

OHIO POULTRY ASSOCIATION

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20852

RE: Docket Numbers 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504 and
RIN Number 0910-AC14.

The Ohio Poultry Association would like to thank you for this opportunity to comment on your proposed rule regarding SE prevention measures in shell eggs. Ohio is the second largest producer of eggs in the nation, and since 1997 the Ohio Department of Agriculture and the Ohio Poultry Association have administered the voluntary Ohio Egg Quality Assurance Program (OEQAP) with success in reducing the incidents of SE poisoning. Since the beginning of the program the incidents of SE have gone from 20% to 2.1%. Ohio egg producers take the reduction of SE very seriously. The goal of this program is to enhance food safety while maintaining consumer confidence in Ohio produced eggs. OEQAP provides step-by-step procedures for egg producers to produce, pack and sell the highest quality, freshest, and safest eggs possible. It is our number one priority to put a wholesome, safe product on America's tables.

The Ohio Poultry Association (OPA) offers the following comments regarding the proposed FDA rule regarding SE prevention measures in shell eggs.

- FDA proposes environmental testing at 40-45 weeks of age, and if molted, 20 weeks after the end of the molting process. Many of the existing Egg Quality Assurance Programs specify testing of the layer house environment at the end of the laying period, prior to depopulation. This is done for a number of reasons: 1) it determines the SE status of a house before new birds are placed; 2) it allows enough time for the producer to properly clean and disinfect the house prior to placing new birds in the house; 3) it avoids excessive sampling, thereby keeping

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costs for the producer reasonable, and minimizes substantial sample loads on testing laboratories, thereby allowing efficient utilization of manpower and resources; 4) birds are being depopulated, thereby eliminating any potential future risk. In addition, we are not aware of any data that indicates that 40-45 weeks of age is the best time to monitor flocks. We believe environmental sampling at end of lay provides a competent monitoring of SE in the environment and does not cause undue burden on the egg producer.

- OEQAP encourages using SE vaccinations as an added preventive measure for SE outbreaks, while FDA barely mentions using SE vaccines as a preventive measure. OPA believes vaccination is a tool that adds to a complete SE reduction program and should be stressed in such programs.

- Can current laboratories handle the increase in SE tests that will need to be carried out? What about additional funding for the additional tests, particularly for the government facilities such as Ohio Department of Agriculture? Why not 480 sample eggs as opposed to 1,000? OEQAP has been successful in reducing the number of SE outbreaks by using 480 eggs. At the Chicago field hearing for this program, the laboratory capacity issue was discussed. When egg producers questioned laboratory capacity, FDA personnel responded with a “build it and they will come” answer. Paraphrasing, the answer was “If FDA requests additional testing, labs will respond with additional capacity to handle the requirement.” This is simply unrealistic.

The larger amount of eggs could prove to be financially disastrous to some producers. Many Ohio producers are considered small family farms, because they are contract “growers” and “layers” under a primary producer. This average cost to “do business” under your proposed regulations will put a substantial number of Ohio egg producers out of business.

The proposed regulations will cost the producer, cost state government, and cost the federal government. Many of the small producers cannot afford the estimated \$20,000 per year cost associated with the proposed egg safety regulations. The types of unfunded mandates that may result in implementation of the regulations as proposed, may force small family farms out of business.

- With programs such as the Ohio Egg Quality Assurance Program proving to be successful, why not recognize current programs such as OEQAP, so that producers complying with these plans would be considered in compliance with the FDA rule? The Centers for Disease Control found in a recent scientific study that these programs have a proven track record of reducing SE-related illness. Ohio and other states with Egg Quality Assurance Programs have a proven track record and the trust and confidence of the consumer in these programs.

- Egg production farms are production agriculture and should not be confused with food processing plants. These barns/houses have (and will always have) manure and waste products associated with them, so it seems unusual to hold barns to the same standards as food processors. These barns/houses produce a raw agricultural product – an egg. The proposed regulations would give a human health agency the authority to test and divert food at the site of raw production, even though there is not an existing relationship with food animal industries. Retail facilities and consumers must also share, equally, in the responsibilities for egg safety. When will retail facilities be required to adopt the Model Food Code? The proposed regulations place all responsibility for SE prevention and control on egg producers.

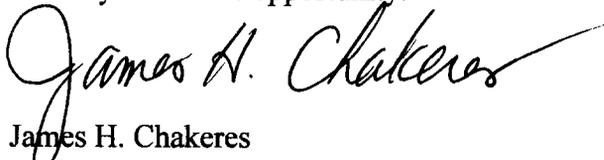
The Ohio Poultry Association has great concern over FDA's proposed direct involvement in raw agricultural production, when in fact, USDA APHIS and FSIS are far more qualified to address disease and pathogen risk reduction in live animal production operations.

- Wet cleaning of a barn, particularly in winter, could prove to be a problem. There is data that shows an increase in SE loads after wet cleaning. The removal of all visible organic matter, followed by appropriate disinfection may be the best available cleaning and disinfecting practice available to a producer, especially during extreme cold. EPA and state regulations may also limit the cleaning and disinfection of facilities. We agree, though, that thorough C&D provides the best reduction of SE.
- OPA agrees with the proposed rule that requires a rodent control plan. OEQAP currently has provisions in the plan requiring a rodent and pest control program.
- FDA's proposal to refrigerate eggs if they are held for 36 hours is too restrictive. When eggs are washed, if they must be warmed, from being refrigerated, to the temperature of the wash water, more checks and cracks will result. This is not in the best interest of food safety.
- The egg industry is changing. The proposed regulation is completely dependent on producers being able to sell diverted eggs to breakers. More and more, breakers have a dedicated supply of eggs. If breakers have no capacity for the eggs, where can the eggs be marketed? This will affect the egg market. Furthermore, it will result in a cost to the industry much greater than predicted by FDA and will reduce FDA's proposed cost-benefit figures.

- As stated several times in the above items, the cost to the producer is an incredible burden. Add several of these factors together and it can be financially catastrophic for the egg producer. OPA strongly recommends that FDA implement an indemnity program to accompany the proposed rules.

As mentioned earlier, Ohio has a successful and working Egg Quality Assurance Program. We would request that you consider states with successful Egg Quality Assurance Programs and allow these programs to continue to operate as a cooperator or in fulfilling the requirements of any new national egg safety program. This would allow the current authorities to continue inspecting and auditing these farms. The Ohio Egg Quality Assurance Program has been successful through the years. We strongly urge you to consider these comments and to rework the regulations to a results-based program, incorporating state Egg Quality Assurance Programs. A successful partnership among state Egg Quality Assurance Programs, State Departments of Agriculture, FSIS, USDA APHIS, USDA AMS, and FDA will provide the solution to increased egg safety in the United States of America. I believe this is our ultimate goal.

Thank you for this opportunity.



James H. Chakeres
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Ohio Poultry Association