

The US Regulatory Pathway to Non-thermal Pasteurization of Milk Products

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Definition of Pasteurized

The term “pasteurized” and “pasteurization” are often used generically.

21 CFR 1240.61 defines pasteurization for milk products (and makes pasteurization mandatory for milk products).

21 CFR 1240.61

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

Temperature	Time
145 °F (63 °C) ¹	30 minutes.
161 °F (72 °C) ¹	15 seconds.
191 °F (89 °C)	1 second.

¹ If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F (3 °C).

Temperature	Time
194 °F (90 °C)	0.5 second.
201 °F (94 °C)	0.1 second.
204 °F (96 °C)	0.05 second.
212 °F (100 °C)	0.01 second.

(c) Eggnog shall be heated to at least the following temperature and time specification:

Temperature	Time
155 °F (69 °C)	30 minutes.
175 °F (80 °C)	25 seconds.
180 °F (83 °C)	15 seconds.

21 CFR 1240.61

(d) Neither paragraph (b) nor (c) of this section shall be construed as barring any other pasteurization process that has been recognized by the Food and Drug Administration to be equally efficient in the destruction of microbial organisms of public health significance.

How does FDA recognize a pasteurization process?

In 2002 the Farm Bill modified the Federal Food, Drug, and Cosmetic Act to regulate the use of the term “pasteurized” in food labeling.

FFDCA Section 403 (21 USC §343)

- Section 403 starts with “A food shall be deemed to be misbranded—”
- Subsections 403(a) – 403(y) start with “If...” and describe conditions where food would be misbranded.
- 403(h) defines the conditions by which a food may be considered “pasteurized.”

FFDCA Section 403(h)(3)

Sec. 403 [21 USC § 343] Misbranded food

A food shall be deemed to be misbranded—

(h) If it purports to be or is represented as—

.....

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this chapter; or

FFDCA Section 403(h)(3)(B)

(B)(i) such food has been subjected to a safe process or treatment that—

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

FFDCA Section 403(h)(3)(B)(ii)

B(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

For purposes of paragraph (3), a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i) shall constitute final agency action under such subclauses.

FFDCA Section 403(h)(3)

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 21 CFR 1240.61

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(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

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Eliminating the most-resistant pathogen

- Identify all of the pathogens that are likely to occur in the food (risk assessment).
- Determine which is most resistant to the specific proposed treatment.
- Eliminating the most resistant organism ensures safety.

A List of Pathogens in Milk*

- *Bacillus cereus*
- *Listeria monocytogenes*
- *Yersinia enterocolitica*
- *Salmonella spp.*
- *Escherichia coli* (O157:H7 and others)
- *Campylobacter jejuni*
- *Mycobacterium*
- *Coxiella burnetii*
- *Brucella*
- Parasites (*Crypto*)
- Viruses (TBEV)

*an incomplete list

Coxiella burnetii

PUBLIC HEALTH MONOGRAPH No. 47

Thermal Inactivation Of *Coxiella burnetii* In Milk Pasteurization

John B. Enright, Ph.D.
Walter W. Sadler, D.V.M.
Robert C. Thomas, M.S.



U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

- Identified as most resistant to *thermal* treatment
- May not be most resistant to other technologies but little data is available

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(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

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(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this chapter; or

Q: What is the log reduction target for milk pasteurization?

- A. >3 Log reduction
- B. >4 Log reduction
- C. >5 log reduction
- D. >6 log reduction

E. The FDA has not established any log reduction equivalents for pasteurization processes defined in 21 CFR 1240.61

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(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

Effective for the shelf life

- The safety of pasteurized food must be maintained despite abusive storage conditions such as temperature.
- The intended shelf life of the product must be defined in the notification.
- The conditions of “moderate abuse” are not defined and must be defined in the notification.



How are they evaluated?

- 403(h) authority has been officially delegated to CFSAN Office of Food Safety
- Point of Contact:



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What about Standardized Dairy Products?

Pasteurization is defined as a thermal process in:

- 21 CFR 131 MILK AND CREAM
- 21 CFR 133 CHEESES AND RELATED CHEESE PRODUCTS
- 21 CFR 135 FROZEN DESSERTS

What about the PMO?

- 2019 Grade “A” Pasteurized Milk Ordinance, Definitions (Page 11) **RR. Pasteurization:**
“...nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by FDA as provided in Section 403 (h)(3) of the FFD&CA.”

(But obviously, PMO changes will be necessary to account for non-thermal process parameters)



THANK YOU!

