goat.

A 1994 study found that premature infants fed raw human milk had lower rates of infection compared to those fed pasteurized human milk (Lancet November 17, 1984). In fact, pasteurization of human milk for babies carries considerable risk. A recent outbreak of *Pseudomonas aeruginosa* in a neonatal intensive care unit caused by a contaminated milk bank pasteurizer resulted in 31 cases of infection and 4 deaths (Arch Dis Child Fetal Neonatal Ed 2003 Sep;88(5):F434-5).

The intrinsic safety of raw milk has been proven in several published reports showing that raw milk passes the “challenge test.” That is, when pathogenic bacteria are introduced to raw milk, their numbers rapidly decline; subsequent testing reveals no pathogens even though they were introduced in large numbers. For example, Lactoperoxidase in raw milk has been shown to kill added fungal and bacterial agents (Life Science 2000 66(25):2433-9; Indian Journal of Experimental Biology 1998;36:808-11).

In a challenge test, raw goat milk killed *Campylobacter jejuni* (Hygiene (London) 1985 Feb;94(1):31-44).

When *Campylobacter* was added to raw milk at 4 degrees C at levels of 13,000,000 per ml, levels were less than 10 per ml nine days later (Doyle, et al. Applied and Environmental Microbiology, 1982;44(5):1154-58). The anti-microbial properties of raw milk are even more active when milk is not refrigerated. Researchers found that bovine strains of *Campylobacter* were decreased by 100 cells per ml and poultry strains decreased by 10,000 cells per ml in 48 hours in raw milk at room temperature (37 degrees C) (Diker KS. Mikrobiyol Bul 1987 Jul;21(3):200-5).

Most recently, the University of California conducted challenge tests on Organic Pastures raw milk in California, finding that pathogens added to raw milk disappeared completely within 36 hours (www.organicpastures.com).

“On August 10, 1987, FDA published 21 CFR Part 1240.61, a final regulation mandating the pasteurization of all milk and milk products in final package form for direct human consumption. This regulation addresses milk shipped in interstate commerce and became effective September 9, 1987. In the Federal Register notification for the final rule to 21 CFR Part 1240.61, FDA made a number of findings including the following: ‘Raw milk, no matter how carefully produced, may be unsafe.’ ”

This statement may be part of the official record but it contradicts other statements published by the US government. A study carried out over 19 years and posted on the Centers for Disease Control website gives the incidence of food-borne illness from raw milk at 1.9 cases per 100,000 people, 1973-1992 (American Journal Public Health Aug 1998, Vol 88., No 8). This report cites many incidents reputed to be caused by raw milk but not necessarily proven; the actual rate of illness caused by raw milk, on a per-consumer basis, may in fact be much lower.

Based on the same CDC website, the incidence of food-borne illness from all foods including pasteurized milk during the period 1993-1997 is 4.7 cases per 100,000 people (US Census Bureau 1997 population estimate 267,783,607). Based on CDC website, the incidence of reported food-borne illness from other foods (not including milk) is 6.4 cases per 100,000 people, per year from 1993-1997. Therefore, the
incidence of food-borne illness from consuming raw milk is at least 2.5 times lower than the incidence of food-borne illness from consuming pasteurized milk; and at least 3.5 times lower than the incidence of food-borne illness from consuming other foods.

Thus the statement published in the FDA register is false; raw milk is safer than any other food in the food supply. If a food is to be taken out of the food supply because it “may be unsafe,” then we would have nothing left to eat. Raw salads, fruits, vegetables, shellfish, eggs and meat, plus pasteurized milk, soy products, baby formula and mayonnaise have all caused proven outbreaks of illness. Yet these foods remain in the food supply, putting the citizens of Maryland at continued risk.

According to our government, food-borne diseases cause approximately 76 million illnesses, 325,000 hospitalizations and 5,000 deaths per year; the most common source of these infections is fruits, vegetables and salads. For example, in 1997, there were 1104 reported cases of food-borne illness from salads and 719 from fruits and vegetables while only 23 from milk, mostly pasteurized milk (MMWR Vol 45, No SS-5).

"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."

This statement would not hold up in a court of law. Today it is completely feasible to perform routine bacteriological tests on raw milk; these can be performed at the farm and are very inexpensive. There is even a test for E. coli O157:H7 that can be carried out on the farm and costs only $8 per test. It is shameful that health officials of the state of Maryland are unfamiliar with these tests.

“Opportunities for the introduction and persistence of Salmonella on dairy premises are numerous and varied, and technology does not exist to eliminate Salmonella infection from dairy herds or to preclude re-introduction of Salmonella organisms. Moreover recent studies show that cattle can carry and shed S. dublin organisms for many years and demonstrated that S. dublin organisms cannot be routinely detected in cows that are 'mammary gland' shedders.”

This statement applies only to large confinement herds. It has proven completely possible to eliminate pathogens from dairy premises when cows are raised on pasture and reasonable sanitary protocols are followed. Over several years of testing, not a single human pathogen has been found on the premises of Organic Pastures dairy in California, not in the manure and not in the milk (www.organicpastures.com).

“During this rulemaking process, the American Academy of Pediatrics and numerous other organizations submitted comments in support of the proposed regulation. In deciding upon mandatory pasteurization, FDA determined that pasteurization was the only means to assure the destruction of pathogenic microorganisms that might be present.”

This statement is completely false. Pasteurization does not ensure the destruction of pathogenic microorganisms in milk. A study published in 2002 found evidence of Mycobacterium paratuberculosis in many samples of pasteurized cow’s milk (Appl Environ Microbiol 2002 May;68(5):2428-35). M. paratuberculosis has been associated with Crohn’s disease.


Furthermore, the US government has documented numerous outbreaks of food-borne illness from pasteurized milk. These include:

- 1945—1,492 cases for the year in the US
- 1945—1 outbreak, 300 cases in Phoenix, Arizona.
1945—Several outbreaks, 468 cases of gastroenteritis, 9 deaths, in Great Bend, Kansas
1976—Outbreak of *Yersinia enterocolitica* in 36 children, 16 of whom had appendectomies, due to pasteurized chocolate milk
1978—1 outbreak, 68 cases in Arizona
1982—over 17,000 cases of *Yersinia enterocolitica* in Memphis, TN
1982—172 cases, with over 100 hospitalized from a three-Southern-state area.
1983—1 outbreak, 49 cases of *Listeriosis* in Massachusetts
1984—August, 1 outbreak *S. typhimurium*, approximately 200 cases, at one plant in Melrose Park, IL
1984—November, 1 outbreak *S. typhimurium*, at same plant in Melrose Park, IL
1985—March, 1 outbreak, 16,284 confirmed cases, at same plant in Melrose Park, IL
1985—197,000 cases of antimicrobial-resistant *Salmonella* infections from one dairy in California
1985—1,500+ cases, *Salmonella* culture confirmed, in Northern Illinois
1987—Massive outbreak of over 16,000 culture-confirmed cases of antimicrobial-resistant *Salmonella typhimurium* traced to pasteurized milk in Georgia
1992—2 outbreaks statewide, 28 cases *Salmonella* infection
1994—3 outbreaks, 105 cases, *E. Coli* & *Listeria* in California
1993—1994—outbreak of *Salmonella enteritidis* in over 200 due to pasteurized ice cream in Minnesota, South Dakota and Wisconsin
1995—1 outbreak, 3 cases in California
1995—outbreak of *Yersinia enterocolitica* in 10 children, 3 hospitalized due to post-pasteurization contamination
1996—2 outbreaks *Campylobacter* and *Salmonella*, 48 cases in California
1997—2 outbreaks, 28 cases *Salmonella* in California

The fact that Mr. Elkins does not present the full story, by enumerating the many outbreaks of food-borne illness in pasteurized milk, provides clear evidence of bias on the part of a Maryland health official.

“This decision was science-based, involving epidemiological evidence. FDA and the Centers for Disease Control and Prevention (CDC) in Atlanta have documented illnesses associated with the consumption of raw milk, including ‘certified raw milk’ and have stated that the risks of consuming raw milk far outweigh any benefits.”

It is obvious that this decision was not science-based and that it contradicts the epidemiological evidence provided by our government agencies.

“Based on research, which has failed to demonstrate a significant difference between the nutritional value of pasteurized and unpasteurized milk, the FDA and CDC reiterate that the health risks associated with raw milk consumption far outweigh the benefits.”

Mr. Elkins seems to be unaware of numerous studies showing the benefits of raw milk over pasteurized. For example, studies carried out during 1935-1940 at Randleigh Farm, a research facility in upstate New York, found that rats fed raw milk had better growth and denser bones than those fed pasteurized milk. The rats on pasteurized milk developed hairless patches due to vitamin B6 deficiency and on autopsy showed poor integrity of internal organs (*Annals of Randleigh Farm*).

These studies confirm the findings of Francis Pottenger who noted that the organs of cats fed raw milk were in excellent condition, with creamy yellow subcutaneous tissue of high vascularity. The heart size of raw-milk fed cats was moderate, the liver in good condition, the intestines firm and the uterus well supported. By contrast the internal organs of pasteurized-milk fed cats were inferior, with slight fatty atrophy of the liver, inferior condition of the heart, lack of intestinal tone and moderate distention of the uterus. The skin of the pasteurized-milk fed cats had a purplish discoloration due to congestion and the fur was of poor quality (*Pottenger’s Cats*, Price-Pottenger Nutrition Foundation).
During 1930-31, Dr. Ernest Scott and Professor Lowell Erf of Ohio State University carried out rat studies that compared the effects of a diet of whole raw milk with one of whole pasteurized milk. Rats fed whole raw milk had good growth, sleek coats and clear eyes. The rats had excellent dispositions and enjoyed being petted. By contrast, rats fed whole pasteurized milk had rough coats, slow growth, anemic, and loss of vitality and weight. They were very irritable, often showing a tendency to bite when handled (Jersey Bulletin 1931 50:210-211, 224-226, 237).

Studies of guinea pigs carried out by Dr. Rosalind Wulzen and Paul N. Harris, Department of Zoology, Oregon State College are particularly revealing. Animals fed whole raw milk had excellent growth and no abnormalities. By contrast, those fed pasteurized milk had poor growth, muscle stiffness, emaciation and weakness and death within one year. Autopsy revealed atrophied muscles streaked with calcification and calcium deposits under the skin, in the joints, the heart and other organs (American Journal of Pathology Vol XXVI, Jul-Nov 1950 pp 595-615).


The scientific literature contains many case histories of recovery from these conditions by eliminating pasteurized milk from the diet. Meanwhile, reports of recovery from these and other conditions by consuming raw milk are accumulating. The growing numbers of Maryland consumers—especially growing children—who cannot tolerate pasteurized milk deserve to have a choice for raw milk.

“Numerous documented outbreaks of milk borne disease involving Salmonella and Campylobacter infections have been directly linked to the consumption of raw milk in the past twenty years. Since the early 1980’s, cases of raw milk-associated campylobacteriosis have been reported in the states of Arizona, California, Colorado, Georgia, Kansas, Maine, Montana, New Mexico, Oregon, and Pennsylvania. An outbreak of salmonellosis, involving 50 cases was confirmed in Ohio in 2002. Recent cases of E. coli O157:H7, Listeria monocytogenes and Yersinia enterocolitica infections have also been attributed to raw milk consumption.”

It would be helpful if Mr. Elkins would provide references so that they could be evaluated for legitimacy and bias. Given the double standard applied to raw milk, it is likely that many of these cases were merely reported, not proven. The 2002 Ohio outbreak that he cites was a case in which health officials demonstrated clear evidence of bias. According to the CDC report, “The source for contamination was not determined; however, the findings suggest that contamination of milk might have occurred during the milking, bottling or capping process." There were many possible vectors of illness on the dairy besides raw milk—besides providing raw milk, the dairy also operated a petting zoo. There have been several incidences of illness contracted by children visiting a petting zoo, cases that have nothing to do with raw milk. Based on this one incident, in which raw milk was not proven the culprit, the dairy, which had been in business for decades without incident, caved in to health department pressure and stopped the sale of raw milk.

“State health and agricultural agencies utilize the U.S. Public Health Service/FDA Pasteurized Milk Ordinance (PMO) as the basis for the regulation of Grade ‘A’ milk production and processing. The PMO has been sanctioned by the National Conference on Interstate Milk Shipments (NCIMS) and provides a national standard of uniform measures that is applied to Grade ‘A’ dairy farms and milk processing facilities to assure safe milk and milk products. Section 9 of the PMO specifies that only Grade ‘A’ pasteurized milk be sold to the consumer.”
This issue is a red herring. The individual states do not need to follow the PMO. The PMO is a choice, not an obligation. California, the top milk-producing state, does not follow the PMO but created its own regulations. Furthermore, the state can accept the PMO but have exceptions in certain areas, as does Colorado. In any event, PMO regulations do not prohibit consumers from drinking raw milk. It must be stressed that neither the federal government nor the individual states prohibit the consumption of raw milk. Such laws would be inherently unconstitutional, depriving citizens the right to liberty and property without due process of law.

“In summary, since raw milk may contain infective doses of human pathogens, its consumption increases the risk of a variety of illnesses. Even when milk is produced and handled under sanitary conditions, the only proven, reliable method of reducing the level of human pathogens in milk and milk products to safe levels is pasteurization. The FDA has strongly advised against the consumption of raw milk. As the State agency responsible for health of the citizens of Maryland, the Department of Health and Mental Hygiene cannot, in good conscience, condone or encourage the sale of raw milk.”

As we have demonstrated in this letter, raw milk does not contain "infective doses of human pathogens" and its consumption does not “increase the risk of a variety of illnesses.” Pasteurization does not guarantee a safe product and the risk of contracting food-borne illness from raw milk is lower than the risk of contracting food-borne illness from pasteurized milk. The statements made in writing by Mr. Elkins would not hold up in a court of law and are an insult to Maryland consumers.

But in any event, Maryland consumers are not asking for legalization of the sale of raw milk, but only confirmation of the right to drink the raw milk from their own cows, which is a public policy of the state of Maryland. Maryland consumers are not asking the Department of Health and Mental Hygiene to condone or encourage the sale of raw milk, but merely insisting that the state of Maryland support the rights of its citizens to enter into contractual agreements guaranteed by Maryland law (title 16, Section 401), which recognizes the right of an owner of dairy livestock to contract with another for the boarding and care of that livestock. MDHMH is interfering in areas where it has no jurisdiction whatsoever and is overstepping the bounds of its regulatory authority.

Sally Fallon, President
The Weston A. Price Foundation
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