



FEDERAL REGULATION OF RAW MILK CHEESE

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Background

- Safety of raw milk cheeses is a public health concern.
- The presence of pathogens in dairy products is an indicator of poor sanitation, temperature abuse, inadequate pasteurization, fermentation failure, or obtaining milk from sick animals.
- Raw milk has been shown to be a major source of foodborne pathogens from prevalence studies.



Background cont.

- Consumption of contaminated raw milk products has led to several foodborne outbreaks including brucellosis, salmonellosis, listeriosis, HUS associated with *E. coli* 0157:H7, staph. enterotoxin poisoning etc.
- Between 1941 to 1944, there were outbreaks of illnesses due to the consumption of cheeses made from raw milk.
- By 1946, there were scientific reports indicating the survival of pathogenic bacteria in raw milk cheeses.



Background cont.

- FDA in 1949 promulgated standards for cheese as a response to numerous foodborne outbreaks due to consumption of improperly heat treated or raw milk cheeses.
- In the 1960's more challenge studies were carried out to investigate the survival of pathogens after the 60-day aging period.



Regulation /Policy

- In 1987, FDA prohibited interstate sale or distribution of non-pasteurized dairy products to consumers.
- Current Federal Regulations (21 CFR 1240.61) require:
 - “mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption”



Regulation /Policy cont.

Exception:

- Cheeses identified by standards at 21 CFR 133 *et seq.* may be made from raw milk. They typically have to be aged for a defined time period in order to control microbial pathogens.
- 21 CFR 133 *et seq.* regulates cheeses made with alternative procedures to pasteurization; requires raw milk cheeses to be aged for not < 60 days at $\geq 35^{\circ}\text{F}$.



Regulation /Policy cont.

- There are cheese varieties not covered by either specific varietal standards or category standards at 21 CFR 133.
- These cheeses are covered by 21 CFR 1240.61 when in interstate commerce.



Examples of standardized cheeses with optional pasteurization requirement

Types of cheese	Aging Requirements
○ Asiago fresh/soft	≥60 days
○ Asiago medium	≥6 months
○ Cheddar	≥90 days
○ Colby	≥60 days
○ Gorgonzola	≥90 days
○ Gouda	≥60 days
○ Grated cheeses	≥60 days
○ Hard grating	≥60 days
○ Gruyere	≥6 months
○ Parmesan and Reggiano	≥10 months
○ Romano	≥5 months



NACMCF Recommendation

- FDA (1996) commissioned the Cheese Subcommittee of NACMCF to evaluate the current aging period for raw milk cheese.
- NACMCF findings indicated that pathogens can survive in some raw milk cheeses aged for 60 days.
- NACMCF recommended that FDA re-examines current policy regarding minimum 60-day aging period.



FDA Guidance

- Compliance policy guides (CPGs) provide direction to FDA investigators and the regulated industry as to how FDA will enforce laws.
 - CPG Sec. 527.300 Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity (CPG 7106.08).



CPG Sec. 527.300

- FDA reviews available evidence to determine whether a dairy product is adulterated and, in doing so, will be guided but not bound by this CPG. E.g.:
- Dairy products may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health when:



CPG Sec. 527.300, cont.

- *Staphylococcus aureus* are present at levels greater than or equal to 10^4 cfu/g.
- *Bacillus cereus* are present at levels greater than or equal to 10^4 cfu/g.
- *Escherichia coli* is found in Cheese and cheese products made from raw milk at levels greater than 100 MPN/g in two or more subsamples or greater than 1000 MPN/g in one or more subsamples.



Outbreaks from Raw Milk Cheeses

- CDC published a 2012 survey of foodborne outbreaks from 1993 to 2006 due to consumption of pasteurized and nonpasteurized cheeses.
 - 121 outbreaks with known pasteurization status.
 - 73 (60%) from nonpasteurized dairy products.
 - 65/121 from cheeses
 - 27(43%)/65 from nonpasteurized cheeses



Outbreaks, cont.

- Various recalls and outbreaks over the past 20 yrs are associated with soft and semi-soft cheeses.
- These outbreaks resulted in over 3000 illnesses, 140 hospitalization and at least 50 deaths.
- In 2010, 2 multistate outbreaks from raw milk cheese contaminated with *E. coli* 0157:H7- about 46 cases.



Traditional Cheese Manufacturing

- FDA has noted an increase in the number of artisanal cheese manufacturers within the US. Often these cheeses are made from raw milk.
- Also a lot of “traditional” or “premium” cheeses imported from other countries is a concern since the cheeses are often made from raw milk.



FDA's Goals

- FDA is conducting inspections of soft/semi soft, including artisanal cheese manufacturing facilities for presence of *L. monocytogenes*.
- FDA is currently developing a Risk Profile on Raw Milk Cheeses.



Raw Milk Cheese Risk Profile

- This risk Profile is being developed in response to NACMCF/FDA's concerns regarding cheeses contaminated with microbial pathogens with emphasis on raw milk cheeses.
- Current scientific research investigations have concerns on the effectiveness of the 60-days minimum aging period to control microbial pathogens in raw milk cheeses.
- Some studies suggest that aging allows an outgrowth of pathogens in certain varieties of cheeses e.g. soft cheeses.



Raw Milk Cheese Risk Profile, cont.

- Other studies suggest that pathogens can survive for prolonged periods of time in semi-soft and hard cheeses.
- The Risk profile reviews the current scientific literature relevant to the microbiological safety of major classes of cheese and strategies to reduce or prevent contamination of raw milk cheeses.



Raw Milk Cheese Risk Profile, cont.

Objectives:

- To aid the agency to scientifically assess the safety of raw milk cheeses.
- Be able to identify those cheeses that are high, medium or low risk.
- Evaluate the utility of the 60-day aging as an alternative to pasteurization.



Raw Milk Cheese Risk Profile, cont.

- To comprehensively review the characteristics of the microbial pathogens implicated in raw milk cheese-associated illnesses.
- Identify the contributing factors to outbreaks from raw milk cheese consumption.



Some Challenge Studies

- **Growth of *Listeria monocytogenes* in Camembert and other soft cheeses at refrigeration temperatures.**

Back et al. (1993).

Summary: *Listeria monocytogenes* survived and multiplied when inoculated directly into the cheese milk of laboratory made Camembert cheeses. The rate and extent of growth was reduced at lower storage temperatures. Significantly higher rates of growth occurred at the surface compared with the centre of the cheeses. Similar results were obtained with Camembert cheeses surface inoculated after manufacture.



Challenge Studies, cont.

- **Survival of Enterohemorrhagic *Escherichia coli* 0157:H7 During the Manufacture and Curing of Cheddar Cheese**

Reitsma and Henning (1996).

Summary: Cheese made with milk inoculated with $1 \cdot 10^3$ CFU/ml E coli 0157-H7 showed a 2-log to <1 CFU/g reduction after 60 days of ripening but was detected in 25g of cheese @ 158 days.



Challenge Studies, cont.

- **Comparison of media and sampling locations for isolation of *Listeria monocytogenes* in Queso Fresco cheese.**

Lin et al. (2006).

Summary: *L. monocytogenes* survived and multiplied in soft cheeses. Queso fresco cheese was inoculated @ 10^0 or 10^1 CFU/g with 5-strain mixture of *L. monocytogenes* and stored @ 21, 12 and 4 °C. At the end of storage (12 to 21 weeks), higher counts of *L. monocytogenes* were obtained from both the surface and the interior of cheese samples.



Challenge Studies, cont.

- **Survival of a five-strain cocktail of *Escherichia coli* O157:H7 during the 60-day aging period of cheddar cheese made from unpasteurized milk.**

Schlesser et al. (2006).

Summary: This study confirmed that 60-day aging is inadequate to eliminate *E. coli* O157:H7 during cheese ripening.

- **Behavior of *Escherichia coli* O157:H7 during the manufacture and aging of gouda and stirred-curd cheddar cheeses manufactured from raw milk.**

D'Amico et al. (2010).



Some Risk Management Questions

- What are the risk factors associated with raw milk?
- Which cheeses pose the greatest risk? (i.e., where should we focus our attention?)
- Is the 60-day aging process sufficient to protect public health when raw milk is used in cheese manufacturing?
- Are there any effective alternatives to milk pasteurization & the 60-day aging process when raw milk is used?
- What is the contamination rate in raw milk?



Risk Management Options

- There is a need to identify risk management options to prevent or reduce illnesses associated with consumption of raw milk cheese.
- These options need to be evaluated in terms of safety and efficacy.



Summary

- The majority of the outbreaks associated with cheese consumption is linked to consumption of raw milk cheeses.
- So far, fresh soft cheeses made from raw milk pose the greatest risk.
- Manufacturers of raw milk cheeses should consider using additional risk management options provided they are permitted by law generally so as to reduce risk of further outbreaks of illnesses associated with raw milk cheeses.



Summary cont.

- Research has shown that the 60-day aging period seems ineffective to stop the survival and growth of pathogenic microorganisms in certain raw milk cheeses.
- FDA's intention for developing the Raw Milk Cheese Risk Profile is to determine what risk management options are available to manage the risks posed by raw milk cheeses.

Thank You!!!

