



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-34-NH

DATE: May 20, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy of Revised F371; Interpretive guidance and Procedures for Sanitary Conditions, Preparation of Eggs in Nursing Homes

Memorandum Summary

- **Guidance for Nursing Homes:** Skilled nursing and nursing facilities should use pasteurized shell eggs or liquid pasteurized eggs to eliminate the risk of residents contracting Salmonella Enteritidis (SE). The use of pasteurized eggs allows for resident preference for soft-cooked, undercooked or sunny-side up eggs while maintaining food safety. In accordance with the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) standards, skilled nursing and nursing facilities should not prepare nor serve soft-cooked, undercooked or sunny-side up eggs from unpasteurized eggs.
- **Guidance for Surveyors:** Signed health release agreements between the resident (or the resident's representative) and the facility that acknowledges the resident's acceptance of the risk of eating undercooked unpasteurized eggs are not permitted. Pasteurized eggs are commercially available and allow the safe consumption of eggs. If the facility prepares or serves unpasteurized or undercooked eggs which are not cooked until both the yolk and white are completely firm, surveyors should consider citing deficiencies at F371. Determination of the appropriate scope and severity shall be based upon the actual or potential negative resident outcomes in accordance with guidance given at F371. We are revising F371 to clarify this section; a revised F371 is attached.

The Centers for Medicare & Medicaid Services (CMS) is clarifying the acceptability of long-term care (LTC) facilities serving soft-cooked, undercooked or sunny-side up eggs to their residents. CMS recognizes the U.S. Food and Drug Administration's (FDA) Food Code and the Centers for Disease Control and Prevention's (CDC) food safety guidance as national standards to procure, store, prepare, distribute and serve food in a safe and sanitary manner. Therefore, while honoring resident requests for soft cooked or sunny side up eggs is an appropriate practice

as outlined in §483.15(b) Self Determination and Participation, however the CDC and the FDA *strongly advise against serving unpasteurized, undercooked eggs* to highly susceptible populations which includes elders and persons residing in LTC facilities. Specifically, CDC literature states, “Although anyone can get a Salmonella infection, older adults, infants and people with impaired immune systems are at increased risk for serious illness. In these people, a relatively small number of Salmonella bacteria can cause severe illness.”¹ The CDC states, “A person who eats eggs can lower the risk of SE infection by eating eggs that are thoroughly cooked, or by eating foods that are made from pasteurized eggs”.² CMS agrees with the FDA and CDC’s guidance against serving unpasteurized, undercooked eggs to LTC facility residents.

CMS is aware of facilities having secured signed health release agreements from residents (or the resident’s representative) requesting to be served undercooked eggs. Health release agreements allowing soft-cooked, undercooked or sunny-side up unpasteurized eggs for resident preference are not acceptable.

Eggs are the most common food source linked to SE infections, and the predominant route of egg contamination is transovarian. SE will infect the ovaries and oviducts of some egg-laying hens, permitting transovarian contamination of the interior of the egg while the egg is still inside the hen.³ If unpasteurized eggs contaminated with SE are eaten raw or undercooked the bacterium can cause illness and death particularly in the elderly, infants, and those with impaired immune systems. Shell egg safe handling labeling specifically states, “To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly”.⁴

The FDA Food Code which has been adopted by all 50 states, the US territories and most of the tribal Nations, advises that eggs prepared and served to highly susceptible persons in nursing homes should be pasteurized or cooked until both the yolk and whites are firm.⁵ Pasteurized shell eggs are commercially available, are clearly labeled and allow the safe consumption of undercooked eggs. Federal regulations expect nursing facilities to make reasonable efforts to respect resident choices and can honor resident choice while maintaining health and safety standards through the use of pasteurized eggs.

If a skilled nursing or nursing facility has a resident who prefers undercooked eggs such as soft-cooked or sunny-side up, the facility must use pasteurized eggs.⁶ If the facility uses unpasteurized shell eggs for individual resident consumption, those eggs must be cooked until both the yolk and white are completely firm and served immediately.

The surveyor interpretive guidance in Appendix PP at F371 will be revised in two ways to provide additional clarification: (1) unpasteurized eggs must be cooked until both the yolk and white are completely firm; and (2) deletion of the example of a negative outcome that could rise to the level of immediate jeopardy. For all other forms of egg preparation, including hot holding of eggs, and pooling (combining) of eggs for recipes where more than one egg is broken and the eggs are pooled and used as an ingredient immediately before baking, such as in a meat loaf mixture, muffins or cake,

the eggs must be pasteurized or thoroughly cooked to an internal temperature of 160°F (71°C).^{7, 8, 9}

If the facility serves soft-cooked, undercooked or sunny-side up unpasteurized eggs, surveyors should determine the appropriate scope and severity based upon the negative actual and potential outcomes and in accordance with instructions and guidance given at F371. To determine whether the evidence rises to the level of an immediate jeopardy, surveyors are expected to review evidence about resident's immediate risk of serious injury, harm, impairment or death, the number of residents affected, the surveyor's observations of egg availability, food preparation and meals and other system failures of the facility that could lead to food borne illness (i.e. whether undercooked, unpasteurized eggs are served widely to many residents, and the result of interviewing facility staff to identify additional system failures).

An advance copy of the guidance revisions is attached. The final version of this document, when published may differ slightly from this advanced copy.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information must be shared with all nursing home survey and certification staff, surveyors, managers, and the State and CMS regional office training coordinators.

/s/

Thomas E. Hamilton

Attachment:

Advance Copy of Revised F371; Sanitary Conditions

cc: Survey and Certification Regional Office Management

References:

¹ Salmonella is a Sneaky Germ: Seven Tips for Safer Eating
<http://www.cdc.gov/features/vitalsigns/foodsafety/>

² Salmonella serotype Enteritidis
http://www.cdc.gov/nczved/divisions/dfbmd/diseases/salmonella_enteritidis/

³ Federal Register / Vol. 74. No. 130 / Thursday, July 9, 2009 / Rules and Regulations. (Final Rule) Page 33032. <http://www.gpo.gov/fdsys/pkg/FR-2009-07-09/pdf/E9-16119.pdf>

⁴ <http://www.fda.gov/downloads/food/resourcesforyou/consumers/ucm278445.pdf>

⁵ U.S. Food and Drug Administration Food Code
Section 3-401.11(A) (Note the word “except”); > 3-401.11(D)(1). Note “not” highly susceptible population”.
<http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm>

⁶ U.S. Food and Drug Administration Food Code. Section 3-801.11 (C) (2).
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>

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⁷ Centers for Disease Control and Prevention - Tips to Reduce Your Risk of Salmonella from Eggs <http://www.cdc.gov/features/salmonellaeggs/>

⁸ U. S. Food and Drug Administration - Playing It Safe With Eggs
<http://www.fda.gov/food/resourcesforyou/Consumers/ucm077342.htm>

⁹ Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs (Final Update) <http://www.cdc.gov/salmonella/enteritidis>