

from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

V. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2596]

Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting comments and scientific data and information that would assist us in identifying and evaluating intervention measures that might have an effect on the presence of bacterial pathogens in cheeses manufactured from unpasteurized milk. We are taking this action in light of scientific data on potential health risks associated with consumption of cheese made from unpasteurized milk.

DATES: Submit either electronic or written comments and scientific data and information by November 2, 2015.

ADDRESSES: Submit electronic comments and scientific data and

information to <http://www.regulations.gov>. Submit written comments and scientific data and information to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Andrew Yeung, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1541, andrew.yeung@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A 2012 review of outbreaks of foodborne illness that occurred in the United States between 1993 and 2006 that were attributed to dairy products determined that more than 50 percent of the outbreaks reviewed in the study involved cheese, with the remaining outbreaks being attributable to fluid milk (Ref. 1). Forty-two percent of the 65 cheese-associated outbreaks (*i.e.*, 27 outbreaks) were attributable to products manufactured from unpasteurized milk, even though the contribution of unpasteurized dairy products to all dairy product consumption in the United States during the time period under study was estimated at below 1 percent (on a weight or volume base) (Ref. 1). The 65 analyzed outbreaks due to cheese made from unpasteurized milk resulted in 641 associated illnesses with 131 hospitalizations (*i.e.*, a hospitalization rate of more than 20 percent). Pathogens associated with these outbreaks included *Listeria monocytogenes*, *Escherichia coli* (*E. coli*) O157, *Salmonella*, and others (Ref. 1). All of these pathogens can cause significant illness and even death.

FDA and Health Canada recently collaborated on the development of a model to evaluate the impact of factors, such as the microbiological status of milk used in cheese production, various cheese manufacturing steps, conditions during distribution and storage, and cross-contamination during processing and handling, on the public health risk of listeriosis from consumption of soft-ripened cheese. Elsewhere in this issue of the **Federal Register**, we are announcing the release of the “Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada” (the FDA/Health Canada QRA) (Ref. 2).

FDA establishes food standards of identity, to promote honesty and fair

dealing in the interest of consumers, under the authority set forth in section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341). Some of these standards of identity (*e.g.*, the standard of identity for soft-ripened cheese in § 133.182 (21 CFR 133.182)) permit the manufacture of cheese from unpasteurized milk. These standards of identity specify that the process for cheese manufactured from unpasteurized milk include an aging period. A typical aging period is not less than 60 days at not less than 35 °F (see § 133.182(a) in the standard of identity for soft-ripened cheese).

The aging period for cheese manufactured from unpasteurized milk was presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was consumed. However, the available data and information raise questions about the safety of cheese manufactured from unpasteurized milk, even when aged. For example, research has demonstrated that pathogens such as *E. coli* O157:H7 can survive a 60-day aging period in a hard cheese such as Cheddar cheese (Refs. 3 and 4). In addition, a 1997 memorandum from a subcommittee of the National Advisory Committee on Microbiological Criteria for Foods stated that the scientific literature confirms that pathogens can survive the 60-day aging process for cheeses manufactured using unpasteurized milk (Ref. 5). More recently, the results of the FDA/Health Canada QRA suggest that the 60-day aging period for soft-ripened cheese may increase the risk of listeriosis from consumption of soft-ripened cheese by allowing more time for *L. monocytogenes*, if present, to multiply (rather than decrease) as the soft-ripened cheese ages (Ref. 6).

FDA recognizes that there is broad diversity in cheese manufacturing operations and approaches and that many factors go into ensuring the safety of the food. Many types of raw milk cheeses are made using traditional methods that require a successful balance involving the quality of the milk, the equipment, and the environment, including ensuring the presence of bacteria critical to the nature of the cheese while preventing the introduction or growth of pathogens. In issuing this call for data and information, we are particularly interested in learning more about the standards and practices in use by the growing artisanal cheese manufacturing community.

II. Request for Comments, Scientific Data, and Information

We are continuing to evaluate the safety of processes for the manufacture of cheese, particularly processes for the manufacture of cheese from unpasteurized milk. We are requesting comments and scientific data and other information to:

- Understand what (if any) aspects of the current regulatory framework for the production of cheese manufactured from unpasteurized milk act as an impediment to efficient and effective control measures to significantly minimize pathogens that may be present in unpasteurized milk.

- Understand current practices to reduce the potential for foodborne illness during the manufacture of cheese from unpasteurized milk. To what extent do producers of cheese manufactured from unpasteurized milk solely rely on an aging period to significantly minimize pathogens that may be present in unpasteurized cheese? If such producers rely on control measures other than the aging process, what are those control measures and what is the prevalence of those control measures among such producers? How effective and practical are these control measures?

- Understand the availability and feasibility of various treatments (e.g., to achieve bacterial reductions of from 100- to 1,000,000-fold) that could reduce the risk of listeriosis and other foodborne illness from the consumption of all types of cheeses manufactured from unpasteurized milk. We are aware of non-thermal control measures such as added substances (such as bacteriocins, lactoferrins, lysozyme, other enzymes, and salt), bacterofugation, carbon dioxide, high hydrostatic pressure, microfiltration, microwave, pulsed electric field, pulsed light, ultrasound, and ultraviolet light. However, we would like to receive additional data regarding the efficacy, on a consistent basis, of such treatments when used to minimize the broad spectrum of pathogens that may be present in unpasteurized milk.

- Evaluate the impact of the currently required 60-day minimum aging period for soft-ripened cheese on pathogens other than *L. monocytogenes* in soft-ripened cheese. For example, how does the minimum aging period affect the safety of the cheese with respect to pathogens other than *L. monocytogenes*? Are there alternatives to the currently required 60-day aging period for soft-ripened cheese that would ensure the safety of such cheese with respect to these pathogens?

- Evaluate the impact on pathogens of a minimum aging period for all those cheeses that are subject to a required minimum aging period through an applicable standard of identity. As discussed in section I, research and a literature review show that pathogens can survive the 60-day aging process for cheeses manufactured using unpasteurized milk. For pathogens other than *L. monocytogenes*, is a 60-day aging period effective in adequately reducing a broad spectrum of pathogens that could be in cheese manufactured from unpasteurized milk?

- Determine whether, consistent with modern international approaches to food safety (Ref. 7), a performance objective (or standard) for *L. monocytogenes* should be used as a replacement for the 60-day aging requirement and whether a second performance standard for Gram-negative enteric pathogens should also be used. If a second performance standard is used for Gram-negative enteric pathogens, which Gram-negative pathogen should be specified?

- Understand the prevalence of testing during manufacture (e.g., testing for pathogens of each lot of cheese manufactured from unpasteurized milk and of bulk shipments of unpasteurized milk). If testing is not currently being used, how practical would such testing be? How much would it cost?

- Determine the extent to which consumers understand the risk of foodborne listeriosis or other illness from consumption of cheese manufactured from unpasteurized milk. To what extent are consumers aware that an aging process has had (and may continue to have) a role in food safety as well as a role in the particular type of cheese produced? To what extent do consumers consider whether a cheese is made from pasteurized or unpasteurized milk in making purchase decisions?

III. Comments

Interested persons may submit either electronic comments and scientific data and information regarding this document to <http://www.regulations.gov> or written comments and scientific data and information to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify submissions with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Langer, A. J., T. Ayers, J. Grass, *et al.*, "Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993–2006," *Emerging Infectious Disease* 18(3): 385–391, 2012.
2. FDA and Health Canada, "Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada." Accessible at <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm> (2015).
3. Reitsma, C.J. and D.R. Henning, "Survival of Enterohemorrhagic *Escherichia coli* O157:H7 During the Manufacture and Curing of Cheddar Cheese," *Journal of Food Protection*, 59(5): 460–464, 1996.
4. Schlessler, J.E., R. Gerdes, S. Ravishankar, *et al.*, "Survival of a Five-Strain Cocktail of *Escherichia coli* O157:H7 During the 60-Day Aging Period of Cheddar Cheese Made From Unpasteurized Milk," *Journal of Food Protection*, 69(5):990–998, 2006.
5. Memorandum from Chair, Cheese Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods to Chair, National Advisory Committee on Microbiological Criteria for Foods, "Review of Scientific Literature Regarding the Sixty-Day Aging Process for Hard Cheese," April 3, 1997.
6. FDA and Health Canada, "Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Interpretative Summary." Accessible at <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm> (2015).
7. Codex Alimentarius Commission, "Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods, CAC/GL 21–1997," 1997.

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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