

July 19, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**RE: Food Labeling: Safe Handling Statements: Labeling of Shell Eggs
Docket No. 2004N-0382
70 Fed. Reg. 23813 (May 5, 2005)**

The Center for the Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposal to amend the agency's food labeling regulations regarding the labeling of shell eggs. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Summary

CSPI has long been concerned with the safety of shell eggs and the appropriate labeling warning of potential safety issues. Generally, CSPI has been very supportive of FDA's actions to improve the safety of shell eggs, including the issuance of the final rule requiring the placement of a safe-handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms.¹ CSPI has stated in the past, and continues to believe, that the safe-handling instructions should be placed prominently on the outside lid of the egg carton. However, if the agency chooses to allow the safe-

¹ CSPI, while supporting the labeling of eggs, has stated, and still believes, that the FDA should require a cautionary statement, rather than a safe-handling statement, on all shell eggs.

handling instructions to be placed on the inside of the lid, certain specifications must be required. The foregoing recommendations are discussed more fully below.

Safe-Handling Instructions Should Remain on the Outside of Egg Cartons

Raw or undercooked eggs pose a public health threat. Between 1990 and 2003, *Salmonella* Enteritidis has been implicated in at least 273 egg outbreaks, which accounted for 83% of all egg outbreaks.² Under the current FDA regulations, a safe-handling statement is required on all cartons of shell eggs. 21 C.F.R. § 101.17(h) The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that “information be placed on the label with such conspicuousness as to render it likely to be read and understood by ordinary individuals under customary conditions of use.” 21 U.S.C. § 343(f) On egg cartons, it is required to appear either on the principle display panel, which is usually on the top of the egg cartons, or on the nutrition panel.

In order to ensure consumers read the message, the outside of the egg carton is the most reliable spot for the safe-handling statement to appear. According to the regulations, the label must be conspicuous so that ordinary individuals can see it. In 1999, the FDA sought comments on the proposed rule for labeling of shell eggs. At that time, CSPI, along with numerous others, argued that the safe-handling statement should be prominently placed on the outside lid of the egg cartons so that consumers could see the warning with little effort. The FDA agreed and enacted regulations requiring the safe-handling statement to be located on the outside of the egg carton. Because *Salmonella* in shell eggs is such a serious public health threat, the safe-handling statement should remain on the outside lid of the egg cartons.

² See CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (revised Mar. 2004).

Warnings on the Inside Lid Should Have Size Requirements

Should FDA amend the regulations and allow the egg industry to place safe-handling statements on the inside of egg cartons, egg producers should be required to follow strict guidelines. Currently, the font size of safe handling instructions on egg cartons is not regulated. Some egg cartons have the safe handling instructions printed directly on the gray cardboard carton in font size as small as 7-point. This cannot possibly satisfy the requirement of being conspicuous to the ordinary customer – especially the elderly – as the regulation requires. To make the statement conspicuous so that all consumers, especially the elderly, can read it, the statement should be printed using a font size of no smaller than 12-point. Furthermore, the statement should be printed in a dark color, preferably black or blue, on a light background and outlined by a hairline box so as to appropriately enhance its legibility. While current FDA regulations do not regulate the type style and font size of warning labels on products it regulates, labels on other products are regulated. For instance, on children’s clothing, the flammable warning label must be printed in the Arial or Helvetica font type and in at least 18-point font size.³ The energy and water-use labeling of appliances also requires the Helvetica typeset and requires black ink to be used.⁴ FDA should replace the current vague standards of “conspicuous” with specific, strict formatting requirements.

CSPI agrees with FDA that the statement “Keep Refrigerated” should remain on the principle display panel of all egg cartons. However, this statement should also be

³ 16 C.F.R. § 1615.1

⁴ 16 C.F.R. § 305.11(a)(2)

accompanied by a referral statement so that consumers will know to look on the inside of the lid for further safe-handling instructions.

Conclusion

Because of the importance of a safe-handling statement on shell egg cartons, CSPI believes that the FDA should continue to require that the statement be placed on the outside of the egg carton and any amendment should further regulate the font and type used to ensure readability.

Respectfully submitted,

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