

December 17, 2004

Division of Dockets Management (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
RIN Number 0910-AC14
Comments on Proposed Regulation: Prevention of Salmonella Enteritidis in
Shell Eggs during Production

Dear FDA,

The Ohio Department of Agriculture, Division of Animal Industry respectfully requests serious consideration of the comments presented, including closer review and study of the impact expected from the above identified proposed egg safety regulation.

The Ohio Department of Agriculture has participated in the administration of the Ohio Egg Quality Assurance Program in cooperation with the Ohio Poultry Association, USDA APHIS VS, and the Ohio Department of Health. In 1997, when our program began, 20% of the layers reflected SE positive environments. At the end of 2003, environmentally positive rates had dropped to an impressive 2.1%. The Ohio's poultry producers that participate in the voluntary Ohio Egg Quality Assurance Program produce over 95% of Ohio's table eggs. Ohio has had great success and acceptance of its program and feels very qualified to provide comments and input regarding FDA's proposed regulations.

First and foremost, the proposed regulation places the greatest cost and responsibility on the producer of a raw agricultural product, an egg. This proposed legislation gives a human health agency the authority to test and divert food at the site of raw production, even though there is no existing relationship with food animal industries. We take issue with the fact that this regulation places exceptional and undue hardship on a part of the industry that does not have full control or responsibility for "egg safety". Retail facilities and consumers must also share, equally, in the responsibility for egg safety. As of yet, FDA does not require retail facilities to adopt the Model Food Code. Nor are there similar requirements or regulations proposed by FDA, or FSIS to regulate egg processors in a same or similar manner. The proposed approach indicates an uncoordinated, disjointed federal strategy that may be misdirected at attempting

to protect public health. In essence, all responsibility for SE prevention and control has been placed on egg producers.

ODA, Division of Animal Industry has great concern over FDA's proposed direct involvement in raw agricultural production, when in fact; USDA APHIS and FSIS are by far more qualified to address disease and pathogen risk reduction in live animal production operations.

ODA, Division of Animal Industry does not believe a one size fits all "regulatory" program will work consistently across the United States due to the great geographical variances present in production practices, sizes and types of operations across the states. In addition, other "risk reduction" programs in food animal production have incorporated "HAACP" best management program philosophies in order to provide the most efficient and economically feasible disease and pathogen reduction efforts. We believe that an egg safety program would be best provided under these same and similar conditions.

We believe that FDA needs to spend more time and effort in coordinating a more comprehensive and flexible plan that guarantees inclusion of the other key components of egg safety. The proposed rule narrowly focuses on production with no real proposed strategy for distribution, processing or retail. The net effect on reducing SE is doubtful since the SE risk assessments concluded that multiple interventions are necessary to reduce the incidence of SE in humans. In this sense, the proposed rule is neither science based nor comprehensive.

The following provides directed comments and information on specific segments of the proposed rule:

Manure Testing and Laboratory Testing Issues

The FDA proposal states "you must conduct environmental testing for SE as an indicator of whether your SE prevention measures are working effectively".

We agree that the best screening method to determine if a flock is positive for SE is environmental testing. However, finding SE in the environment of a poultry house does not necessarily indicate that the birds infected with SE, nor does it indicate that the eggs may be contaminated with SE.

The FDA proposal specifies testing a house within 40-45 week of age, and if molted, 20 weeks after end of the molting process.

A majority 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 does not result in excessive sampling, whereby keeping costs for the producer reasonable and minimizes substantial sample loads on testing laboratories, whereby allowing efficient utilization of manpower and resources; 4) birds are being depopulated, whereby eliminating any potential future risk. This practice has resulted in the reduction of environmentally positive houses in Ohio.

In addition, we are not aware of any specific data that indicates that 40-45 weeks of age is the best time to monitor flocks. The reference cited in the proposal is a memo from Richard Wood of Food Animal Concerns Trust to FDA.

The FDA proposal specifically identifies environmental samples and the methods of sampling.

Developing an equitable program for environmental sampling is a challenge because of the vast number of styles or types of layer houses in the United States. These may vary greatly in a given geographic area and across geographic regions. Because of the difference in manure collection/disposal systems it is difficult to test these various houses on an equivalent basis. Because of the variations in housing types and management systems it is difficult to specify a single sampling procedure. We recommend that the types of samples that are collected should depend on the type of house that is to be sampled. The same holds true for the number of samples. Flexibility must be available to states currently providing quality assurance programs and consideration must be given to variations in type and size of house.

We believe that a distinction between a sampling plan for verifying or monitoring an on farm program and the sampling for an SE outbreak trace back needs to be made. In addition, ODA is interested in obtaining a better understanding of the scientific justification for FDA's required 1000 egg pulled sample for an SE outbreak trace back, no matter the size of the operation. Does sampling for monitoring purposes need to be as extensive as that undertaken for outbreak trace back situations? The cost of this substantially increased amount of sampling and testing would be very prohibitive for not only FDA, but for producers and testing laboratories as well.

The FDA proposes that "you must test for SE in environmental samples according to the method "Detection of Salmonella in Environmental Samples for Poultry Houses". They state that these methods are required unless you test for SE using other methods that are at least equivalent in accuracy, precision and sensitivity.

Various modifications to the FDA testing protocol have been made throughout the country. Most of these modifications have been made by the American

Association of Veterinary Laboratory Diagnosticians (AAVLD) Accredited Laboratories that use the National Veterinary Services Laboratory (NVSL) as a confirmatory lab. Modifications are made for a variety of reasons, many of which include more current and efficient technology, better available media, additional screening and reliability. The Ohio Department of Agriculture strongly recommends that FDA carefully review and modify required methods according to recommendations and comments submitted by the United States Animal Health Association (USAHA).

A major consideration and issue that was not clearly identified in the proposed regulation was, WHO IS GOING TO DO ALL OF THIS TESTING? At the present time the Ohio Department of Agriculture Animal Disease Diagnostic Laboratory (ADDL) conducts environmental and egg testing for participants of the Ohio Egg Quality Assurance Program and for FDA upon their request related to SE food borne outbreak trace backs. We also conduct a large percentage of the NPIP testing done for Ohio producers. The expected increase in testing as a result of the FDA proposed regulations will create a substantial hardship on the ADDL as we can barely handle the current testing load, let alone an increase. State revenue has gradually declined over the years. Producers currently pay a nominal fee of \$7.50 that covers only disposable material costs. The state of Ohio currently covers the cost of manpower. The testing methods for both environmental samples and eggs are very dependent upon manpower. Producers could not afford to pay for the level of testing proposed in the FDA. A majority of Ohio producers would most likely go out of business because they could not afford to cover the total cost, especially when the amount of testing is excessive. The USAHA is providing FDA with more accurate cost data relevant to testing costs. The costs estimated by FDA were by far underestimated. We assume that should FDA continue to pursue the regulation as proposed, that FDA will provide states with substantial financial assistance needed to conduct testing, or FDA laboratories will do the testing. Has FDA also consulted with NVSL to determine if they could handle the expected increase in confirmatory testing that would result from the proposed regulation?

In terms of sample collection, unless FDA plans on collecting all of these samples, producers must be allowed to collect and submit their own samples, unless FDA is going to pay the state to do so. Currently, Ohio producers submit their own samples and this practice works well.

Requiring egg testing within 24 hours notification of positive environmental samples is not practical or possible. Laboratories need time to schedule such work loads and most states are not in a position to pay the overtime that would be incurred in many collection and testing scenarios. Until such time an egg related outbreak occurs we see no need for a "regulatory" or "official" sampling.

BIOSECURITY

A one size fits all approach to biosecurity will not work. Flexibility must be allowed due to variation in size and type of operations throughout the United States. A HACCP risk reduction approach would allow each producer to identify risks based upon their type of operation. Agricultural biosecurity is an issue for all raw agricultural product producers. The diversity of the industry will require diversity of biosecurity plans. Any number of combinations and systems can be used, including: restricting access to birds and barns, screening of employees, cleaning and disinfection procedures, health status of incoming birds, vaccination, rodent and pest control, fly control, feed sourcing, and the ability to modify plans to address changing status, environments or other potential regulatory requirements, such as EPA requirements for manure management.

CLEANING AND DISINFECTION (C&D) OF ENVIRONMENTALLY POSITIVE HOUSES

Mandatory wet cleaning for all producers experiencing environmentally positive houses will present a problem for some states and producers. In Ohio, a number of producers are permitted and are required to follow EPA and Large Livestock Facility requirements regarding the removal of manure according to nutrient management plans. In addition, recent science is questioning whether wet cleaning provides the best assurance of SE elimination; in fact some evidence has suggested that wet cleaning may increase SE development in a house. The removal of all visible organic matter, followed by appropriate disinfection may be the best available C&D practice available to a producer, especially during extreme cold, or under regulation of EPA of Large Livestock permits. We do agree that thorough C&D provides the best reduction of SE.

FUNDING ISSUES

The Ohio Department of Agriculture has determined that should FDA implement the proposed regulations, substantial federal funding assistance will be necessary for the substantial increase in testing of both environmental and egg sample testing that will result from regulatory requirements. The producers in Ohio already pay for the disposable cost of supplies necessary to conduct the environmental and egg testing associated with the Ohio Egg Quality Assurance Program. Staff costs, thus far are absorbed by state tax dollars and are subsidized with Food Safety Grant funds from FSIS (NOT FDA). The ODA can not absorb any additional costs that would be associated with the unfunded federal mandates anticipated from implementation of the proposed FDA Egg Safety Regulations.

Not only do we not have funds to do the tests, we do not have the manpower and lab staff necessary to under take the responsibilities identified in the proposed regulations. We are also assuming that FDA can not afford such either.

The average cost to “do business” under these regulations, as reported by FDA, will put a substantial number of Ohio producers out of business. The majority of Ohio producers are contracted “growers” or “layers” under a primary producer. They are what many would consider “small family farms”.

The proposed regulations will cost the producer, cost state government and cost the federal government. Many small producers will not afford the estimated \$20,000 per year cost associated with the proposed egg safety regulations.

We feel FDA has underestimated the cost of this regulation and are very concerned with the expected unfunded federal mandates that may result in implementation of the regulation as proposed.

The big question is – Is the cost of the regulation worth the benefits that will be derived from their implementation?

There is any number of food safety issues confronting production agriculture today. Since we have in fact seen a substantial reduction over the last seven years in the incidence of SE in table eggs, why can we not continue the voluntary egg quality assurance programs and let market demands for safe eggs drive the efforts towards safe eggs, much like FSIS has done with meat safety.

OEQAP is used as not only an egg safety initiative, but also a marketing tool. The elimination of the OEQAP as a marketing tool will result in less check off dollars, whereby decreasing the revenues available to market Ohio eggs. So not only do we increase the cost of producing eggs in Ohio, we potentially reduce the funds available to market eggs.

The following is an indication of the costs that can be expected from the proposed regulation and the underestimated costs reflected in the FDA proposal.

Ohio recently conducted egg testing on 28,000 eggs from Ohio’s largest table egg producer as a result of an FDA “inspection”, not related to an SE trace back. The 28,000 eggs came from 7 houses, 1000 eggs each, four times. At pools of 20 eggs each (28,000 divided by 20 eggs each pool) 1400 pools at a cost of \$32.50 each pool, cost a total of \$45,500, of which the producer paid \$10,500. The Ohio Department of Agriculture had to absorb the remaining balance of \$35,000. That was for one egg testing situation. All egg tests were negative.

The Ohio Department of Agriculture appreciates the opportunity to submit comments regarding the proposed egg safety regulations. We ask that you carefully weigh and consider our recommendation and those of USAHA. While we agree that egg safety is very important, we strongly urge FDA to allow those states that have successful programs some type of waiver from the requirements

and to rework the regulations to a results based program, following the successful lead of FSIS and USDA APHIS. Maybe FDA needs to reconsider if Health and Human Services FDA is the best agency to handle egg safety at the raw agricultural product level.

Respectfully,

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