

December 21, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

**Re: Comments on Proposed Rule Establishing Regulations on the Prevention of *Salmonella* Enteritidis in Shell Eggs During Production
Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504.
69 Fed. Reg. 56824 (September 22, 2004)**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposed regulations aimed at preventing *Salmonella* Enteritidis (SE) contamination in shell eggs during production. 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 supports FDA's and the U.S. Department of Agriculture's (USDA) long-term goal of eliminating egg-associated SE illnesses in the United States.¹ We have been working for years to help realize this goal. In 1997, CSPI petitioned the FDA asking for mandatory on-farm controls for *Salmonella* Enteritidis in eggs, including environmental sampling and diversion of eggs from contaminated flocks. We had hoped for more

¹ EGG SAFETY—From Production to Consumption: An Action Plan to Eliminate Salmonella Enteritidis Illnesses Due to Eggs, President's Council on Food Safety, December 10 1999

timely action from the agencies but we are pleased that FDA has issued this proposal and that the proposed measures target SE contamination at the earliest stage of production.

While generally supporting the FDA's proposed rule, CSPI has some concerns that we would like to see addressed in the final rule. In particular, we believe that the FDA has relied on data that show an artificially low estimate of SE illnesses, resulting in an underestimation of the ultimate economic benefit that would be brought about by promulgation of the rule. Furthermore, we believe that testing and diversion requirements should apply to all producers, regardless of size or other considerations, in order to achieve the maximum public health benefit.

Quantitative Risk Assessments Show Higher Rates of SE Illness

CSPI supports FDA's preliminary determination that the expected benefits of the proposed SE regulations (estimated at \$580 million) overwhelmingly outweigh their expected costs (\$82 million). But we believe the potential benefits are even greater. The proposed rule is based upon data from the Centers for Disease Control and Prevention's (CDC) passive surveillance system which estimated 118,000 SE illnesses per year owing to egg consumption.² Other quantitative risk assessments done by the U.S. government, however, show higher estimates of illness.

In 1998, USDA carried out a comprehensive risk assessment for *Salmonella* Enteritidis in shell eggs.³ It sought to characterize the human health risk of SE in eggs and egg products, to identify and evaluate potential risk reduction strategies, to identify data needs and to prioritize future data collection efforts.⁴ That risk assessment indicated

² 69 Fed. Reg. at 56825 (2004)

³ *Salmonella* Enteritidis Risk Assessment (SERA): Shell Eggs and Egg Products (May 1998) [hereinafter *1998 Risk Assessment*]

⁴ *1998 Risk Assessment* page 1

that about 660,000 cases of human illnesses per year would result from the consumption of shell eggs,⁵ and its conclusions supported on-farm sanitation and egg diversion programs.

Earlier this year, almost simultaneously with FDA's release of their proposed rule, USDA released a new draft risk assessment.⁶ Like the 1998 Risk Assessment, the 2004 Draft Risk Assessment is a comprehensive quantitative analysis. Indeed, it is even more robust as it includes several additional dimensions, such as new data from recent studies including a national baseline survey to measure SE levels in liquid egg products, clarification of scientific issues associated with SE contamination in egg yolk, and studies on lethality kinetics of *Salmonella spp.* in liquid egg products. In addition, it uses updated modeling techniques such as an improved dose-response model for *Salmonella spp.*, and more germane risk assessment objectives to evaluate the effectiveness of egg safety performance standards. The 2004 Draft Risk Assessment estimated that 350,000 illnesses per year would result from the consumption of SE-contaminated eggs.⁷

CSPI is concerned that in using only the CDC surveillance data, FDA risks underestimating the economic benefit that would be achieved by promulgating stronger egg safety regulations.

Testing and Diversion Requirements Should Apply to All Producers

In an effort to reduce its impact on small business entities, the FDA's proposed rule would exempt the smallest egg producers—those with fewer than 3,000 hens— as well as those who sell all of their eggs directly to consumers and those that treat their

⁵ 1998 Risk Assessment page 14

⁶ Draft Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella spp.* In Egg Products (October 2004) [hereinafter 2004 Draft Risk Assessment]

⁷ 2004 Draft Risk Assessment page 3

eggs to reduce SE contamination from other requirements (these last would be subject to on-farm refrigeration requirements). We are concerned that such a broad exemption for these producers would diminish the public health benefit that this new rule has the potential to generate.

CSPI urges the FDA to apply its proposed testing and diversion requirements to all egg producers, regardless of size. Testing of the environment and shell eggs provides verification that on-farm sanitation programs are effective in controlling SE. In addition, a positive finding of SE would provide an early warning of disease in a flock and a prompt for quick action to halt its spread. Diversion of eggs when SE is found could significantly reduce the likelihood of illnesses and outbreaks.

The evidence is clear that there is a strong correlation between an SE-positive environment and SE-positive eggs, as illustrated by the Pennsylvania Egg Quality Assurance Program⁸ and acknowledged in the proposed rule.⁹ Exempting small producers from broader sanitation mandates while maintaining testing and diversion requirements would mitigate the burden on these small businesses without reducing the public health benefit from these much-needed regulations.

⁸ Center for Science in the Public Interest, Petition for Regulatory Action to Require That (1) Warning Labels About the Risks of *Salmonella* Enteritidis (SE) BE Placed on Shell Egg Cartons and (2) SE Control HACCP Programs Be Implemented on All Egg-Producing Farms, May 14, 1997, pages 13-14

⁹ 69 Fed. Reg. at 56838 (2004)

Conclusion

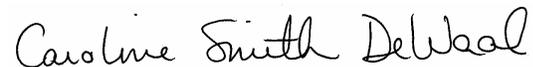
CSPI urges FDA to move quickly to finalize these important new regulations, and we hope that they are strengthened in the manner outlined above.

In addition, we urge that any suggestions to weaken the proposal be put out for comment during agency consideration, as we have noted in recent years that strong public health regulatory proposals have been significantly weakened during the comment review process.

Respectfully submitted,



Linda McIntyre
Food Safety Staff Attor+ney



Caroline Smith DeWaal
Food Safety Director