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Mr. Louis Carson  
FDA-HFS 32  
200 C Street S.W.  
Washington, D.C. 20204

Dear Mr. Carson:

The President's goal to assure safer eggs for consumers is laudable. The entire farm to table continuum is addressed in the current program and that is commendable. However, we think there are some parts of the proposed production and processing programs that need to be revised. Collectively, we have considerable experience in egg processing and production. We also have 5 years of experience with the California Egg Quality Assurance Program (CEQAP). CEQAP is a voluntary program that has garnered the participation of producers representing over 90% of the eggs produced in California. Our program is based on the principle of reducing SE occurrence in eggs by assuring that effective programs are in place to prevent the introduction of SE into flocks, minimizing stress, and preventing disease by good management practices. We have recently added environmental testing as a means of further validating the program.

We have several comments about the President's proposed program based on the limited information on Option 1 that was included in the release. Some of our concerns are summarized here for your consideration.

1. **Egg testing for SE.** University of California epidemiologists, who have reviewed this proposal, report that egg sampling is not useful because the sample size required to detect an event which occurs in only one in 20,000 eggs at reasonable probability levels is not possible (economically or physically). Based on the considered opinions of experts, we therefore conclude that egg culture for SE cannot be used to protect public health because it will not address the problem of SE in eggs.
2. **Timing of the proposal.** There are currently two studies nearing completion (NAHMS and the CEQAP prevalence study), that will provide valuable information, useful for the development of a plan to improve egg safety. We urge you to delay the finalization of a draft program until the results of these studies are available and can be included for a maximally effective program.

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3. ***Environmental testing to identify high risk flocks.*** Egg laying chickens are housed in various types of systems and most types are represented in California. These various housing styles mean that manure rows may arise from as few as 500 and as many as 30,000 hens. Hence, the sampling of manure rows does not represent the sampling of a uniform-sized group of chickens. Further, many houses have no manure rows at all but rather manure belts, which are difficult to swab and clearly are not the equivalent of manure row sampling. Other houses have manure trenches that are flushed with water daily. Any plan for sampling must take these differences into consideration in order that representative samples from all systems can be gathered without placing an unfair financial burden on any producer.

Environmental sampling is an expensive procedure especially when the value of the data obtained is considered. One sample culture for SE with standard delayed secondary enrichment methods, has a laboratory cost of \$45 in our laboratory system. Sample collection, plus culture would more than double this. Our recent study of California egg production farms indicated an average of 1250 to 2169 hens per row of manure. Based on USDA statistics, California has a population of about 25 million hens. One environmental sample per laying flock, taking 2 swab samples per row of manure would result in the collection and culture of 23,000 to 40,000 swabs at an estimated cost of \$1,035,000 to \$1,800,000. This approach to egg safety is likely to provide little reduction in egg contamination and will result in very high costs. If this alternative is considered it is critical to the industry and state governments that FDA pay for the testing.

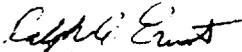
A second negative impact of this approach is the work load involved with the program. It would overwhelm the present capacity of diagnostic laboratory systems just for Salmonellae culturing. Of course, laboratories would be expanded in the long term, but the initial impact could have serious negative impacts on other critical food-animal disease control programs.

4. ***Vaccination.*** Vaccination of hens could be a very valuable part of a quality assurance program. Vaccination could cost from 4.8¢ to 20¢ per bird but effectively reduces infection of hens and their shedding of SE in eggs.
5. ***Quality assurance (QA) program for egg safety.*** We strongly believe that a good QA program for production farms and processing plants is the best plan to improve egg quality and safety. To be effective such a program must include producer education, development of specific farm quality assurance plans, farm records to support plan objectives and facilitate oversight, and effective best management practices to reduce Salmonellae in laying hens. The program should have achievable requirements, effective oversight, and continuing educational support from FDA. We suggest that FDA work with Cooperative Extension at state universities to provide educational support for QA programs. Education could be done using group contacts, internet resources, and home study materials. Ethnic minorities and certain religious groups will present unique challenges but these can be overcome with local support from Cooperation Extension agents.

6. *Alternatives to reduce costs.* We would suggest that you accept test results from farms that are presently part of an approved state or national quality assurance program. To make a program feasible, sampling once during the life of an egg production flock is adequate to validate the program and is useful to the producer in evaluating their plan and preparing their facility for the next pullet flock. Producers who choose not to participate in quality assurance plans could have their facilities tested and if found positive, eggs could be diverted to breakers.

Small flocks (e.g. less than 10,000 hens) should be exempt from environmental testing but might be required to vaccinate future pullet flocks to reduce risk of infection. Even though they represent a relatively small percentage of total eggs produced, if infected, they could produce a significant number of infected eggs.

In conclusion, we hope that these comments will be helpful in developing a plan that will effectively improve egg safety. We invite you to learn from our experiences with the CEQAP program. Our program has proved highly successful in achieving egg quality and safety goals here in California. And we believe that this is largely due to the support the CEQAP program has from the California poultry industry, state and federal agencies and the University of California. We encourage you to listen to the concerns of egg producers and consider the facts when you develop your plans. If we can be helpful please call on us.



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CROSS FILE SHEET

File Number: 98N-1230/ C 816

See File Number: 97P-0197/ C 817  
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