



July 19, 2005

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
12420 Parklawn Drive
Rockville, MD 20852

Re: Docket No. 2004N-0382
Food Labeling; Safe Handling Statements: Labeling of Shell Eggs

AARP appreciates the opportunity to comment on this proposed rule that would grant the egg industry flexibility on the placement of the "safe handling statement" on egg cartons.

Salmonella enteritis (SE) contamination in shell eggs is a serious public health problem, particularly for older persons.¹ While efforts by government and industry have led to a reduction in the incidence of SE infection,² the levels of infection remain significant.³

The U. S. Centers for Disease Control and Prevention (CDC) has recognized the need for a more concerted SE-prevention effort and has endorsed stronger SE-control measures.⁴ Hopefully, the FDA will act quickly to finalize proposed regulations that will finally establish some on-farm SE controls. In the meantime, the last line of defense for consumers against SE infection is the "safe handling statement" that has been required on eggs cartons since 2001.

AARP does not object to granting egg producers flexibility on the placement of the safe handling statement if, at the same time, FDA revises its regulations to enhance the statement's noticeability and readability. Currently, the regulation requires only that the statement shall appear "prominently and conspicuously" on the carton. A non-statistically significant survey of egg cartons sold in the Washington, D.C. metropolitan area found that the safe handling statement is printed in type as small as 7 point. Moreover, in some instances, the statement is printed directly on a gray cardboard

¹ See U.S. General Accounting Office, *Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety* 3 (1999). Moreover, the U.S. Centers for Disease Control (CDC) has determined that the likelihood of dying from a foodborne illness contracted in a nursing home is 13 times higher than from outbreaks in other settings. *Id.* at 12.

² The rate of culture-confirmed SE infections reported to the CDC declined from a high of 3.8 per 100,000 in 1995, to 1.9 per 100,000 in 1999. No further decline was experienced through 2001, the most recent year for which data is available. Mary E. Patrick et al., *Salmonella Enteritidis Infections, United States, 1985-1999*, 10 *Emerging Infectious Diseases* 6 (January 2004).

³ The most recent review of data collected through the CDC's FoodNet reveals that, of the *Salmonella* serotypes tracked, only the incidence of *Salmonella* Typhirium has decreased significantly. D. Vugia, MD et al, *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food - 10 Sites, United States, 2004*, 54 *MMWR* 352 (2005).

⁴ U.S. Centers of Disease Control and Prevention, *Outbreaks of Salmonella Serotype Enteritidis Infection Associated with Eating Shell Eggs --- United States, 1999-2001*, 51 *MMWR* 1149 (2003), available online at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5151a1.htm>. See also Institute of Medicine, National Research Council of the National Academies, *Scientific Criteria to Ensure Safe Food* 57 (2003) ("The surveillance data clearly show that progress is being made in slowing the *S. Enteritidis* problem in eggs, but further efforts are needed to completely control it.")

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carton, which makes the statement difficult to read. As a result, we would not be surprised if a significant number of consumers do not notice, or have difficulty reading, this important information.

AARP recommends that FDA replace the existing vague "prominent and conspicuous" standard for the safe handling statement with some specific formatting requirements. Designers and publishers of written information follow widely accepted standards that ensure that this information is noticeable and readable.⁵ We urge the agency to incorporate at least two of these standards into the regulation governing the safe handling statement for shell eggs: (1) require that the statement be printed in no smaller than 10- inch type; and (2) require that there be good contrast between the ink and paper colors (black, dark blue, or brown on pale yellow or white).⁶

These two, relatively minor changes should make the safe handling statement much easier for everyone to both notice and read. They are especially important for older consumers, who are particularly susceptible to SE infection and who often have impaired vision. These simple changes could have a significant impact on the effectiveness of the safe handling statement, critical information that, for some people, may mean the difference between life and death.

FDA would not be setting a precedent by enacting specific format requirements. Regulations adopted by other federal agencies prescribe the type size and contrast to be used in required labeling.⁷

If you have any questions regarding these comments, please contact Larry White (at 202-434-3800) of our Federal Affairs staff.

Sincerely,



David Certner
Director
Federal Affairs

⁵ See, e.g., The Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, *Action Plan for the Provision of Useful Prescription Medicine Information*, Appendix G at pages 55-56 (December 1996) available online at http://www.keystone.org/Public_Policy/FinalActionplan.pdf. While the optimal type size for older consumers is 12 point, we understand that this size may not be practical for egg cartons. AARP recommends that FDA focus on type size and contrast in its formatting of the safe handling statement, but it should certainly consider other formatting factors discussed in the attached guidelines.

⁶ While AARP encourages FDA to test possible revised formats for the egg handling statement on actual consumers, we understand that the agency may not have the resources necessary to undertake such testing. Nevertheless, FDA can make the requested revisions with confidence, given that they are well-established and widely accepting standards.

⁷ See, e.g. 16 C.F.R. §305.11(a) (energy- and water-use labeling for appliances)