Food Protection Trends, Vol. 25, No. 10, Pages 767–770

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International Association for Food Protection

Origin of the 60-day Minimum Holding Period Requirement for United States Cheeses Made from Sub- or Unpasteurized Milk

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SUMMARY

The 60-day minimum holding period requirement for cheeses manufactured from sub- or unpasteurized milk in the United States is intended to reduce the likelihood of consumer exposure to pathogenic microbes that may be present in the cheese milk.

The efficacy of the 60-day holding period for pathogen reduction has come under scrutiny for multiple reasons, including, foodborne illness outbreaks associated with cheese consumption, scientific research suggesting that some pathogenic bacteria survive for longer than 60 days in cheeses, and a recognized need for science-based decision making for establishment of food safety regulations. The origin of the 60-day holding rule for unpasteurized cheeses is presented, within the context of current food safety concerns regarding the safety of raw milk cheeses.

INTRODUCTION

Anecdotal observations that linked consumption of milk and milk products with the spread of disease spurred scientists and physicians around the world to undertake targeted public health research to investigate the role of milk consumption in foodborne disease as early as the turn of the twentieth century. Consumption of unpasteurized milk was found to be associated with many serious diseases, including diphtheria, typhoid, tuberculosis, and brucellosis *(11)*. Gastrointestinal disease outbreaks associated with milk consumption were first summarized in 1925 by the United States Public Health Service. To control milkborne diseases, these early reports recommended application of sanitation measures at all points in the food system, from the farm to the consumer *(6)*. The need for technical research to determine bacterial destruction efficacies of food processing treatments for pathogenic microbes likely to be present in raw milk also was highlighted *(4, 7)*. The results of many scientific studies, in combination with testimony by dairy product experts, led to development

A peer-reviewed article

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of specific recommendations for pasteurization and other intervention strategies intended to reduce public exposure to hazardous microorganisms that may be present in raw milk.

The microbiological safety of cheese made from heat-treated milk was previously covered in an extensive three-part review by Johnson et al. *(10, 11, 12)*. The objective of the present article is to describe the scientific origins of the current 60-day holding rule for cheese manufactured from sub-pasteurized milk within the context of emerging information on currently recognized milkborne pathogens.

DEVELOPMENT OF MILK PASTEURIZATION REQUIREMENTS

The public health objective of milk pasteurization, as defined in the 2003 United States Pasteurized Milk Ordinance (PMO), is to eliminate all non-spore-forming pathogens commonly associated with milk. Pasteurization, as first adopted in the US, was defined in the 1939 Milk Ordinance and Code as "the process of heating every particle of milk to at least 143°F (61.7°C) and holding at such temperature for at least 30 minutes, or to at least 160°F (71.1°C) and holding at such temperature for at least 15 seconds, in approved and properly operated equipment" *(14)*. These heat treatments were referred to, respectively, as the "holding method" or vat/batch pasteurization and the "flash method," or high-temperature short-time pasteurization. To address recognized gaps in knowledge regarding the microbes associated with milkborne disease, extensive research was conducted to determine the heat treatment required to kill *Mycobacterium tuberculosis*, which, at the time, was considered to be the most heat resistant pathogen associated with milk *(9)*. This work led to the widespread recognition of the public health significance of thermal milk processing and formed the basis for modern pasteurization processes *(9)*. In 1956, minimum pasteurization conditions were increased to assure destruction of *Coxiella burnetti*, the organism associated with Q-fever, which was found to be more heat resistant than *M. tuberculosis (4)*. The conditions prescribed in 1956 remain in effect today; minimal pasteurization requirements specify that milk must be heated to 145°F (63°C) and held for at least 30 minutes, or to at least 161°F (72°C) and held for at least 15 seconds, or to a scientifically determined thermal equivalent *(6)*.

CHEESE SAFETY

Modern dairy products made in the United States are rarely associated with outbreaks of foodborne illness (< 1% of reported outbreaks) despite the possible presence of pathogenic microbes in raw milk *(1)*. However, in 1938, fully 25% of illnesses due to contaminated food consumption were traced back to dairy products *(6)*. Cheese products were linked to 59 disease outbreaks in the United States between 1883 and 1946, and resulted in 2,904 illnesses and 117 deaths, with 40 outbreaks occurring between 1935 and 1945 *(5)*. Seventeen of these outbreaks were traced to Cheddar cheese consumption, with much of the implicated cheese aged for less than 30 days *(18)*. Typhoid fever epidemics linked to cheese consumption in 1944 *(18)* caught the attention of the Surgeon General of the United States *(10)*, who recommended in a letter to state health officials dated June 16, 1944 that "all cheese be either adequately ripened (e.g., cured) or made from pasteurized milk". The 1944 outbreaks were largely attributed to war-time conditions during World War II, including food rationing and shortages, and the lack of qualified cheesemakers and appropriately manufactured cheesemaking equipment *(10, 18)*. Several states enacted legislation promptly in response to the Surgeon General's letter. In early 1946, the Food and Drug Administration published proposed standards for several cheeses *(10)*.

The 60-day holding period recommendation, which was first published in the August 24, 1950 Final Rule (15 FR 5653), was established following expert testimony from hearings conducted in development of cheese Standards of Identity in April 1947 *(10)*. Statements from this 1947 hearing included the observation that no disease outbreaks had been associated with cheeses held more than 60 days, although the specific length necessary for a "safe" holding period was "uncertain" *(10)*. It was also deemed "unreasonable" to require holding cheese for a period that would ensure death of all pathogens *(10)*.

The scientific underpinnings of the 60-day holding period recommendation are obscure, but were derived at least partially from a study that investigated survival of *Brucella abortus* in Cheddar cheese *(7)*. This study reported that *Brucella abortus* survived for up to 6 months in cheeses that had been inoculated at levels of approximately 1,000 CFU/ml and held at 4.4°C. *B. abortus* was not recovered from commercial Limburger cheeses that had been held for 57 days, although the cheese milk used to manufacture two of the cheeses had tested positive for *B. abortus*. Test Cheddar cheese made from milk that naturally bore 700–800 CFU/ml were positive for culturable *B. abortus* for three months. Viable *B. abortus* were recovered from some, but not all, of these test cheeses at 6 months. Cheeses made from milk collected from herds positive for *B. abortus* were negative after storage for at least 41 days at temperatures ranging from 1.1°C to 2.7°C. In the discussion of the manuscript, authors stated that Cheddar cheese had not been proven as a vector for human brucellosis (undulant fever) and that typhoid fever epidemics had not been attributed to cheeses cured for more that 63 days, and they therefore believed that epidemiological evidence suggesting a lack of association between cheese consumption and disease provided strong support for an aging period of approximately 2 months for commercial cheeses. The final stated conclusion was that "an aging period of 60 days is reasonable assurance against the presence of viable *Brucella abortus* organisms in Cheddar cheese" *(7)*.

Even prior to publication as a Final Rule (15 FR 5653), the 60-day holding period for sub-pasteurized cheese was recognized as "not infallible" for pathogen destruction *(7, 18)*. Viable *M. tuberculosis* were recovered from Cheddar cheese after 100 days; hemolytic streptococci were recovered after 160 days and *S.* serotype Typhi was recovered after up to 10 months, depending on cheese storage temperature *(18)*. Ultimately, however, the 60-day holding period was deemed to offer some level of protection from pathogenic organisms present in freshly manufactured cheese *(18)*.

Current United States cheese regulations

The Food and Drug Administration's Division of Dairy and Egg Safety, Office of Plant and Dairy Foods and Beverages, is currently responsible for development and implementation of regulations to protect the safety of cheese and other dairy foods that enter interstate commerce. According to the US Code of Federal Regulations (CFR) 21 CFR part 1240.61, no milk or milk products in final package form

intended for direct human consumption can enter interstate commerce unless it is manufactured from pasteurized milk or pasteurized milk ingredients, except where alternative procedures are provided for by regulation, such as in 21 CFR 133, which contains regulations for cheeses and related cheese products.

As described in 21 CFR 133, Standards of Identity have been established for most natural cheeses, process cheeses, cheese foods, and cheese spreads. All cheeses belonging to a given variety must comply with the published standard and must be labeled with the name prescribed in the standard. In general, standards specify a maximum permissible moisture content and minimum milk fat content. A few natural cheeses are required to be made from pasteurized milk (e.g., Monterey Jack, cream cheese, mozzarella cheese); however, most, including many soft ripened cheeses (21 CFR 133.182) and semisoft cheeses (21 CFR 133.187), may be made from either raw or pasteurized milk. The Code of Federal Regulations (7 CFR sec. 58.439) states "if cheese is labeled as 'heat treated' 'unpasteurized' 'raw milk' or 'for manufacturing' the milk may be raw or heated at temperatures below pasteurization. Cheese made from unpasteurized milk shall be cured for a period of 60 days at a temperature not less that 35°F. If the milk to be used for cheesemaking is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45°F or lower until time of setting" *(3)*. Standards of identity may stipulate a holding period longer than 60 days if further aging is required to develop the characteristics of the cheese variety.

Why is the 60-day holding period under scrutiny now? Evidence of the ability of bacterial pathogens to survive throughout a 60-day holding period and to cause human disease has arisen from investigations of outbreaks of foodborne illnesses that have been traced back to aged cheeses as well as from additional scientific research. Specifically, three outbreaks of salmonellosis following consumption of Cheddar cheese, two in Canada and one in the United States, suggest that various *Salmonella* strains can survive for extended periods in cheese products.

In the first outbreak, which was traced to Cheddar cheese manufactured in Kansas in 1976, raw milk had been held unrefrigerated in the processing plant for 1–3 days prior to pasteurization and cheese manufacture. While it is not known for certain, total bacterial numbers in the pre-pasteurized raw milk could have exceeded the thermal destruction capacity of the pasteurizer. Microbiological analyses revealed the presence of *Salmonella* serotype Heidelberg at very low levels (0.36–1.8/100 grams of cheese) in the aged cheeses. The average pH of cheese batches bearing *Salmonella* was 5.6 vs. 5.4 for uncontaminated product; thus it is possible that slow acid production by starter cultures could have contributed to *Salmonella* survival, as well. This outbreak resulted from numerous lapses in good manufacturing practices and cannot be attributed solely to inadequacy of a 60-day holding period for microbial destruction *(11)*.

The second incident consisted of a series of *Salmonella* outbreaks that occurred in Ontario, Canada, from 1980 to 1982. In these cases, *S.* serotype Muenster was isolated from raw milk Cheddar cheese even after 125 days of curing at 41°F.

In the third outbreak, which affected over 2,700 people in Canada in 1984, *S.* serotype Typhimurium was isolated at very low levels from Cheddar cheese (0.39 –9.3/100 grams of cheese) that may have been prepared from a mix of raw and pasteurized milk. *S.* Typhimurium was found to persist in this cheese for 8 months at 41°F *(11)*.

Research at the University of Wisconsin *(16)* and at South Dakota State University *(15)* demonstrated survival of *Listeria monocytogenes* and *Escherichia coli* O157:H7, respectively, for more than 60 days in Cheddar cheese. To illustrate, Ryser and Marth showed that *Listeria monocytogenes* could persist for up to 434 days post-processing in artificially contaminated Cheddar cheese *(16)*.

CONCLUSIONS

Together with outbreak information, laboratory research demonstrates that various foodborne pathogens can survive current raw milk Cheddar cheese manufacturing practices under some circumstances. It is possible that illnesses associated with cheese consumption have been historically underestimated. Underestimation of illness associations could occur for many reasons, including a lack of appropriate detection tools for very low numbers of pathogens that may be present in cheese products *(11)*, the overall under-reporting of illnesses due to food consumption *(13)*, and the fact that most foodborne illnesses are not successfully traced back to source. Additional research is critically needed to enable accurate attribution of foodborne illnesses back to specific foods *(17)*. Current information needs include comprehensive outbreak data on illnesses traced back to originating foods and an enhanced capacity to assess illness risks based on evolving food contamination and consumption data. Additional research is also required on the persistence of pathogens during cheese manufacture and ripening, with a particular need to focus on survival of pathogens recognized as human hazards since 1950 (e.g., *L. monocytogenes*, *E. coli* O157:H7). It will be particularly important to understand and accurately quantify illness risks associated with low levels of pathogens that may be present in fermented foods.

Development and application of molecular subtyping-based surveillance methods has dramatically improved our ability to identify foods associated with illness outbreaks *(8)*. Recent advances in tracking bacterial pathogens back to source *(2)* ultimately will allow more accurate assessment and quantification of foodborne illness risks associated with specific foods, including dairy products. Evaluation of data from multiple sectors, including public health, dairy science, and food science, and epidemiology, are essential for ensuring that food safety regulations reflect the best available scientific knowledge to protect consumers from foodborne illnesses.

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