

***Federal Regulations  
and Information about  
Raw Milk and Raw Milk Products***

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# ***The Federal Regulation of Raw Milk***

## ***21 CFR 1240.61***

“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.....”

# 21 CFR 1240.61

## Mandatory Pasteurization with Three Exceptions

- One: “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”.



# 21 CFR 1240.61

## Mandatory Pasteurization with Three Exceptions

- Two and Three: “The final rule does not apply to the interstate transportation of raw (unpasteurized) milk to dairy processing plants for pasteurization or to raw milk products in intrastate commerce”. 52 Fed. Reg. 29509 (1987) at 29509



# Federal Definition of Milk Products

## 21 CFR 1240.3 (j)



- **Definition. Milk products.** Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following:
- lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation),



# Federal Definition of Milk Products

## 21 CFR 1240.3 (j) (continued)

- whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and

# Federal Definition of Milk products



## 21 CFR 1240.3 (j) (continued)

- any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

# Raw Milk - Public Health Risk

- FDA has had a longstanding position that unpasteurized (raw) milk is an inherently unsafe food that poses a significant health risk to the public.
- FDA's position is consistent with that of the American Medical Association, which holds as policy the position that "all milk sold for human consumption should be required to be pasteurized." The elderly, children, infirm, and immuno-compromised persons are at particular risk for severe illness from pathogens that can be found in raw milk.



# Organizations Endorse Pasteurization

- In a press release issued jointly by FDA and CDC in 2007, the agencies noted that in addition to CDC and the FDA, “the American Medical Association, the American Academy of Pediatrics (AAP), the National Conference on Interstate Milk Shipments, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials and other organizations have endorsed the pasteurization of milk and prohibition of the sale of raw milk and products containing raw milk.”

# Position Statements

## Public Health Risks of Raw Milk

- American Medical Association, see American Academy of Pediatrics,  
<http://pediatrics.aappublications.org/content/pediatrics/early/2013/12/10/peds.2013-3502.full.pdf>
- Association of Food and Drug Officials, available at  
<http://www.afdo.org/Resources/Documents/4-news-and-events/AFDO-Position-Statement-Raw-Milk-Dec-2006.pdf>
- CDC. The Ongoing Public Health Hazard of Consuming Raw Milk. May 9, 2014 Letter to State and Territorial Epidemiologists and State Public Health Veterinarians.  
<http://www.cdc.gov/foodsafety/pdfs/raw-milk-letter-to-states-2014-508c.pdf>

# CDC

- In 2012, Langer et al. from CDC reported that during 1993 to 2006, 73 outbreaks were associated with unpasteurized dairy products.
- 1,571 cases, 202 hospitalizations, and 2 deaths
- Seventy-five percent (55 outbreaks) of the unpasteurized dairy outbreaks occurred in 21 states where raw milk sale is legal.

# CDC

Langer et al. (2012) made several key conclusions, including:

- legal intrastate sale of unpasteurized dairy products is associated with a high risk for dairy-related outbreaks;
- the rate of outbreaks caused by unpasteurized dairy products was about 150 times greater than outbreaks linked to pasteurized dairy; and
- unpasteurized dairy outbreaks led to much more severe illnesses in, and disproportionately affected, younger people (under age 20).

# CDC

- In 2017, the Centers for Disease Control and Prevention (CDC) calculated that consumers of unpasteurized dairy products (milk and cheese) were 840 times more likely to experience foodborne illness and 45 times more likely to be hospitalized due to foodborne illness, when compared to consumers of pasteurized dairy products.
- CDC reported that sixty percent (60%) of the people sickened in raw milk outbreaks from 1993 through 2006 were younger than twenty (20) years of age.

# References and Information

“Raw Milk & Pasteurized Milk”

with additional web links can be found at

- <https://www.fda.gov/Food/PopularTopics/ucm293042.htm>
- <https://www.cdc.gov/phlp/publications/topic/anthologies/anthologies-rawmilk.html>
- <https://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html> .

# References

- American Medical Association (H-150.980, Milk and Human Health) <https://policysearch.ama-assn.org/policyfinder/detail/milk?uri=%2FAMADoc%2FHOD.xml-0-654.xml>
- FDA, Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption. 52 FR 29514 (1987) and 21 CFR 1240.61. 21 CFR 1240.61  
<https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol8/pdf/CFR-2012-title21-vol8-sec1240-61.pdf>
- Definition of Milk Products. 21 CFR 1240.3 (j)  
<https://www.govinfo.gov/content/pkg/CFR-2018-title21-vol8/pdf/CFR-2018-title21-vol8-sec1240-3.pdf>

# References

- Costard et al. 2017. Emerging Infectious Diseases. 23:957-964.  
<https://wwwnc.cdc.gov/eid/article/23/6/pdfs/15-1603.pdf>
- Langer et al. Emerging Infectious Diseases. 2012. 18:385-391. Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws- United States, 1993–2006,  
[https://wwwnc.cdc.gov/eid/article/18/3/11-1370\\_article](https://wwwnc.cdc.gov/eid/article/18/3/11-1370_article)
- CDC’s webpage on raw milk-associated outbreaks  
<https://www.cdc.gov/foodsafety/rawmilk/rawmilk-outbreaks.html>
- FDA, CDC. “FDA and CDC Remind Consumers of the Dangers of Drinking Raw Milk,” <https://wayback.archive-t.org/7993/20161022191258/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108856.htm>





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