

FDA Citizen Petition

Request to Amend CFR 1240.61 Interstate commerce of Tested, State Inspected Raw Milk

Division of Dockets Management
FDA, Department of HHS
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The undersigned submits this “Citizens Petition” as a request for the FDA Commissioner to amend CFR 1240.61 and hereby request “for good cause as shown in this petition” that the FDA commissioner through his or her power make the changes requested herein.

A. Action requested:

Amend CFR 1240.61 to include an *exception as shown below.
For reference the full text of CFR 1240.61 is copied below:

TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN SERVICES
SUBCHAPTER L - REGULATIONS UNDER CERTAIN OTHER ACTS
ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION
PART 1240 - CONTROL OF COMMUNICABLE DISEASES
subpart d - SPECIFIC ADMINISTRATIVE DECISIONS REGARDING
INTERSTATE SHIPMENTS

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

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized *or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except

where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

****Exception requested: Raw milk that is tested, state inspected, state regulated, carries a “government warning statement” and labeled for retail sale in one state may be transported to another state if that other state allows the sale of raw un-pasteurized milk and or dairy products.***

B. Statement of grounds:

Raw un-pasteurized milk that is tested and authorized by a state dairy regulatory agency for retail sale within a state is not the same raw milk that is produced as intended for pasteurization under the PMO. The standards and testing protocols are completely different. In some states including California, Washington, and Pennsylvania, Raw milk intended for authorized retail sale must pass “finished pasteurized milk standards” without first being pasteurization. This includes the requirement of less than 10 coliforms and less than either 15,000 or 20,000 SPC in finished retail product. This is the same as allowed by the PMO for pasteurized products. It is extremely safe but not perfect. No food is perfect. Not even pasteurized products.

This state inspected and approved raw milk is insured for liability by the producer, labeled especially with a “warning label” that notifies the consumer that pathogens could be present because the product is not pasteurized and is tested intensively by the producer in addition to state standards.

Advances in technology and understanding of microbiology now allow the production of safe raw milk to a reality and not just random chance. A good example is Claravale Dairy in California. In more than 80 years of continuous raw milk production not one pathogen has ever been detected in its raw milk.

At Organic Pastures Dairy Company in California more than 110 million servings of its raw milk products have not found one pathogen in its “raw milk”. This amounts to more than 5000 environmental and raw milk samples...all negative. There has been only one sample of raw cream that tested positive for a pathogen (Campylobacter). The raw milk that this cream was taken from tested negative. This incident produced no reported illnesses.

One additional incident involved a positive test for Listeria Monocytogenes in raw cream. But this cream was being made into butter and had been purchased from a pasteurized milk plant and was not a product of the raw dairy. No illnesses were reported.

Twenty one years ago, CFR 1240.61 was first enacted to stop the interstate shipment of raw milk that could possibly carry pathogens. While it is true that raw milk that is not tested or regulated but is intended for pasteurization may contain pathogens a certain amount of the time, this has not proven to be true with regulated, retail authorized and tested raw milk that is intended to be consumed raw. In California more than 410 stores

carry raw milk consumed by more than 40,000 consumers. The safety of this raw milk market example has been shown to be excellent. Yet Nevada which does allow the sale of raw milk if certified can not provide this same product to its consumers.

This growing consumer demand creates a “state-line underground black market”. The same black market conditions are occurring in Pennsylvania, Washington DC and the surrounding states. In these areas raw milk is a multimillion dollar black market. History tells us that where ever there is a black market there is an increased chance of illness because regulation and testing is not performed and the consumer truly has no idea what they are getting. In New York, there are thousands of people that get their raw milk from ice chests at mid-night from raw milk “speak easy” rendezvous points. This raw milk is smuggled from Pennsylvania where raw milk sales are legal. Consumers will do anything for raw milk.

Contrary to the official FDA policy position on raw milk, raw milk consumers do not want milk that has been pasteurized or rendered biologically denatured by heat. This is because these consumers very much intend and desire to consume the biodiversity of good bacteria and active enzymes found in raw milk. For the hard science behind why raw milk and or raw colostrum is bio-actively different than pasteurized products please see Gapper et al. (peer reviewed research in the Analysis of Bovine Immunoglobulin G in milk and colostrum and dietary supplements as published in the 2007 Anal of Bioanalytical Chemistry attached). Research tells us that there are dramatic bioactive changes that occur when raw milk is pasteurized. These biological changes effect nutrition and effectiveness of the milk as a healing food.

The recent market success of Dannon Activa yogurt is a good example of consumers wanting bacteria in their food. Raw milk contains literally one hundred (or more) different kinds of beneficial bacteria at very low levels. Dannon Activa contains perhaps six at high levels. Raw milk also contains raw fats and enzymes that are rare in the American diet today and missing in yogurt. Raw milk consumers define nutrition differently than the FDA. These consumers see any destruction of enzymes and beneficial bacteria to be a detriment to the nutrition and digestibility of a whole food. The FDA position has historically been that pasteurization does not change the nutritional value found in milk. Raw milk consumers disagree and should be free to consume foods that are whole and un processed.

Arguments for raw milk are framed below:

- The physical location of raw milk does not change its safety. If it is safe on a retail store shelf in California then that same raw milk if delivered to Las Vegas is still safe. It is bottled in a tamper proof evident sealed container and kept cold for the one hour drive from California to Las Vegas where consumers demand the product but can legally get it because of CFR 1240.61.
- Nearly all enzymes are inactivated permanently by heat pasteurization.

(PMO- negative alpha phosphatase test shows enzymes are inactivated permanently- the definition of pasteurized milk). Raw milk consumers demand enzyme rich raw milk. Enzymes matter to raw milk consumers.

- Nearly all bacteria are destroyed by heat pasteurization. Consumption of a biodiversity of good bacteria is directly related to increased immune function and strength. This is demonstrated by doctors and pediatricians when they recommend pro-biotics or yogurt consumption after chemotherapy or antibiotics. Raw milk is much more effective than pro-biotics or yogurt because it contains a broader biodiversity in their natural form. Raw milk consumers demand pro-biotic whole raw milk that still contains its bacteria.
- Lysing action (secondary to pasteurization) create pieces of denatured bacteria that can often trigger histamine reactions in milk consumers. This reaction is especially hard on Asthmatics. Raw milk does not cause this reaction and raw milk has been shown to improve asthma (PARSIFAL study of 15000 children in EU). Raw milk consumers report a benefit to asthma and other immune system challenges after consuming raw milk and demand that they be able to treat themselves with whole foods and not be reduced in their treatment choices to just FDA approved drugs with their side effects which can be very serious. FDA approved drugs treat the signs and symptoms of illness and many times allow the underlying process to continue. Raw milk nutritionally treats the underlying conditions of the disease process.
- It has been found that people that drink raw milk actually become immune to pathogens that may make others ill. This is central to the prevention argument that this petition makes. A pathogen is not a pathogen unless the immune system is weakened and susceptible. Raw milk consumers intentionally decide to strengthen their immune systems by exposure to a biodiversity of good bacteria. This consumption and exposure provides immunity and improved health. See research on Campylobacter.
- It has also been found that raw milk does not cause lactose intolerance when pasteurized milk does cause lactose intolerance in a large percentage of the population. This is because raw milk enzymes are active and lactobacillus bacteria found in raw milk create the missing lactase enzyme for those that do not make enough of this enzyme. This means that for 10-25% of the population pasteurized milk is not an option for them and raw milk is the preferred choice.
- In addition, raw milk still has active phosphatase enzymes. Pasteurization by definition destroys all of this enzyme. If a person suffers from osteoporosis, they can not effectively absorb or utilize minerals because this enzyme is missing or less active. Raw milk satisfies this problem and bone density increases are seen as a direct result. Evidence of this science was presented at the SB 201 Senate hearings held in Sacramento California in 2008.

- People want the choice to build their immunity. Currently western medical doctrine does not build immunity, but rather prescribes antibiotics to kill the invading pathogen. This may or may not work. But in the end, the continued use of antibiotics weakens the immune system and creates super bugs that sicken and kill Americans like never before. These statistics are not counted in the food safety data base. Exposure to low levels of biodiversity increases immunity to pathogens. Immunoglobulins found in raw milk bio-actively protect against infection and illness (Gapper et al). These properties are inactivated by heat.

For these many reasons consumers seek out raw milk even at “double the price” for its healing and nutritional qualities. Raw milk is not a drug but yet it has incredible healing qualities because of its natural biological effects on human physiology.

Safety and Fairness:

Raw milk is not made safer because of physical location. If it is safe to sell in California then it should be safe to sell that same raw milk in Nevada or Arizona where ever it is also legal to sell raw milk.

The CDC and the FDA have historically statistically bunched together incidents of raw milk cheese, pasteurizer failures and raw milk illnesses. We argue that this is improper and misstates the facts. When researching deaths caused by raw milk, some of these deaths were not from raw milk at all but instead from raw milk cheeses. Raw milk cheeses have the lowest sanitary standards of any of the dairy products and do not require pathogen testing. The single standard used for production of raw milk cheese is the aging of the raw milk cheese for more than 60 days. **Raw milk cheese can be made from milk intended for pasteurization.** Raw milk cheese source milk does not require any pathogen testing.

Raw milk that is intended to be sold raw at retail stores must pass intensive biological testing and pathogen tests and this safety data must not be combined with raw milk cheese data. The incidence of food borne illness from retail approved, tested, state inspected raw milk is much lower than other raw food products or even pasteurized milk.

In 2007 three people died after drinking pasteurized milk in Massachusetts at Whittier Farms . In August 2006, three died after eating spinach and more than 200 were made sick. Yet these foods are not subject to state line regulation. This petitioner requests that the FDA look at raw milk intended for human consumption differently than it looks at raw cheese or raw milk that is intended for pasteurization. All three of these products have completely different standards and protocols for testing and production.

FDA policy requires individual standards to be applied to each instance and that over broad standards often can not be applied because of erroneous outcomes from misapplied

science or standards. The CDC does not list one single *Listeria Monocytogenes* illness that was caused by raw milk consumption that was sold at a retail store. All of the illness cases were related to pasteurized milk or raw cheeses that had been heated to below pasteurized temperatures. If a raw milk illness was listed as associated with raw milk consumption, that illness was from raw milk that was not tested or from a state inspected program.

The CDC lists hundreds of thousands of people sickened by *Salmonella* secondary to pasteurized milk. *E. coli* O157H7 does have some raw milk related illnesses reported but none that were confirmed to be from retail approved and tested raw milk products. These cases were generally from untested black market sources. *Campylobacter* is a very fragile pathogen and rarely causes disease in those that drink raw milk on a regular basis and University studies show that raw milk consumers routinely test positive for *Campylobacter* antibodies etc. Again, consumers of raw milk want to build immunity to pathogens so that they are immune to them. It is type of oral vaccination per se. Please see supportive studies.

The petitioner agrees that raw milk that is intended to be pasteurized can and does often contain pathogens that could make an immune depressed consumer of that raw milk ill.

The petitioner agrees that while there is no guarantee that tested raw milk from any source could possibly contain a pathogen. This is a very rare incident. Consumers weigh this very slight possibility of illness against the certainty of improved health and make an informed decision when they purchase raw milk. All raw milk carries a government warning on the label just like all meats and most other unprocessed foods.

No other foods have been singled out for state line FDA prohibition. Raw Milk stands alone as the single food that can not be taken across state lines and consumed. There is no rational argument that can be made to defend this regulation. In places where raw milk is illegal...people buy their own cows and sell the extra raw milk in a black market. In places where raw milk can be sold, consumers love it and are angered when they move or travel and can not buy it in other areas of the USA.

C. Environmental impact:

There is no negative environmental impact from this petition or change of CFR 1240.61.

D. Economic impact:

There is no negative economic impact from this petition. If anything, the impact will be positive because more consumers will have an opportunity to build their immune systems so that they can resist infection and illness. At present 247 citizens die every day (CDC data) secondary to antibiotic resistant infections, immune depression and MRSA and VRA infections. This number is actually much larger when considering other immune related diseases.

In America, we are all coping with an economic and health care crisis with few answers as to how to make preventative care and nutrition a reality. This petition can offer a consumer grass roots solution to immune depression by allowing consumers to take charge of their own health and prevent disease by strengthening immunity through nutrition.

It is hoped that by building immunity fewer citizens will become ill or die. Natural doctors and many Western trained doctors now recommend consuming raw milk after antibiotic use to rebuild essential biology in the gut that is killed off by antibiotics. Russian Space program doctors recommend that their Cosmonauts drink raw milk and Kefir made from raw milk to build immunity.

E. Certification:

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

If accepted by the FDA, this “citizens petition” will submit thousands of testimonials and medical doctors reports in support of raw milk. This will include PhDs from leading Universities including Rutgers, Stanford and others.

We are hopeful that based on the facts and the will of the people that the FDA will permit this “citizens petition” to proceed forward.

Raw milk can not guarantee a perfect promise of safety, neither can any other food....it is instead, a promise of a stronger immune system and better health. It is living, whole, enzyme rich, bio-diverse food in a world of processed, preserved, irradiated, denatured, non bioactive food.

Health is the pathway to happiness. Surely you can not be happy if you are not healthy. Happiness is a right assured by our constitution.

We ask that the FDA allow consumers to make their own food choices and “tear down that wall” created by CFR 1240.61 for tested retail approved raw milk.

For the people across state lines,

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Enclosures and attachments:

Binder-Raw milk the unheard argument AB 1735
Binder-For the Raw Milk Consumers of CA
Binder-Pathogen tests in CA
Published Analysis of Raw colostrum and Raw milk IgG, (peer reviewed Gapper et al.)