

Emily Brown Rosen
Organic Research Associates
PO Box 5
Titusville, NJ 08560
609-737-8630
fax: 609-737-6652
ebrownrosen@earthlink.net

December 21, 2004
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Re: Prevention of Salmonella Enteritidis in Shell Eggs During Production, FDA Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504, 69 Fed. Reg. 56,824 (Sept. 22, 2004).

I am a consumer concerned about food safety, and also own a consulting business advising farmers, agricultural professionals, and organic certification agencies accredited under the USDA National Organic Program. I am concerned that this proposed rule does not take into consideration alternate production systems, such as organic and pasture-poultry systems that do not maintain birds in a strictly confined operation.

I support the comments of Rural Advancement Foundation International as submitted by the Farmers Legal Action Group, and would like to add a number of points.

1. Retain and Clarify the Proposed Exemption for Producers Who Raise Fewer than 3000 Hens or Who Sell Directly to Consumers

It is important to retain the exemption implicit in proposed section 21 C.F.R. §118.1 for shell egg producers with fewer than 3,000 laying hens at a particular farm and for shell egg producers who sell all of their eggs directly to consumers. The wording of §118.1 is phrased in the negative, and could be improved to make it clear that producers that have less than 3000 birds and market cooperatively to the wholesale market are exempt. This is a common practice on organic farms, and this provision should be retained.

2. Biosecurity provisions will have an impact on organic and pastured poultry operations

Organic poultry producers are required under the USDA National Organic Program, at 7CFR Part 205 to provide outside access for all livestock (7CFR 205.239). The proposed

rule at 118.4(b) requires non-exempt producers to “Prevent stray poultry, wild birds, and other animals from entering grounds and facilities;” This provision seems difficult to comply with on a farm that is based on pastured poultry system, which typically provide a substantial percentage of the birds diet from pasture. Organic and sustainable systems often raise over 3000 birds on a particular farm, so this requirement may have dire consequences for ability of moderate size farms to use these alternative types of production systems.

The NAHMS Layers study used to base recommendations included only operations over 30,000 birds in size, of which 99% were cage-layer operations. This data does not accurately reflect the type of production system used in organic and sustainable pastured poultry farms, and should not be the justification for the added burden, or loss of ability to market certified organic eggs that would result from this proposed rule.

Organic farmers should not have trouble complying with the record-keeping requirements, as they already are required to file detailed organic system plans to their certification agent. (7CFR 205.201). These include detailed records on livestock health and facility management that can be modified to supply the necessary information regarding SE prevention measures. Organic farmers are required to monitor pests, including facility pests and document control measures, so these requirements are not burdensome. Sanitation measures are also monitored, so these proposed requirements for disinfecting and sanitizing are not burdensome.

As an alternative approach, the use of treatment to achieve a 5-log pathogen reduction may be an option some organic farmers can pursue, however this will add cost and is likely not available in many parts of the country. The use of ionizing radiation is prohibited for organic eggs, though water-bath pasteurization is not prohibited. Water bath pasteurization entails use of a food grade wax to seal the eggs. Organic standards require that all food additives, such as egg oils or waxes be reviewed and specifically listed in the regulation, there are currently none approved for this use. Again, it places an unfair burden on organic producers to require this expensive type of pasteurization if there has not been a data review of the risks of SE infection on pastured farms and on moderate intensity organic operations that must provide outside access to all birds.

A modification of the wording at 118.4(b)(4) is warranted until further data is collected on this risk. This proposed wording would moderate the implication that a zero tolerance for stray animals is required.

“Apply methods to prevent stray poultry, wild birds, and other animals from entering ~~grounds~~ and facilities;”

Thank you for considering these comments.

Emily Brown Rosen