



Nature's perfect food made perfectly safe.

December 16, 2004

DIVISION OF DOCKET MANAGEMENT
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 2000N-0504

SUBJECT: PREVENTION OF *SALMONELLA*
ENTERITIDIS IN SHELL EGGS DURING PRODUCTION

Dear Sir or Madam:

We appreciate the opportunity to submit comments on the subject proposed rule. We are also pleased to see the FDA take such a comprehensive, science-based approach to the issue of SE in shell eggs. The Healthier People goal of reducing Salmonella related infections 50% by 2010 now appears to be achievable.

NATIONAL PASTEURIZED EGGS, LLC (NPE) is a proponent of the "farm to table" approach to solving this food safety problem. We also believe *In-Shell Egg Pasteurization* is a vital adjunct to the successful achievement of the Healthier People goals.

The FDA has asked for comments in many areas relating to the "farm to table" continuum. Our comments are limited to areas in which we have specific knowledge or experience.

Request for Comment: Should we include additional requirements in the final rule, particularly in two areas? First, should we expand the recordkeeping requirements to include a written SE prevention plan and records for compliance with the SE prevention measures? Second, should the safe egg handling and preparation practices in FDA's 2001 Model Food Code (as outlined in section IV.D of this document) be Federally mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers)?

Comment: *We do not have a comment on the first question. With respect to the second question, however, we do have a comment. NPE has been selling pasteurized shell eggs since late 2001. During this period of time the Model Food Code has been through two updates and is now adopted in some 43 states. Despite the tremendous efforts of the FDA to provide science-based advice to retail establishments, which not only prevents illnesses but*

can save lives, most establishments refuse to implement the advice. The comment we frequently hear in the field is “We will adopt the Model Food Code when the FDA mandates it”. This attitude is confirmed by the work done by EHS-Net and more fully explained in their paper “Prevalence of High-Risk Egg-Preparation in Restaurants That Prepare Egg Entrees: An EHS-Net Study”. Clearly the success of the proposed rule rests not only on the reduction of SE during production, but also pushing through the continuum to the “Table” and mandating guidelines nationwide which will more adequately protect consumers from SE infected eggs. The staggering statistic - 68% of the deaths associated with SE outbreaks were from nursing homes - should be sufficient to demonstrate the impact of SE on the highly susceptible populations. Mandating Federal guidelines will provide the necessary incentive to retail establishments to begin implementing the advice provided in the Model Food Code.

Request for Comment: Is a 5-log reduction or an alternative approach to achieve an equivalent level of protection still appropriate to ensure the safety of shell eggs?

Comment: *Clearly the answer to this question is “yes”. While the proposed rule is comprehensive, it estimates only a 28% reduction in illnesses. With a goal of 50% reduction by 2010 and preferably a higher reduction, the 5-log reduction or equivalent provides an additional method of reducing SE and achieving or exceeding the goal.*

Request for Comment: If you contend that the desired public health outcome for high-risk populations can only be achieved through mandatory Federal standards, we specifically request comment on which, if any, of the following measures should be mandated for retail establishments that serve highly susceptible populations:

- Using raw eggs that are clean, sound, and meet the restricted egg tolerances for U.S. Consumer Grade B, which minimizes the entry of surface bacteria to the inside of eggs;
- Using raw eggs that have been transported under refrigeration, because refrigeration lengthens the effectiveness of the eggs’ natural defenses against SE and slows the growth rate of SE;
- Using only egg products that have been pasteurized in accordance with USDA’s requirements under 9 CFR 590.570, which are designed to kill or inactivate SE and other bacteria;
- Cooking raw eggs and raw egg-containing foods thoroughly, which kills viable SE that may be present;
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods, e.g., soft-boiled, poached, or sunny-side up eggs, meringue, Caesar salad, hollandaise or Béarnaise sauce, homemade mayonnaise, eggnog, homemade ice cream, that will be served undercooked, which minimizes the risk of egg-associated SE illnesses in consumers of those foods; and
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods where eggs are combined, since combining raw eggs to prepare a large volume of food that is

subsequently temperature-abused or inadequately cooked can cause illness in large numbers of people if any of the eggs were initially contaminated with SE.

Comment: *We believe all of these measures should be implemented in a mandated Federal Standard.*

Request for Comment: FDA is now requesting comment on whether: (1) the current FDA Food Code system with State adoption and implementation achieves the desired public health outcome among high-risk populations, or (2) the public health outcome for high-risk populations can only be achieved through mandatory Federal standards and, if so, how those standards would be best implemented. We consider high-risk populations to be those persons who are more likely than other people in the general population to experience food-borne disease because of the following reasons: (1) immunocompromised, preschool age children, or older adults and (2) obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital, or nursing home, or that provides nutritional or socialization services, such as a senior center.

Comment: *We assume this question pertains only to eggs and egg products. Based on that assumption, we respond as in the previous comments. While the FDA Model Food Code has been beneficial to those establishments who have implemented the code, inconsistency in the enforcement nationally has prevented it from achieving the public health outcome desired by the FDA. Only through mandatory Federal standards can adoption and implementation of the practices described in the Food Code be implemented thus insuring that high-risk populations are properly protected from unsafe food sources.. Once standards are mandated, a baseline of national performance beginning at the farm and ending at the table can be established and monitored.*

Thank you for the opportunity to comment on this comprehensive rule, and we look forward to the outcome.

Sincerely,

NATIONAL PASTEURIZED EGGS,

R.W. Duffy Cox
Technical Advisor

RWDC/fc