

CITIZEN PETITION

Submitted under 21 CFR 10.30

Date: September __, 2026

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Submitted electronically at www.regulations.gov
Docket No. [FDA-2013-S-0610](https://www.fda.gov/oc/ohrt/FDA-2013-S-0610)

Re: Citizen Petition to Require a Warning Statement on Cheese Made From Unpasteurized Milk, and to Complete the Reevaluation of the 60-Day Aging Requirement Announced in 2013

The undersigned submits this petition under sections 201(n), 403(a)(1) and 701(a) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.30, and requests that the Commissioner of Food and Drugs amend 21 CFR 101.17 to require a warning statement on cheese made from unpasteurized milk, and complete the reevaluation of the 60-day aging requirement that this agency announced in 2013.

Twenty-eight years ago this agency required a warning on the label of unpasteurized juice. Twenty-six years ago it required a safe handling statement on shell eggs. Both requirements sit in the same regulation this petition asks the agency to amend, and both were adopted because of an outbreak record. Unpasteurized milk may not be shipped across state lines in a bottle. It may be shipped as cheese, on the strength of a 60-day aging provision written in the 1940s that the agency's own science has since found does not reliably kill the pathogens it was presumed to control, and can, for soft-ripened cheese, increase risk rather than reduce it. The label says nothing.

A. ACTION REQUESTED

The petitioner requests that the Commissioner take the following actions.

1. Require a prescribed warning statement. Amend 21 CFR 101.17 by adding a new paragraph requiring that the label of any cheese or cheese product made from milk that

has not been pasteurized, or subjected to an equivalent validated process to reduce pathogens, bear the following statement:¹

WARNING: This product is made from unpasteurized (raw) milk and may contain harmful bacteria that can cause serious illness in children, older adults, pregnant women, and persons with weakened immune systems.

2. Prescribe the words rather than the elements. The agency concluded in the juice rulemaking that a prescribed statement produces uniform comprehension and removes the drafting judgment from the regulated firm. The same reasoning applies here, and the words above are modeled on the juice warning already codified at 21 CFR 101.17(g)(2).

3. Prescribe placement and prominence. Require, as 21 CFR 101.17(g)(4) through (g)(6) do for juice, that the word WARNING be capitalized and in bold type, and that the statement appear prominently and conspicuously on the information panel or the principal display panel, in type of a size and contrast sufficient to be read under customary conditions of purchase.

4. Reach cut-to-order cheese, imported cheese and online sales. Provide that the requirement applies to domestic and imported cheese alike; that cheese cut, wrapped or sold at a service counter without a manufacturer's label may satisfy the requirement by a sign or placard at the point of sale bearing the same statement in the same form; and that a seller offering the cheese online display the statement on the product page. Cheese sold from a service counter carries no manufacturer label at all, and that is a substantial share of how this product reaches consumers.

5. Exempt product that has been made safe, and product not sold at retail as shipped. Provide that the statement is not required where the milk has been pasteurized or the cheese has been subjected to a process validated to achieve a pathogen reduction equivalent to pasteurization, and that cheese not for distribution to retail consumers in the form shipped is exempt provided the absence of such processing is disclosed in the documents accompanying the shipment. That structure is taken from 21 CFR 101.17(g)(3) and (g)(7) and requires no new drafting.

6. Complete the reevaluation of the 60-day aging requirement. Within one year, publish either a proposed rule addressing the 60-day aging requirement in the standards of identity at 21 CFR part 133, or a written explanation of why the agency will not, and place it in the public docket.² In 2013 the agency stated that it intended to use the joint risk assessment described below, together with other scientific assessments, in its

¹ 21 CFR 101.17 (food labeling warning, notice, and safe handling statements):

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-A/section-101.17>.

² 21 CFR part 133 (cheeses and related cheese products), in which the 60-day curing provision appears in the individual standards of identity: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-133>.

reevaluation of the existing 60-day aging requirements for cheeses made with raw milk.³ The assessment was completed. The reevaluation has not been published.

7. Publish the raw milk cheese sampling data the agency already collects. Publish annually, at the sample level, the results of raw milk cheese sampling conducted under the agency's domestic and imported cheese compliance program and under any assignment covering aged raw milk cheese, including the fiscal year 2025 collection of aged raw cow's milk cheese for highly pathogenic avian influenza.⁴ The samples are already pulled and the analyses already performed.

8. Set prompt effective and compliance dates. Make any final rule effective 60 days after publication, permit the statement to be given by sign or placard for the first year as the agency did for juice, and require labels to bear the statement thereafter, so that the requirement is satisfied in the ordinary course of label turnover.

9. Act expeditiously. The petitioner requests a response within the 180 days required by 21 CFR 10.30(e)(2).⁵

B. STATEMENT OF GROUNDS

I. The petitioner

William D. Marler is the managing partner of Marler Clark, Inc., PS, a law firm whose practice is confined to foodborne illness. He has represented victims of foodborne illness since 1993, including children who developed hemolytic uremic syndrome after consuming unpasteurized dairy products. The petitioner represents a claimant in the 2025 Shiga toxin-producing *E. coli* outbreak linked to aged raw milk cheese from Twin Sisters Creamery in Washington State, which is discussed below and is disclosed here so that the agency may weigh the source of this petition.⁶ **[CONFIRM AND KEEP, OR DELETE: The petitioner also represented the family of a Vermont man who died in the 2017 listeriosis outbreak linked to Vulto Creamery raw milk cheese, discussed in Ground IX.]**

II. What this petition asks for, and what it does not

This petition does not ask the agency to ban raw milk cheese, to extend the aging period, or to restrict who may buy it. It asks for a sentence on the label. Adults who want cheese

³ Notice of availability, Draft Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada (Feb. 11, 2013), stating the agency's intent to use the assessment in reevaluating the existing 60-day aging requirements:

<https://www.federalregister.gov/documents/2013/02/11/2013-02960/draft-joint-food-and-drug-administration-health-canada-quantitative-assessment-of-the-risk-of>.

⁴ FDA, Microbiological Surveillance Sampling, listing the FY25 aged raw cow's milk cheese collection and analysis for highly pathogenic avian influenza: <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling>.

⁵ 21 CFR 10.30 (citizen petitions): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-10/subpart-B/section-10.30>.

⁶ Washington State Department of Health, 2025 outbreak of Shiga toxin-producing *E. coli* infections linked to Twin Sisters Creamery aged raw milk cheese: <https://doh.wa.gov/you-and-your-family/illness-and-disease-z/foodborne-illness/outbreaks/2025-outbreak-shiga-toxin-producing-e-coli-stec-infections-linked-twin-sisters-creamery-aged-raw>.

made from unpasteurized milk would remain free to buy it, with the information the government already gives them about the same milk in a bottle and about unpasteurized juice in a carton. The request is the smallest intervention available that addresses the problem, and it is the one most consistent with consumer choice, because a choice made without the material fact is not the exercise of a preference.

III. Cheese is the route by which unpasteurized milk lawfully enters interstate commerce

Since 1987 the agency has prohibited the delivery into interstate commerce of milk and milk products in final package form for direct human consumption unless the product has been pasteurized.⁷ The regulation names its own exception: "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." Cheese made from unpasteurized milk is that exception, permitted where the cheese is cured at a temperature not lower than 35 degrees Fahrenheit for at least 60 days under the standards of identity.⁸ The 60-day rule is therefore not a detail of cheese making. In the regulation's own words it is the alternative to pasteurization, and it is the entire legal basis on which unpasteurized milk crosses state lines in a form people eat.

IV. The precedent for the requested label is exact, and it is in the same regulation

In 1998 the agency required a warning statement on packaged juice that has not been processed to prevent, reduce or eliminate pathogens, in the words now codified at 21 CFR 101.17(g): a capitalized, bolded WARNING advising that the product has not been pasteurized and may contain harmful bacteria that can cause serious illness in children, the elderly and persons with weakened immune systems.⁹ The agency adopted that warning while it was still developing the juice hazard analysis rule, as an interim measure, on two findings: that untreated juice had caused outbreaks of serious illness, including a death, and that consumers were largely unaware that a product they regarded as healthful could carry pathogens. It rejected the argument that labeling juice "unpasteurized" was warning enough, because that word tells the consumer what was not done to the product and nothing about the risk.¹⁰ Both findings apply to cheese made from unpasteurized milk, and the second applies with more force, because on this product the absence of pasteurization is presented as a virtue.

⁷ 21 CFR 1240.61 (mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1240/subpart-D/section-1240.61>.

⁸ See, for example, 21 CFR 133.182 (soft ripened cheeses), one of the individual standards in which the 60-day curing provision appears: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-133/subpart-B/section-133.182>.

⁹ Food labeling: warning and notice statement; labeling of juice products, final rule, 63 FR 37030 (July 8, 1998): <https://www.govinfo.gov/content/pkg/FR-1998-07-08/html/98-18287.htm>.

¹⁰ Food labeling: warning and notice statement; labeling of juice products, final rule, 63 FR 37030, at 37031-37034 (July 8, 1998), setting out the outbreak record, the agency's finding from its consumer research that consumers were largely unaware of the hazard, and the agency's response (comment 11) to the argument that labeling juice as "pasteurized" or "unpasteurized" would be sufficient: <https://www.govinfo.gov/content/pkg/FR-1998-07-08/html/98-18287.htm>.

The same regulation carries a second precedent. In December 2000 the agency required a safe handling statement on cartons of shell eggs not treated to destroy *Salmonella*, and required refrigerated storage and display at retail, because of the number of outbreaks and deaths associated with shell eggs.¹¹ Two categories of raw agricultural product, two mandatory statements, both in section 101.17, both adopted on an outbreak record. A third belongs there.

V. The agency's own risk assessment says the risk is not small

The joint quantitative risk assessment prepared by this agency with Health Canada evaluated listeriosis risk from soft-ripened cheese.¹² Its conclusions are the strongest scientific support for this petition, and they come from the agency itself. The assessment found the risk of listeriosis from a serving of soft-ripened cheese made from raw milk to be approximately 50 to 160 times greater than from a serving of the same cheese made from pasteurized milk.¹³ It found that a reduction of roughly six logs, or its equivalent, in the contamination of the milk is necessary to make raw milk cheese as safe from listeriosis as cheese made from pasteurized milk. And it found that for surface-ripened cheeses the 60-day aging requirement can increase the risk of listeriosis rather than reduce it, because the pH of the rind and core rises during ripening and permits growth.¹⁴

That last finding is the one that matters most for item 6. On the agency's own analysis the 60-day rule is not merely an incomplete control for one class of these cheeses. It can work in the wrong direction, and it has stood unchanged since the middle of the last century.

VI. The agency said in 2013 that it would reevaluate the rule, took comments on it in 2015, and stopped

When it announced the draft risk assessment for comment in February 2013, the agency stated that it intended to use the assessment, along with other information and scientific assessments covering the different pathogens that can be present in all types of cheeses made from raw milk, in its reevaluation of the existing 60-day aging requirements. It finalized the assessment on August 3, 2015. In the same issue of the Federal Register it published a request for comments and scientific data on cheese manufactured from unpasteurized milk, Docket No. FDA-2015-N-2596, asking among other things whether a 60-day aging period is effective against pathogens other than *Listeria monocytogenes*, whether a performance standard should replace the 60-day aging requirement, and to what extent consumers understand the risk and consider whether a cheese is made from

¹¹ Food labeling: safe handling statements: labeling of shell eggs; refrigeration of shell eggs held for retail distribution, final rule, 65 FR 76092 (Dec. 5, 2000), establishing 21 CFR 101.17(h):

<https://www.federalregister.gov/documents/2000/12/05/00-30761/food-labeling-safe-handling-statements-labeling-of-shell-eggs-refrigeration-of-shell-eggs-held-for>.

¹² Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: <https://www.fda.gov/food/risk-and-safety-assessments-food/joint-fda-health-canada-quantitative-assessment-risk-listeriosis-soft-ripened-cheese-consumption>.

¹³ Joint FDA/Health Canada risk assessment, interpretive summary:

<https://www.fda.gov/media/90493/download>.

¹⁴ Joint FDA/Health Canada risk assessment, technical report:

<https://www.fda.gov/media/90488/download>.

pasteurized or unpasteurized milk when they buy it.¹⁵ Comments were due November 2, 2015, and seventy-five were filed, including comments from cheesemakers, dairy trade associations and consumer organizations.

Eleven years later, no proposed rule, no completed reevaluation and no published explanation has followed. Item 6 asks for one or the other, which is the minimum a member of the public is entitled to when an agency announces a reevaluation, takes public comment on it, and stops.

VII. The agency's own 2015 notice says the 60-day rule does not reliably control *E. coli* O157:H7 in cheddar

The 2015 request for comments is more than a procedural marker. In it the agency described the premise of the 60-day rule and then set out the evidence against it. The aging period, the agency wrote, had been presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was eaten, but the available data raised questions about the safety of the product "even when aged."¹⁶ The agency then cited two peer-reviewed studies for the proposition that *E. coli* O157:H7 can survive a 60-day aging period in a hard cheese such as cheddar,¹⁷ and a 1997 memorandum of a subcommittee of the National Advisory Committee on Microbiological Criteria for Foods stating that the scientific literature confirms that pathogens can survive the 60-day aging process for cheeses manufactured from unpasteurized milk.¹⁸ The same notice recorded that of 65 cheese-associated outbreaks in a 2012 review by the Centers for Disease Control and Prevention, 27 involved products made from unpasteurized milk, although such products were less than one percent of dairy consumption.¹⁹

Three points follow. First, the evidence that matters is not confined to *Listeria* or to soft-ripened cheese. The agency's own notice identifies *E. coli* O157:H7 in aged cheddar as a documented failure of the rule, and cheddar is the cheese in three of the four outbreaks set out in Ground IX. Second, the rebuttal that the risk assessment addressed only one

¹⁵ Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk; request for comments and for scientific data and information, 80 FR 46023 (Aug. 3, 2015), Docket No. FDA-2015-N-2596; the docket records 75 comments: <https://www.federalregister.gov/documents/2015/08/03/2015-18972/understanding-potential-intervention-measures-to-reduce-the-risk-of-foodborne-illness-from>. The final risk assessment was announced in the same issue: <https://www.federalregister.gov/documents/2015/08/03/2015-18960/joint-food-and-drug-administrationhealth-canada-quantitative-assessment-of-the-risk-of-listeriosis>.

¹⁶ 80 FR 46023, at 46023, cited above.

¹⁷ 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); Schlesser, J.E., 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). Both are cited by the agency as references 3 and 4 at 80 FR 46023, and again in the FY 2014-2016 sampling report cited below.

¹⁸ Memorandum from the Chair, Cheese Subcommittee, National Advisory Committee on Microbiological Criteria for Foods, to the Chair of the Committee, Review of Scientific Literature Regarding the Sixty-Day Aging Process for Hard Cheese (Apr. 3, 1997), cited by the agency as reference 5 at 80 FR 46023 and on file in Docket No. FDA-2015-N-2596.

¹⁹ 80 FR 46023, at 46023, citing Langer, A.J., et al., Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993-2006, *Emerging Infectious Diseases* 18(3):385-391 (2012).

pathogen in one type of cheese was anticipated by the agency itself, which asked in 2015 whether the 60-day period is effective against other pathogens and whether a performance standard should replace it. Third, the agency has known for at least eleven years, and the federal advisory committee on microbiological criteria for twenty-nine, that the premise of the rule does not hold, and the label has not changed.

VIII. The agency's own sampling, and the honest reading of it

The agency selected aged raw milk cheese for large-scale sampling in fiscal years 2014 through 2016 because, in its own words, evidence indicated that aging raw milk cheese for 60 days may not eliminate or adequately reduce disease-causing bacteria, thus posing a potential hazard to consumers.²⁰ Of 1,606 samples, pathogens were detected in 14: three *Salmonella*, ten *Listeria monocytogenes* and one pathogenic Shiga toxin-producing *E. coli* of serotype O111:H8. Generic *E. coli*, which the agency uses as an indicator of insanitary processing conditions, was found in 5.4 percent of samples.²¹

The petitioner states the industry's reading of those results because it is a fair one: a pathogen prevalence under one percent is not a catastrophic figure, and the agency concluded that further large-scale sampling was not warranted. Three answers follow. First, this is a ready-to-eat food with no kill step between the sample and the plate, so prevalence translates directly into exposure, and at national consumption volumes a fraction of one percent is a large number of servings.²² Second, six of the *Listeria* isolates recovered from cheese collected in 2014 were identical by whole genome sequencing to the isolate from a 2013 human illness, which is the sampling program detecting exactly what it was designed to detect. Third, the decisive evidence is not prevalence at all. It is the outbreak record since.

Prevalence per sample also understates the burden per serving. A 2017 analysis published in the Centers for Disease Control and Prevention's journal estimated that unpasteurized milk, consumed by 3.2 percent of the population, and unpasteurized cheese, consumed by 1.6 percent, accounted for 96 percent of the illnesses caused by contaminated dairy products in the United States from 2009 to 2014, and that unpasteurized dairy products cause 840 times more illnesses and 45 times more hospitalizations than pasteurized products. The same analysis found, and the petitioner notes it because the certification below requires it, that illnesses and hospitalizations from *Listeria monocytogenes* in that period were more often attributed to pasteurized cheese than to unpasteurized cheese.²³

²⁰ FDA, FY 2014-2016 Microbiological Sampling Assignment Summary Report: Raw Milk Cheese (Aged 60 Days): <https://www.fda.gov/media/99340/download>.

²¹ FDA, constituent update announcing the completed survey (July 2016): <https://www.fda.gov/food/hfp-constituent-updates/fda-shares-completed-survey-and-data-ongoing-sampling-program>.

²² Pew Charitable Trusts, FDA sampling of raw milk cheese reveals contamination, serious risks (Aug. 2016), describing the CDC analysis finding the outbreak rate per unit consumed to be roughly 150 times greater for products made from unpasteurized milk: <https://www.pew.org/en/research-and-analysis/articles/2016/08/04/fda-sampling-of-raw-milk-cheese-reveals-contamination-serious-risks>.

²³ Costard, S., et al., Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009-2014, *Emerging Infectious Diseases* 23(6):957-964 (2017): <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5443421/>.

IX. Four outbreaks in thirty-one months, in cheese that complied with the rule

Each of the following outbreaks involved cheese made from unpasteurized milk and aged as the standards of identity require. None of them is a case of a producer evading the 60-day rule. They are cases of the 60-day rule doing what the agency's own science, described in Grounds V and VII, predicted. The fourth was announced on September 25, 2026, while this petition was being prepared, and that investigation remains open.

Outbreak	Product	What happened
February 2024, <i>E. coli</i> O157:H7, five states	Raw cheddar cheese	Eleven people infected, five hospitalized, two cases of hemolytic uremic syndrome; seven of the nine people interviewed reported eating the same brand of raw cheddar; the firm withdrew its recall ten days after initiating it ²⁴
October 2025, Shiga toxin-producing <i>E. coli</i> , Washington and Oregon	Aged raw milk cheese, four varieties	Ten cases across two states, one hospitalized; the state found two outbreak-associated strains, <i>E. coli</i> O103 and <i>E. coli</i> O26, in cheese sampled from a consumer's home and from retail; the state's own notice records that the cheese was aged at least 60 days, as required by law ²⁵
March 2026, <i>E. coli</i> O157:H7, three states	Raw cheddar cheese and raw milk	Nine people infected, three hospitalized, one case of hemolytic uremic syndrome, with over half the illnesses in children under five; onsets from September 1, 2025 to February 20, 2026; the firm declined the agency's request for a voluntary recall before recalling on April 2, 2026 ²⁶

²⁴ FDA, Outbreak Investigation of *E. coli* O157:H7: Raw Cheddar Cheese (February 2024), final update (Mar. 26, 2024), reporting eleven illnesses in five states, five hospitalizations and two cases of hemolytic uremic syndrome; the February 28, 2024 update records that seven of nine people interviewed reported eating the cheese and that the firm withdrew its recall on February 26, 2024: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-raw-cheddar-cheese-february-2024>.

²⁵ Washington State Department of Health, Twin Sisters Creamery outbreak page, cited above. <https://doh.wa.gov/you-and-your-family/illness-and-disease-z/foodborne-illness/outbreaks/2025-outbreak-shiga-toxin-producing-e-coli-stec-infections-linked-twin-sisters-creamery-aged-raw>.

²⁶ CDC, *E. coli* outbreak linked to raw dairy, investigation updates (March and April 2026): <https://www.cdc.gov/ecoli/outbreaks/rawcheese-03-26/investigation.html>.

Outbreak	Product	What happened
September 2026, <i>E. coli</i> O26:H11, nine states	Aged raw milk cheddar and jack cheeses, four varieties	Thirteen people infected, eight hospitalized, three cases of hemolytic uremic syndrome; median age five, with over half the illnesses in children age five or younger; all nine people interviewed reported eating the cheese; illnesses began between July 7 and August 26, 2026; ²⁷ the agency contacted the firm on September 24 and the firm recalled every Graziers raw milk cheese the same day; the labels state that the cheese is aged at least 60 days ²⁸

Table 1. Four outbreaks linked to cheese made from unpasteurized milk, February 2024 to September 2026. Case counts are as published by the investigating agencies; the September 2026 counts are as of September 25, 2026, and that investigation remains open.

The third is also the clearest demonstration of what the present regulatory structure can and cannot do. The agency asked for a recall and was refused, the recall came two and a half weeks later, and members of a congressional food safety caucus asked the agency to compel one.²⁹ A warning label would not have prevented that outbreak. It would have told the parents of the children who were hospitalized what they were buying.

The fourth arrived while this petition was being prepared. On September 25, 2026, the Centers for Disease Control and Prevention and this agency announced a multistate outbreak of *E. coli* O26:H11 infections linked to Graziers grass-fed raw milk cheese made by Sierra Nevada Cheese Company of Willows, California: thirteen people in nine states, eight of them hospitalized, three with hemolytic uremic syndrome, and over half of them children age five or younger. The first illness began on July 7. The agency contacted the firm on September 24, eleven weeks later, and the firm recalled every Graziers raw milk cheese the same day. That interval is ordinary for an outbreak investigation, and it is the interval during which the label is the only warning a parent will see. The cheese was sold nationwide, in stores and online, in retail packages and in five-pound loaves to food service customers and wholesalers, and the agency has told retailers that repackaged it

²⁷ CDC, Investigation Update: *E. coli* Outbreak, September 2026 (Sept. 25, 2026), reporting thirteen cases in nine states, eight hospitalizations, three cases of hemolytic uremic syndrome, illness onsets from July 7 to August 26, 2026, a median age of five with over half of those sickened age five or younger, and that all nine people interviewed reported eating Sierra Nevada Cheese Company's Graziers raw milk cheese: <https://www.cdc.gov/ecoli/outbreaks/raw-milk-cheese-09-26/investigation.html>.

²⁸ FDA, Outbreak Investigation of *E. coli* O26:H11: Raw Milk Cheese (September 2026) (Sept. 25, 2026), stating that the agency contacted the firm on September 24, 2026 and recommended a recall, and that the firm agreed and initiated a recall of all Graziers raw milk cheeses the same day; the product image accompanying the advisory shows the labels, which state that the cheese is aged at least 60 days (the sharp cheddar, over 120 days): <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o26h11-raw-milk-cheese-september-2026>.

²⁹ Congressional Research Service, Food and Drug Administration (FDA) Response to a Raw Dairy Toxic *E. coli* Outbreak, IN12681 (Apr. 2026): <https://www.everycrsreport.com/reports/IN12681.html>.

for individual sale not to sell it.³⁰ A five-pound loaf cut and re-wrapped at a service counter carries no manufacturer's label at all, which is the case item 4 addresses. The serogroup, O26, is the one Washington found in the Twin Sisters cheese eleven months earlier. Across the four outbreaks, 43 people have been sickened, 17 hospitalized and at least six have developed hemolytic uremic syndrome, all from cheese that complied with the 60-day rule.

Whatever the source of contamination at each producer, and the petitioner attributes no fault here, the rule permitted every one of these cheeses to be sold, and the label told no one anything.

The record before that window points the same way. In 2017 a soft, washed-rind raw milk cheese made in New York was linked to a multistate listeriosis outbreak: eight people infected in four states, all eight hospitalized, one of them a newborn, and two dead.³¹ A soft, surface-ripened raw milk cheese is the class the joint risk assessment modeled, and the outcome was the one it predicted.

X. The burden falls on children

Over half the illnesses in the March 2026 outbreak were in children under five, and over half the people sickened in the September 2026 outbreak are children age five or younger; the median age in that outbreak is five, and three of the thirteen have hemolytic uremic syndrome. A child with a Shiga toxin-producing *E. coli* infection may develop hemolytic uremic syndrome, which is acute kidney failure, and which in the petitioner's experience means dialysis, transfusions, and in the worst cases stroke, colectomy or death, followed by decades of monitoring for chronic kidney disease. The people making the purchasing decision in these cases are parents, and the warning statement requested here is addressed to them. When the agency wrote the juice warning it noted that the median age of the people sickened in the *E. coli* O157:H7 juice outbreak it was responding to was five, and it declined for that reason to narrow the word "children."³² The median age in the September 2026 cheese outbreak is five.

XI. The current label does not tell the consumer what the agency intends

Cheese made from unpasteurized milk is frequently labeled as such, but the statement appears as an ingredient description or as a marketing claim, in the same type as everything else on the package, and it conveys craft rather than hazard. The package in the September 2026 outbreak calls the product grass-fed raw milk cheese and states that

³⁰ FDA, Outbreak Investigation of *E. coli* O26:H11: Raw Milk Cheese (September 2026), cited above, stating that the cheese was sold at retailers nationwide and online and to food service customers and wholesalers in 5-pound loaves, and that retailers that received recalled product and repackaged it for individual sale should not sell it; the onset dates are from the CDC investigation update, cited above: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o26h11-raw-milk-cheese-september-2026>.

³¹ CDC, 2017 Outbreak of *Listeria* Infections Linked to Soft Raw Milk Cheese Made by Vulto Creamery (final update, May 3, 2017), reporting eight people infected in four states, all eight hospitalized, one illness in a newborn, and two deaths, in Connecticut and Vermont; the firm recalled all lots of its raw milk cheeses on March 10, 2017: https://archive.cdc.gov/www_cdc.gov/listeria/outbreaks/soft-cheese-03-17/index.html.

³² 63 FR 37030, at 37044 (response to comment 49), cited above.

it is aged at least 60 days, which tells the buyer that the cheese complied with the rule and nothing about what the rule does not do. Nothing on the label tells a pregnant woman, the parent of a toddler or a person on immunosuppressive therapy that this is a product the government advises them not to eat. Cheese cut at a service counter carries nothing at all.

The agency publishes that advice itself. Its consumer page on raw milk states that while raw milk puts all consumers at risk, the elderly, immune-compromised people, children and pregnant women are especially vulnerable; that the agency's position is in concert with the Centers for Disease Control and Prevention and the American Academy of Pediatrics; and that since 1987 there have been 143 reported outbreaks associated with raw milk and raw milk products.³³ The agency has also conceded, in the published instructions for its own 2025 sampling assignment, that aged raw cow's milk cheese "is not required to be labeled" as such, so that its investigators must identify the product from shipping documents and by asking distributors.³⁴ If the agency's own investigators cannot identify the product from its label, a parent in a grocery aisle cannot be expected to.

The states that have acted have stopped at the bottle. California has required since 1991 that raw milk and raw milk products bear a boxed WARNING that they may contain disease-causing microorganisms, naming the groups at highest risk, and it deems a product without the warning misbranded; but its definition of a raw milk product expressly excludes cheese ripened or cured at least 60 days.³⁵ Washington has required a warning on containers of raw milk sold to consumers since 1997, and the rule by its terms applies to containers of raw milk, not to cheese.³⁶ The producers in three of the four outbreaks in Ground IX are in those two states. Under state law none of their cheese had to carry a warning, and under federal law none of it did. California's exclusion rests on the assumption the agency's own science has undermined: that 60 days of aging makes the warning unnecessary.

In 1998 the agency considered and rejected the argument that labeling juice as unpasteurized was warning enough, because the word describes the treatment the product did not receive and says nothing about the risk.³⁷ The words "raw milk cheese"

³³ FDA, Food Safety and Raw Milk (consumer page, content current as of March 5, 2024):

<https://www.fda.gov/food/buy-store-serve-safe-food/food-safety-and-raw-milk>.

³⁴ FDA, Microbiological Surveillance Sampling: FY25 Aged Raw Cow's Milk Cheese Collection and Analysis for HPAI (Dec. 30, 2024), Questions and Answers, asking how field staff will identify the product "when it is not required to be labeled": <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy25-aged-raw-cows-milk-cheese-collection-and-analysis-hpai>.

³⁵ California Code of Regulations, title 17, section 11380 (operative 1991), subsections (a), (c)(2) and (e): <https://www.law.cornell.edu/regulations/california/17-CCR-11380>. The California Department of Public Health describes the requirement on its raw milk page: <https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/RawMilkandRawDairyProductsRiskandRecommendations.aspx>.

³⁶ Washington Administrative Code 16-101-800, raw milk warning labels (adopted Sept. 11, 1997, WSR 97-19-045), which by its terms applies to containers of raw milk intended for sale to consumers: <https://lawfilesext.leg.wa.gov/law/WACArchive/2020/hm/WAC%20%2016%20%20TITLE/WAC%20%2016%20-101%20%20CHAPTER/WAC%20%2016%20-101%20-800.htm>.

³⁷ 63 FR 37030, at 37034 (response to comment 11), cited above.

do the same, and on this product they are a selling point. The label is where the agency's advice would reach the person making the decision.

XII. The legal authority is settled

A food is misbranded if its labeling is false or misleading in any particular.³⁸ Labeling is misleading not only by what it says but by its failure to reveal facts material in light of representations made, or material with respect to consequences which may result from use of the article under the conditions prescribed in the labeling or under customary conditions of use.³⁹ That the milk was not pasteurized, and that the product may therefore carry pathogens causing serious illness in identified groups, is a material fact with respect to the consequences of use. The agency has authority to issue the regulation under section 701(a).⁴⁰ The agency also holds independent authority under section 361 of the Public Health Service Act, which is the authority underlying 21 CFR 1240.61 itself.⁴¹

The requested statement is also the kind of compelled commercial disclosure the courts have sustained. A requirement that a seller disclose purely factual and uncontroversial information about its product is reviewed under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and the United States Court of Appeals for the District of Columbia Circuit, sitting en banc, has held that this standard applies to disclosures that serve governmental interests beyond the prevention of deception. *American Meat Institute v. U.S. Department of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). That the milk was not pasteurized is a fact. That unpasteurized dairy products may contain pathogens is the agency's settled public position and the text of California's own warning. The juice and shell egg statements in the same regulation have stood for more than a quarter century.

XIII. Avian influenza is a new reason, and a current one

The hazard profile of this product has changed since the 60-day rule was written and since the risk assessment was completed. Highly pathogenic avian influenza H5N1 has circulated in United States dairy herds since March 2024. In December 2024 the agency began a sampling assignment to collect 300 samples of aged raw cow's milk cheese from warehouses and distribution hubs and test them for viable H5N1.⁴² In March 2025 it reported interim results, 96 of the first 110 samples negative by PCR and 14 pending, and

³⁸ Federal Food, Drug, and Cosmetic Act section 403(a)(1), 21 U.S.C. 343(a)(1):

<https://www.law.cornell.edu/uscode/text/21/343>.

³⁹ Federal Food, Drug, and Cosmetic Act section 201(n), 21 U.S.C. 321(n):

<https://www.law.cornell.edu/uscode/text/21/321>.

⁴⁰ Federal Food, Drug, and Cosmetic Act section 701(a), 21 U.S.C. 371(a):

<https://www.law.cornell.edu/uscode/text/21/371>.

⁴¹ Public Health Service Act section 361, 42 U.S.C. 264:

<https://www.law.cornell.edu/uscode/text/42/264>.

⁴² FDA, FY25 Aged Raw Cow's Milk Cheese Collection and Analysis for HPAI, cited above, stating that 300 samples would be collected from warehouses and distribution hubs and that the agency would publicize the findings after all testing and analysis were complete. As of the date of this petition the page shows content current as of December 30, 2024: <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy25-aged-raw-cows-milk-cheese-collection-and-analysis-hpai>.

stated that final results were expected later that spring.⁴³ As of the date of this petition the assignment page has not been updated since December 30, 2024, and no final results have been posted. Item 7 asks for them.

The research the agency funded to answer the underlying question has been published. A study at Cornell University, supported by the agency and the State of New York and published in *Nature Medicine* in October 2025, found that aging raw milk cheese for 60 days or longer is not, by itself, effective at eliminating viable H5N1: the virus survived through and beyond the 60-day aging period in cheese made at pH 6.6 and 5.8, and was inactivated only in cheese made at pH 5.0 or from heat-treated milk.⁴⁴ The agency's response has been a recommendation that processors not use milk from infected cows in raw milk products. A recommendation is not a rule, and a rule that rests on 60 days of aging is, on the agency's own funded research, not a control for this virus. That is a further reason to complete the reevaluation requested in item 6, and it is a current one.

XIV. The objections, stated fairly and answered

The first objection is cost to small producers, and it is the most serious one. Many raw milk cheesemakers are small farmstead operations, and a label change is not free. The requested rule answers that in three ways: the statement is a single sentence with no testing, reformulation or process change behind it; the placard option in item 4 allows a retailer to satisfy it without any label at all for cut-to-order cheese; and the compliance dates in item 8 follow the juice model, under which signs and placards were permitted for the first year and labels turned over in the ordinary course.

The second objection is that consumers who buy raw milk cheese already know it is raw. Some do. The person who buys it is not always the person who eats it, the cheese board at a party carries no label, and the pregnant guest did not make the purchase. The juice warning answered the identical objection in 1998.

The third objection is that a warning statement is the first step toward prohibition. This petition is evidence to the contrary. It asks for disclosure and for the completion of a scientific reevaluation the agency itself announced, and it asks for nothing else. If that reevaluation concludes that the 60-day rule is adequate for particular cheese types, the label requested here remains appropriate, because the consumer's interest in knowing is not contingent on the outcome.

The fourth objection is that this is a matter for the states. It is not. The 60-day exception is a federal rule, and the product it permits crosses state lines under federal authority. A consumer in one state buying cheese made in another cannot be protected by either state's

⁴³ FDA, Investigation of Avian Influenza A (H5N1) Virus in Dairy Cattle, reporting on March 14, 2025 the interim sampling results (96 of the first 110 samples negative by PCR, 14 in progress, final results expected later that spring), summarizing the Cornell University research, and recommending that dairy processors not use milk from infected cows in the production of raw milk products such as raw milk cheese: <https://www.fda.gov/food/alerts-advisories-safety-information/investigation-avian-influenza-h5n1-virus-dairy-cattle>.

⁴⁴ H5N1 influenza virus stability and transmission risk in raw milk and cheese, *Nature Medicine* (published Oct. 8, 2025): <https://www.nature.com/articles/s41591-025-04010-0>. The agency's summary of the findings appears on the page cited in the preceding footnote.

labeling law. And the states that require a raw milk warning have not reached this product: as Ground XI shows, California's warning excludes 60-day cheese by definition and Washington's applies to containers of milk. The cheese in the four outbreaks in Ground IX crossed state lines without a warning required by any state.

The fifth objection is warning fatigue, and the petitioner does not dismiss it. The answer is that this warning is not proliferating across the dairy case. It attaches to a narrow category defined by the absence of the one process that makes the rest of the category safe, which is the same line the agency drew for juice. The agency answered the same objection in 1998, when commenters said the juice warning would start a trend toward warnings on all foods, by noting that it had used its authority under sections 201(n) and 403(a)(1) to require warnings only rarely, and only where the statutory criteria are met.⁴⁵ In the twenty-eight years since, the shell egg statement is the only one it has added to the section.

XV. What this would cost, and what the status quo costs

The cost of the requested label is the design of one sentence and the printing of labels reprinted anyway. Against that stands a hospitalized child, a recall that by the firm's own account affected approximately 1.5 million dollars of its product,⁴⁶ and the recurring expense to every producer in the category of being associated with outbreaks they had no part in. A warning statement is also, in the petitioner's experience, the cheapest insurance a producer can buy, because failure to warn is the allegation hardest to defend and the one most likely to be met with a document showing the government knew and said nothing.

XVI. Conclusion

This agency prohibits unpasteurized milk in interstate commerce, permits it in cheese on the strength of a 60-day aging provision it calls an alternative to pasteurization, published a risk assessment finding that the provision can increase risk for an entire class of these cheeses, wrote in 2015 that *E. coli* O157:H7 survives the provision in cheddar and took public comment on replacing it, funded research finding that the provision does not eliminate H5N1, and has finished none of it. In the meantime four outbreaks in thirty-one months have been linked to cheese that complied with the rule, the most recent announced on September 25, 2026 with over half of its victims age five or younger, and the label says nothing. Everything needed to write this rule is in the agency's files. The petitioner asks for the sentence, and for the reevaluation the agency promised.

C. ENVIRONMENTAL IMPACT

The petitioner claims a categorical exclusion under 21 CFR 25.30(k), which covers the establishment by regulation of labeling requirements for marketed articles where there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes. The action requested is a labeling requirement; it does not

⁴⁵ 63 FR 37030, at 37035 (response to comment 17), cited above.

⁴⁶ Congressional Research Service, IN12681, cited above, reporting that the firm stated the April 2026 recall affected approximately 1.5 million dollars of its product:
<https://www.everycrsreport.com/reports/IN12681.html>.

increase the use of cheese made from unpasteurized milk or change its intended use, and it does not individually or cumulatively have a significant effect on the human environment. To the petitioner's knowledge, no extraordinary circumstances exist.⁴⁷ Items 6 and 7 request the publication of a proposed rule or written explanation and of existing data, and any rulemaking that follows will carry its own environmental review.

D. ECONOMIC IMPACT

Information on economic impact will be submitted upon request of the Commissioner in accordance with 21 CFR 10.30(b). The petitioner notes that the agency prepared an economic analysis for the unpasteurized juice warning at 21 CFR 101.17(g) and for the shell egg safe handling statement at 21 CFR 101.17(h), and that both are available to the agency as benchmarks for a labeling requirement of the same form.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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The Honorable Secretary of Health and Human Services
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Deputy Commissioner for Human Foods, U.S. Food and Drug Administration
Director, Office of Microbiological Food Safety, Human Foods Program, U.S. Food and Drug Administration

⁴⁷ 21 CFR part 25 (environmental impact considerations; categorical exclusions):
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Chief Counsel, U.S. Food and Drug Administration
Executive Secretary, National Conference on Interstate Milk Shipments

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