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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

[Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504]

To Whom It May Concern:

The Pacific Egg and Poultry Association (PEPA) is a nonprofit trade association representing producers throughout the Western United States. We are submitting comments on the Food and Drug Administration's (FDA) proposed rule for Prevention of *Salmonella* Enteritidis (SE) in Shell Eggs During Production.

In April and August of 2000 PEPA submitted written comments on the FDA proposed action plan to control *Salmonella* Enteritidis (SE) and the relative "current thinking papers". PEPA also attended the FDA public hearings in Sacramento and Washington D.C. as well as the most recent hearing in November 2004 in Los Angeles. The comments that follow are similar to what was both submitted in written form and stated at the public hearings with the exception that we have had four additional years of experience in controlling *Salmonella* Enteritidis.

The industry recognizes the need to develop national standards relative to egg safety, however; these standards must recognize the regional differences relating to production practices, the presence or absence of egg quality assurance programs that are employed by egg producers, differences in the components of

those plans, and the state statutes that are in place to deal with food and egg safety.

There is precedent for regional flexibility in the federal regulatory arena. For example, not all areas of the United States are subject to the same air emissions control measures. Such measures are based on the status of regional air quality attainment for certain pollutants. Surely FDA can provide guidelines for the states and the states can in turn adapt egg quality assurance plans that best fit their climate and environment.

PEPA represents over 90% of the egg production and distribution in California. The California Egg Quality Assurance Plan (CEQAP) is an excellent example of a state quality assurance program that has a proven track record in reducing the incidence of SE.

Extensive comments by the California Department of Food and Agriculture as well as the California Egg Quality Assurance Plan facilitator and Cooperative Extension have been filed with FDA detailing the success of the award winning California Egg Quality Assurance Plan. Also, the four key issues specified by Mr. Lou Carson at the Los Angeles public hearing have been addressed in the aforementioned entities comments. We ask FDA to scrutinize those comments and respond accordingly.

As an active participant in CEQAP PEPA has over the years provided infrastructure support for the program. Our duties include the following: maintenance of the program's testing materials and video library, meeting notifications and coordination, and bookkeeping responsibilities. The success of the plan lies not only in its built in flexibility for the various types of poultry production facilities located throughout the state but also the cooperation of the various partners including CDFA, Industry, PEPA and Cooperative Extension. The program is constantly evolving as new technologies are developed and implemented in the food safety arena. Continuing education, training, record-keeping, research, and third party auditing are integral parts of the plan. Most recently amendments were adopted by the CEQAP Advisory Committee to strengthen the biosecurity component of the plan. PEPA has also received a \$31,000 grant to further refine the program.

The cost to FDA to administer the proposed regulatory program has been estimated at \$8 million. FDA should consider allocating a significant portion of the \$8 million to those states not currently under the umbrella of a comprehensive egg quality assurance plan to assist them with implementation of the same. We recommend that those producers operating under a proven comprehensive egg quality assurance plant be deemed in compliance with the rules FDA will promulgate.

According to CDFA, California has met and surpassed the Health People 2010 objectives. We believe this empirical evidence clearly demonstrates that the CEQAP program is working exceedingly well. FDA guidelines should be developed utilizing the CEQAP educational and testing materials as a template for a standardized control plan.

In addition to championing state quality assurance plan programs, we would like to reiterate what many of our producer members are asking for in their comments to FDA. Of particular concern to all producers across the country is the test and divert proposal. On the west coast the cost (loss) to divert has been estimated at approximately \$.20 per dozen. Also, the on-farm refrigeration requirements may result in thermal checking which could potentially increase the risk of SE or other pathogen contamination of shell eggs. The industry is also concerned that there may not be enough laboratory capacity for SE testing and that uniform testing protocols need to be developed prior to implementation.

In conclusion, too little emphasis has been placed on the fact that a majority of SE incidents can be traced to improper food handling. California has been extremely proactive in this arena having passed numerous measures to ensure food safety at the retail store, institutional and restaurant levels. The association has worked with industry to pass bills on egg labeling, plant identification, refrigeration and reprocessing. A comprehensive plan to control SE has to include all the players including the general public not just the producers. Producers should not have to bear the burden of zero tolerance when they have no influence on the food handling component in the food chain.

Good communication and effective management are key elements to the success of any food pathogen control program. An unwieldy bureaucracy can undermine the success of any program.

Thank you for considering our comments. We appreciate your due diligence and look forward to working with you as the rule making process progresses.

Sincerely,

R.L. Matteis
Executive Director

Pacific Egg & Poultry Association