

SAFE FOOD COALITION

1424 16th St, NW, Suite 604, Washington, DC 20036 202-387-6121

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* Enteritis in Shell Eggs During Production
Docket Nos. 1996P-0197, 1998P-0203, and 2000N-0504.
69 Fed. Reg. 56824 (September 22, 2004)**

Introduction

On behalf of the following members of the Safe Food Coalition (SFC)¹ – AARP,² the Center for Science in the Public Interest (CSPI),³ the Consumer Federation of America (CFA),⁴ the National Consumers League (NCL),⁵ and Public Citizen⁶ – we appreciate this opportunity to comment on the Food and Drug Administration's (FDA) proposed regulations aimed at preventing *Salmonella* Enteritis contamination in shell eggs during production.

¹ The Safe Food Coalition is an informal group of consumer, public health, whistle blower, senior citizen, and labor organizations. It works to educate the public about the hazards of foodborne illness and seeks congressional and administrative action to improve meat, poultry, and seafood inspection as well as other aspects of government food-safety regulation..

² AARP is a nonprofit, nonpartisan membership organization dedicated to addressing the needs and interests of persons 50 and older. Through information and education, advocacy and service, we seek to enhance the quality of life for all by promoting independence, dignity and purpose.

³ 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.

⁴ CFA is a nonprofit association of 300 consumer groups, representing more than 50 million Americans that was established in 1968 to advance the consumer interest through research, education and advocacy.

⁵ NCL is the nation's oldest nonprofit advocacy group representing consumers on marketplace and workplace issues. Our mission is to identify, protect, represent, and advance the economic and social interests of consumers and workers.

⁶ Public Citizen is a national, nonprofit consumer advocacy organization with 150,000 members founded in 1971 to represent consumer interests in Congress, the executive branch and the courts.

SE contamination in eggs was first identified in the late 1980s, and since that time, federal and state officials, along with egg producers, have taken actions to prevent this serious public-health problem. Those actions – including voluntary quality assurance programs as well as labeling and refrigeration requirements-- have contributed to a decrease in the level of SE infections; by 1999, the rate of culture-confirmed SE infections reported to the U.S. Centers for Disease Control (CDC) had declined from a high of 3.8 per 100,000 in 1995, to 1.9 per 100,000 population.⁷

However, there has been no further decline in SE infections through 2001, the most recent year for which data is available, and the rate of infection remains significant. The CDC has recognized the need for a more concerted SE-prevention effort and has endorsed stronger SE-control measures.⁸

In 1998, FDA, along with the U.S. Department of Agriculture, issued an advanced notice of proposed rulemaking (ANPRM) on SE contamination in eggs. The following year, the President’s Council on Food Safety identified egg safety as a public health issue that warranted “immediate” action.”⁹ While FDA took nearly six years to issue proposed rules (and did not act as immediately as we’d hoped), the resulting regulations – on balance -- are very good.

The SFC generally supports the FDA’s proposal, which targets SE contamination at its source – the farm. In this proposal, FDA expressly acknowledges that the current risk of illness from consuming SE-contaminated eggs is still “too high,”¹⁰ and that “it is important to take practical measures to prevent eggs from becoming contaminated with SE in the first place.”¹¹ As has been demonstrated by the voluntary egg quality assurance programs currently in effect in a number of states, on-farm prevention measures, like those included in FDA’s proposal, reduce the levels of SE contamination, and this reduction, in turn, has led to a decrease in the number of human illnesses caused by SE.¹²

⁷ The 1976 baseline rate for SE infections was 0.55 per 100,000 population. Mary E. Patrick et al., *Salmonella Enteritidis Infections, United States, 1985-1999*, 10 *Emerging Infectious Diseases* 6 (January 2004).

⁸ 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.”)

⁹ President’s Council on Food Safety, *Egg Safety From Production to Consumption: An Action Plan to Eliminate Salmonella Enteritidis Illnesses Due to Eggs 2* (1999) available online at <http://www.foodsafety.gov/~fsg/ceggs.html>.

¹⁰ 69 Fed. Reg. at 56845.

¹¹ *Id.* at 56846.

¹² When the Pennsylvania Egg Quality Assurance Program was implemented in 1992, 38 percent of laying houses had at least one SE positive sample; by 1995, only 13 percent of flocks had a positive sample. The percentage of SE positive flocks continued to drop and, by 1997, was down to 8 percent. Between 1992 and 1995, human illness from SE in the market area for Pennsylvania eggs (New York, New Jersey, and Pennsylvania) saw a similar decline.

With an estimated 50 percent of all farm sites participating in a voluntary egg quality assurance program,¹³ this means that an equal number of farms have no SE-prevention measures. By establishing nationwide standards for preventing SE contamination in shell eggs, FDA is ensuring that consumers are protected from this serious foodborne pathogen, regardless of where they live or buy their eggs.

The proposed regulations contain the key elements necessary for an effective SE-prevention program:

- a requirement that chicks and pullets be purchased from SE-monitored breeder flocks;
- a biosecurity program;
- a pest and rodent-control program;
- an environmental and egg testing program by producers;
- diversion of contaminated eggs to pasteurization plants;
- a requirement for cleaning and disinfection of poultry houses after a positive environmental test; and
- refrigerated storage of eggs on farms.

Before commenting on specific aspects of FDA's proposed SE-prevention regulations, the SFC would like to address one element that is missing from FDA's on-farm SE-prevention proposal: measures to reduce SE contamination in feed. FDA characterizes as "rare" the evidence that feed or water is a source of SE contamination in eggs. At the same time, it encourages producers to include the testing of feed to ensure that it is SE-free as a good management practice. We urge the agency to monitor farms that do test feed for SE and analyze the relevant data, as well as to continue to review and evaluate research studies on the impact of feed on SE contamination.

Comments on Specific Aspects of the FDA's Proposal

Requirements Related to Handling and Preparation of Eggs Served to Highly Susceptible Populations

While the FDA proposal focuses on on-farm measures to prevent SE contamination in shell eggs, the agency is also soliciting comments on whether it should adopt mandatory handling and preparation standards for eggs served to highly susceptible populations (older people, young children, and persons with suppressed immune systems).

Persons residing or simply eating together in institutional settings (nursing homes, independent or assisted living facilities, childcare settings, campus cafeterias, prisons and shelters) are at higher risk of dying from outbreak-associated SE infections.¹⁴ This is

¹³ 69 Fed. Reg. at 56831. These programs are sponsored by States and commodity groups.

¹⁴ W.C. Levine et al., *Foodborne Disease outbreaks in nursing homes, 1975 through 1987*, 266 JAMA 2105 (1991).

particularly true for elderly persons in nursing homes and similar residential facilities.¹⁵ As FDA notes in the preamble to this proposal, 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were nursing-home residents.¹⁶ During 1990-2001, a total of 83 SE outbreaks occurred in institutional settings, representing 12% of reported SE outbreaks. Of the 33 outbreak-associated deaths, 22 (67%) occurred in institutional facilities.¹⁷

The on-farm, SE-prevention measures proposed by FDA will have a significant effect on SE-contamination of shell eggs. The additional step of requiring that facilities serving eggs to high-risk populations follow certain practices to prevent or minimize the transmission of SE would bring us even closer to our target for reducing SE infections by 2010.

Given the disproportionate impact of SE infections on high-risk populations such as the elderly, the SFC supports the adoption of mandatory, federal regulations based on the relevant Food Code provisions. We believe that a positive impact on public health can be achieved in this area only through mandatory standards. Such an approach is appropriate in order to adequately protect vulnerable subpopulations.

On-Farm Measures

Testing and Diversion Requirements

The SFC is addressing this element of the proposed program first because it is the most critical verification element of an SE-control program: testing of the environment and shell eggs for SE is the best way to determine whether a producer's SE-prevention measures are working.

We strongly support requiring the testing of both environment and egg samples for SE contamination. Evidence clearly demonstrates that there is a positive correlation between an SE-positive environment and SE-positive eggs: the SE pilot project found that half of the flocks with an SE-positive environment produced at least one positive egg in the time period studied.¹⁸

FDA is proposing to require testing of the poultry house environment at 40 – 45 weeks; and to mandate that a producer take specific actions if the environmental test is positive, most significantly, either to test eggs within 24 hours of receiving notification of the positive environmental test or divert eggs to pasteurization plants for the life of the

¹⁵ According to the General Accounting Office, 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. General Accounting Office, *Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety* 12 (1999).

¹⁶ *Id.*

¹⁷ 51 MMWR 1149.

¹⁸ 69 Fed. Reg. at 56838.

flock in that poultry house. The regulations also spell out the sampling and testing methodologies to be employed by producers.¹⁹

While we support the proposed testing requirements, we are concerned that FDA's proposal to require only one environmental test during the life of a flock is inadequate. We urge FDA to look at the testing frequencies employed in some of the state egg quality assurance programs, in particular the Pennsylvania program, which requires more frequent environmental testing.²⁰ Testing must occur at a sufficient number of points during the life of the layer flock in order to best ensure that SE- contaminated shell eggs are not leaving the farm.

We do agree with FDA's tentative decision to require a producer to conduct one egg test per month on a flock that had a positive egg test in a flock and is subsequently returned to table egg production after meeting the required number of negative egg tests. This proposed requirement is grounded in sound science: FDA cites to research that suggests that a flock that has been contaminated with SE will continue to produce SE-contaminated eggs sporadically, and periodic testing will help identify when this occurs so that eggs can be diverted.²¹

Biosecurity Program

SFC supports FDA's requirement that all farms and poultry houses institute a biosecurity program. This program includes the following measures to prevent the "horizontal" spread of SE: limitations on visitors; requirements that equipment be kept clean; measures to ensure proper hygiene and protective clothing of persons moving among poultry houses; and prohibition of stray poultry and other animals from entering the grounds as well as of the removal of poultry from the facility or grounds.

We believe that these biosecurity measures should be mandatory: FDA regulations should set the basic minimum requirements, but individual states should be given the authority to add additional measures, where appropriate. A state should also be given the opportunity to petition to be exempt from any federal requirements that it believes are not applicable to the egg production practices within its jurisdiction.

Requirement that Chicks and Pullets be Purchased from SE-monitored Breeder

The SFC supports a requirement that producers certify that the pullets they procure are from a facility that has an SE-monitoring program. Since SE can be transmitted to eggs from a layer's contaminated ovaries, this requirement is a key measure in preventing SE contamination in poultry houses.

¹⁹ Producers should pay for and conduct the testing required by FDA, with government inspectors auditing the testing to ensure that it is being conducted properly.

²⁰ See Nichole Martz, PA Department of Agriculture, *On-Farm Testing*, available online at http://poultryextension.psu.edu/PEQAP%20Training/On%20Farm%20Testing-Monitoring_files/frame.htm

²¹ *Id.*

We agree that producers should be required to certify that the pullets they procure are from a facility that has an SE-monitoring program. Any such program should be required to meet the standards established in the National Poultry Improvement Plan. (*See* 9 C.F.R. Sec. 145.23(d)).

Pest Control

The SFC supports FDA's proposed requirement that each producer develop and implement a pest control program that includes not only rodents, but also flies and other pests. As FDA noted in the preamble to the proposed rule, flies have been shown to harbor SE within the poultry house environment.

Cleaning and Disinfection

The SFC supports FDA's tentative decision to require the cleaning and disinfection of all poultry houses that have had an SE-positive environmental or egg test, before new laying hens are added to a house. We agree with FDA's proposal to include in its cleaning and disinfection regulation a requirement for wet washing, even though the agency acknowledges that there is some evidence (though inconclusive) that wet cleaning of poultry houses may increase SE contamination. In light of this concern, we urge the agency to undertake and sponsor research on the impact of wet cleaning on SE contamination.

We also support the agency's decision to recommend that producers include manure removal and dry cleaning of poultry houses as a general management practice. This should occur every time a poultry house is depopulated, whether or not SE was detected in the house.

Forced Molting

Some members of the SFC oppose the practice of forced molting on the grounds that it renders hens more susceptible to SE infection and can lead to increased shedding of SE organisms. In its proposal, FDA has declined to prohibit this practice and, instead, has proposed a more intensified environmental testing requirement when induced molting occurs.

We support this requirement for intensified testing. At the same time, we urge the agency to continue to monitor the use of forced molting to obtain more data on the impact of this practice on SE contamination. FDA should consider funding a pilot program that would determine the effectiveness of various alternative prevention measures relating to forced molting that it outlined in the proposal rule (the use of alternative diets to replace withdrawal of food and water, the use of competitive exclusion, more frequent renewal of manure during and after molting, and a prohibition of molting in SE-positive houses).

Refrigeration Requirement

FDA tentatively proposes to require that shell eggs be stored at or below 45°F ambient temperature if they are held on the farm for more than 36 hours after laying. We endorse the setting of a temperature limit for eggs stored on the farm, and the proposed limit is consistent with current FDA's refrigeration requirement for shell eggs at retail.²² We continue to have some concern, however, that this temperature limit provides no margin of safety, and urge the agency to continue to monitor research on the impact of different ambient temperatures on SE growth, and to revise its temperature limit, if warranted.

The SFC also supports requiring refrigerated transport of shell eggs not already required by FDA or within USDA's jurisdiction. This would include transport of shell eggs from a farm or a packer to a food manufacturing facility. Such a requirement would ensure that shell eggs are not subjected to temperature abuse at any point along the distribution chain.

Administration of the SE-Prevention Measures

The SFC supports FDA's proposal that one employee at each farm should be responsible for the administration of the SE-prevention program. This person, who would be thoroughly trained in SE-prevention measures, would be responsible for the development and implementation of the SE prevention measures, for reassessing and modifying a plant's particular program when necessary, and would review all relevant records.

Designating one employee as the party responsible for a farm's SE-prevention program better ensures the development of expertise and consistent application of the relevant standards.

Recordkeeping Requirements

The SFC agrees with FDA's tentative decision to require that all records relating to SE prevention measures, as set out in the proposed rule, should be retained for one year after the flock has been taken out of egg production. Such a record-keeping requirement allows an inspector to easily review each farm's SE-prevention program to ensure that it satisfies FDA's requirements, and would also facilitate the investigation of any egg-related SE outbreaks.

Registration of Farms

The SFC supports a registration requirement for farms that produce shell eggs. Such a requirement should be consistent with the program developed under the agency's bioterrorism regulations. By identifying each farm's location and size, a registration

²² See 21 U.S.C. Sec. 115.50.

requirement would enable more efficient inspection, as well as better management and oversight of a shell-egg recall.²³

Enforcement of On-Farm, SE-Prevention Measures

The SFC agrees with FDA's tentative decision to allow its SE regulations to be enforced by an authorized representative of FDA or relevant State or local official. FDA clearly does not have the resources to fully enforce the SE-prevention regulations on its own and, therefore, must rely on the other jurisdictions. At the same time, FDA should work closely with state and local personnel to ensure that they are accurately and adequately enforcing its SE-prevention regulations for shell eggs.

Exemptions from Required SE-Prevention Measures

FDA proposes to exempt from its proposed requirements all producers with fewer than 3,000 hens, those that sell all of their eggs directly to consumers, and those that treat their eggs to reduce SE contamination (this last group would be required to comply with on-farm refrigeration requirements). We are concerned that the exemption for smaller farms is not risk-based and, as a result, the proposed regulations will not have as significant impact on SE contamination in shell eggs as anticipated.

The SFC urges FDA to apply all of its production-related egg regulations to all producers, unless and until there is evidence that SE-contamination rates are positively correlated with the producer's size. If the regulations would apply to all producers, then the agency could provide smaller producers with direct assistance in developing and implementing SE-prevention programs.

As one alternative to a blanket exemption based on size, FDA could provide smaller producers with the opportunity to petition for a waiver of any requirements that are economically burdensome or inapplicable to their operations. Another alternative approach is a "performance-based" regulatory scheme, under which the agency would exempt smaller producers from the regulations' sanitation measures but would mandate that they follow the testing and diversion requirements.

Preliminary Regulatory Impact Analysis

The SFC strongly 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). As the agency indicates in the preamble to its proposed regulations, "the current risk of illness from consuming SE-contaminated eggs is still too high, especially when there are cost-effective measures that can be taken that will reduce the risk."²⁴

²³ We urge FDA to add a related requirement to its proposed egg regulations: that all egg cartons include information on where the shell eggs were produced and packaged. This important information would facilitate traceback in the event of a recall.

²⁴ 69 Fed. Reg. at 56845.

Conclusion

With some modifications, FDA's proposed regulations aimed at preventing SE contamination of eggs on the farm will substantially reduce this serious public-health problem. We urge to agency to make up for lost time and act quickly to finalize this proposal.

Respectfully Submitted,

David Certner
Director, Federal Affairs
AARP

Caroline Smith DeWaal
Director, Food Safety Program
Center for Science in the Public Interest

Carol Tucker Foreman
Distinguished Fellow and Director
The Food Policy Institute
Consumer Federation of America

Alison Rein, MS
Assistant Director, Food & Health Policy
National Consumers League

Wenonah Hauter,
Director, Food Program
Public Citizen