

# Appendix 4

## A Reply to the US Food and Drug Administration's (FDA) Statement on Raw Milk

The following letter summarizes the US government's official arguments against raw milk. My comments are in italics.

Dear [Addressee],

This is in reply to your e-mail message of March 11, 2003, in which you requested a statement on the Food and Drug Administration's (FDA) position on the public health concerns surrounding the sale/consumption of raw milk.

Please be advised that FDA 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 FDA, state health agencies, and others have established a direct causal link between gastrointestinal disease and the consumption of raw milk.

*Authorities have greatly exaggerated the "risks to human health associated with the consumption of raw milk." Even before sanitation procedures became routine in dairy barns, honest investigators have demonstrated that the risk from raw milk is very low. Any raw food may contain harmful bacteria if it is produced or stored in an unsanitary manner. Would the FDA outlaw all raw foods? And while the bacteria that might be present in raw milk and other raw foods can cause temporary gastric upset, it poses a*

*serious danger only to those with compromised immune systems (usually the result of immunosuppressive drugs).*

The microbial flora of raw milk may include human pathogens present on the cow's udder and teats. Further, the intrinsic properties of milk, including its pH and nutrient content, make it an excellent media [sic] for the survival and growth of bacteria.

*Milk is indeed an excellent medium for the survival and growth of bacteria—good bacteria. When pathogenic bacteria are added to raw milk, the good bacteria eliminate them, as shown in published studies and in recent tests with the milk from Organic Pastures Dairy in California (see [www.organicpastures.com](http://www.organicpastures.com)). And raw milk from healthy cows, produced under sanitary conditions, simply does not contain pathogenic bacteria.*

On August 10, 1987, FDA published in 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.

*This ruling was made for the benefit of the dairy industry and has nothing to do with the safety of raw milk. In their argument, the FDA ignores numerous outbreaks of food-borne illness due to pasteurized milk.*

In this 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.

*Careful production of raw milk always ensures a safe product. The same cannot be said for pasteurized milk, most of which comes from animals in suboptimal or outright poor health and which furthermore can be contaminated post pasteurization.*

- ♦ 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.

*It is entirely feasible for producers and inspectors to perform daily tests for bacteria in milk. Mark McAfee of Organic Pastures Dairy in California performs such tests daily and posts the results on his website ([www.organicpastures.com](http://www.organicpastures.com)). His bacteria counts are routinely much lower than the very low standards required for unpasteurized milk and he has never detected any pathogen in his milk. Government-sponsored testing by agencies friendly to producers of raw milk would be a boon to small farms everywhere and would help start a resurgence of American's farming communities.*

- ♦ 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* cannot be routinely detected in cows that are mammary gland shedders.

*These points apply to unhealthy cows in modern confinement dairies. I do not recommend consumption of raw milk from these dairies. However, the FDA fails to make this distinction, or any distinction about differences in the quality of raw milk produced under widely disparate conditions.*

- ♦ During this rule making process, the American Academy of Pediatrics and numerous others submitted comments in support of the proposed regulation.

*For decades, the American medical establishment has argued for compulsory pasteurization of all milk, while endorsing formula feeding for babies and the untenable cholesterol theory of heart disease. It opposes all alterna-*

*tive, nontoxic therapies for cancer, while over half of cancer patients seek such treatment. During the early 1600s, William Harvey discovered that blood circulates in the human body; it took the medical establishment over 100 years to accept this fact. Throughout the 1800s, untold thousands of women died shortly after childbirth of puerperal fever. Philipp Semmelweis discovered that the infectious agent was transmitted by the hands of doctors delivering babies after they had carried out work in the dissecting room. His reward: rejection and ostracism, commitment to a mental institution and suicide at the age of 47. I suggest that the medical establishment's arguments against raw milk are at best erroneous, and at worst malicious. The sanctity of America's food supply and the health of our children are too precious to leave any longer entirely in the hands of a medical establishment that has again and again demonstrated a lack of insight, foresight and character.*

In deciding upon mandatory pasteurization, FDA determined that pasteurization was the only means to assure the destruction of pathogenic microorganisms that might be present.

*The FDA ignores the fact that Johnes' bacteria survive pasteurization. The industry's solution to this problem is ultra-pasteurization, but the FDA avoids informing the consumer of this fact. If the FDA's goal is indeed "to assure the destruction of pathogenic organisms that might be present" in the food supply, we may look forward to compulsory irradiation of all foods—to "ensure our safety," and ensure more profits for the food processing and irradiation industries.*

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.

*Can we trust the "documented" cases published by the CDC? Recently the CDC blamed a Wisconsin outbreak of campylobacter involving 800 people*

*on raw milk. Only 23 of those stricken had consumed raw milk—so obviously raw milk was not the cause (see [www.realmilk.com/pr\\_071402.html](http://www.realmilk.com/pr_071402.html)). And in any event, it is the consumer who should make the decision as to whether the risks of consuming raw milk outweigh the benefits, not a government agency with close ties to the dairy industry. FDA and CDC statements about a lack of any benefit from raw milk consumption make a mockery of their claim to “science-based” decisions.*

In light of research showing no meaningful difference in the nutritional value of pasteurized and unpasteurized milk, FDA and CDC have also concluded that the health risks associated with the consumption of raw milk far outweigh any benefits derived from its consumption.

*Note the adjective “meaningful.” FDA and CDC dismiss the great body of scientific evidence indicating the superior nutritional benefits of raw milk as not “meaningful.” The work of Pottenger and many others has proven the nutritional superiority of raw milk compared to pasteurized. These agencies apply the words “meaningful” and “science” only to information that suits their industry-influenced agenda. Contrary information is simply not “meaningful,” and not “science.”*

There are numerous documented outbreaks of milkborne disease involving Salmonella and Campylobacter infections directly linked to the consumption of unpasteurized milk in the past 20 years. Since the early 1980s, 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.

*Many of these cases were assumed and not proven, while others resulted from drinking shabbily produced raw milk that was intended for pasteurization. But while even licensed raw milk has resulted in rare cases of foodborne illness, the numbers are extremely small compared to those caused by other foods—to the tune of 76 million cases per year. Hamburger, mayonnaise, ice cream, eggs, luncheon meats, seafood, lettuce and pasteurized milk have all caused outbreaks of foodborne illness but the FDA does not*

*call for a removal of these items from the marketplace. The double standard is obvious. Carefully produced raw milk has an outstanding safety record. Organic Pastures Dairy sells over 5,000 quarts of raw milk weekly in California; not a single case of illness has been reported. Local Farm has sold raw milk in Connecticut for over ten years without a single case of illness. With government cooperation, farms all over America could duplicate this success.*

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.

*This was the first incident of this kind at the dairy, which had been in operation for two generations and hosted hundreds of thousands of customers per year. This recent case appears to have resulted from unsanitary conditions in the dairy and infection in several workers who passed Salmonella into the milk they handled. Rather than require the implementation of more careful procedures, the dairy closed down the raw milk portion of their operation. The other cases the FDA mentions are isolated individual cases, "attributed" but not proven, that may have been caused by consumption of raw milk produced under less-than-optimal conditions and in most cases intended for pasteurization.*

In the court case Public Citizen v. Heckler, 653f. Supp. 1229 (D.D.C. 1986), the federal district court concluded that the record presents overwhelming evidence of the risks associated with the consumption of raw milk, both certified and otherwise. The court stated that the evidence FDA has accumulated concerning raw milk conclusively shows that raw and certified raw milk are unsafe and there is no longer any question of fact as to whether raw milk is unsafe.

*Fortunately, this uninformed court decision does not apply to state laws. Raw milk is still legally available in the majority of states in the US.*

State health and agricultural agencies routinely use 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.

*These national standards have resulted in the continued degradation of the American milk supply, with the result that more and more individuals are unable to consume commercial milk without suffering health problems. A shrinking customer base is the price the dairy industry has paid for “uniform standards.” Fortunately, Section 9 of the PMO does not allow the federal government to overrule state laws allowing the sale of raw milk.*

In summary, since raw milk may contain human pathogens, the consumption of raw milk products increases the risk of gastrointestinal illness due to the likelihood that it may contain infective doses of human pathogens. The only method proven to be reliable in reducing the level of human pathogens in milk and milk products is by those milk products being produced and processed under sanitary conditions and subsequently being properly pasteurized. The U.S. Food and Drug Administration, therefore, strongly advises against the consumption of raw milk.

*The US Constitution clearly allows every American the freedom to follow his own conscience in matters of food choice. This freedom has been severely restricted in most states and the FDA would have the federal government completely restrict it in every state with laws compelling mandatory pasteurization and forbidding even on-farm sales of raw milk. Will the US government follow the Canadian model and forbid the farmer to feed even his own family raw milk from their own cow? Clearly, mandatory pasteurization is a fascist tactic, the tool of corporate-and industry-influenced government agencies that would be another step towards the enslavement of a once-free people. They cry “public safety;” what we hear is “corporate profits.”*

References related to this subject may be found in the following documents:

- a. *American Journal of Public Health*, November 21, 1997
- b. *Journal of the American Medical Association* October 1984, May 1999, March 3, 1989
- c. *Journal of Public Health Policy, Inc.* September 1981
- d. *Morbidity and Mortality Weekly* June 28, 2002
- e. *Journal of Food Protection* Volume 61, Number 10, 1998
- f. *United States Department of Agriculture (USDA) Fact Sheet*, July 1995

*Most of these publications are position papers that naturally reflect the FDA bias against raw milk. The Journal of the American Medical Association article October 1984 is the duplicitous "Health Fetish" article that completely distorts the findings of Dr. Pottenger (see [www.realmilk.com/schmid\\_healthfetish.html](http://www.realmilk.com/schmid_healthfetish.html)). The Morbidity and Mortality Weekly article repeats CDC falsehoods about an outbreak of campylobacter in Wisconsin (see [www.realmilk.com/pr\\_071402.html](http://www.realmilk.com/pr_071402.html)). Several of the incidents detailed in the Journal of Food Protection article involved pasteurized milk and cheese. These articles perpetuate FDA's double standard and ignore the long record of safety and benefit from carefully produced raw milk.*

We trust this information responds to your request. If you would like additional information or have any questions, please feel free to call Mr. Robert Hennes, Chief, Milk Safety Team at (301) 436-2175. If we can be of any further assistance, please feel free to contact us.

Sincerely,

Joseph R. Baca, Director, Office of Compliance  
Center for Food Safety and Applied Nutrition

*I urge everyone to contact the Center for Food Safety and Applied Nutrition and insist on your right to consume raw milk produced by America's family farms. To all of you who care about raw milk and freedom, there's work to*



*be done. In the late 1700s, the Irish statesman Edmund Burke wrote, “All that is required for evil to triumph is for good men to do nothing.” Good men and women everywhere should understand that the right to choose the food we eat is basic to life, liberty and the pursuit of happiness. Vigilance is the price of freedom and if ever there was a time for vigilance and for activism, it is now.*