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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: FDA Docket Numbers 1996P-0418, 1997P-1097, 1998P-0203 and 2000N-0504
Prevention of Salmonella Enteritidis in Shell Eggs During Production

I have worked in, for and with the poultry industry as a field veterinarian and an extension veterinarian for over 35 years. My comments are my own and are not meant to represent the University of Minnesota or the Extension Service.

FDA has published an interesting rough draft proposal in the Federal Register and is proposing measures to prevent Salmonella Enteritidis (SE) from contaminating eggs on the farm. FDA is wisely seeking help in improving this draft. My comments are directed at 1. the justification for the proposal, 2. the proposal itself and 3. other issues raised by FDA.

Justification

The primary justifications for the proposal comprise a Risk Assessment and an Economic Analysis that would make an ENRON auditor blanch. Risk assessment and economic analysis are scientific activities; however, the outputs from such activities are not data and should not be referred to as data (GIGO). Estimates multiplied by assumptions do not equal facts; they remain estimates and assumptions.

> "The plural of anecdote is not data." Frank Kotsonis

References that justify low cost estimates for environmental and egg testing could be interpreted as deception by FDA, but we should recognize that the document was probably written over a period of years and the author(s) lost track of the contents (the references describe much less intensive laboratory procedures than the FDA Proposal requires). The same can be said for the recent change in attribution of costs associated with SE infections in humans. As recently as this year (2004) CDC authors and others have stated that, "Deaths account for the majority of the economic burden of *Salmonella* infections." The same authors reported that death rates from all salmonella infections had declined by 86% from 1996 to 2000 according to the National Death Index. http://www.cdc.gov/foodnet/pub/iceid/2004/ADuBois.htm Could it be that this decline in death rate

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is what caused the FDA to decide for the purposes of this proposal that suddenly arthritis was the most important economic burden from *Salmonella enteritidis* infections?

> "....So are they all, all honorable men." Wm. Shakespeare

The FDA Proposal

FDA says that compliance would "exclude" SE on the farm; such a statement is hyperbole.

The Pennsylvania Egg Quality Assurance Program (PEQAP) is the model for the proposal. PEQAP is perhaps the most documented egg quality assurance program in the nation, but when comparing the FDA proposal to PEQAP one can see significant differences. The deviations from PEQAP provoke the most comment:

FDA proposal:	**PEQAP**
1. Provisions for procuring baby chicks and pullets,	similar
2. A biosecurity program,	none
3. A pest and rodent control program,	a *rodent* control program
4. Cleaning and disinfection of poultry houses,	similar, but wash not required
5. Refrigerated storage of eggs and	similar, but no 36 hour rule
6. Monitoring of environmental samples.	similar, but defined number
If positive, eggs are sampled.	similar, but fewer eggs
If eggs are positive, eggs are diverted.	similar
7. Flocks of < 3000 excluded	not excluded

Framework for comments: There are several questions that should be used to test the appropriateness of each proposed rule: 1. Is there a scientific basis? 2. Is there an anecdotal basis? 3. Is it likely to be effective? 4. Is it economical? (The FDA's estimated cost for the proposed program is equal to 25% of the industry's net returns for 2002.)

1. Procurement of chicks and pullets. There is no research basis for this part of the proposal, but we know from parent stock and baby chick monitoring that SE has been eliminated from breeders. The NPIP and the chicken breeder company approach has been practical and effective. Because breeders have succeeded in eliminating SE from hatching eggs it is surprising that FDA did not take time to examine the source of their success for possible emulation.

2. A biosecurity program. Biosecurity is important on an egg production farm. There are five points in the proposed rule that sound like they ought to be effective, but, surprisingly, there are no research or anecdotal reports to support their use for SE control. Specifically, on a farm it is the presence of chickens and mice that maintains the SE infection and contributes to spread from building to building. Biosecurity efforts on the farm should be focused on rodents and other issues threatening to introduce or maintain SE. Limiting visitors; control of workers moving from house to house; employees having poultry at home; and stray poultry, wild birds and other animals on the grounds have neither been observed to be major causes of SE spread on a farm nor major causes of introductions of SE to a farm. With respect to SE these biosecurity rules are not scientifically based

and there is no anecdotal information to indicate that they would be effective. The clothes change between buildings in particular would be impractical, ineffective and expensive and would take resources from more important issues.

The biosecurity issues that threaten to introduce and maintain SE on a farm must be specifically addressed at the farm level. For FDA to prescribe rules that are totally inappropriate could be interpreted as ignorance of salmonella ecology, biosecurity and egg production and the result would be to further undermine FDA's credibility.

PEQAP does not have a biosecurity requirement. The five proposed biosecurity points should be dropped and, if FDA insists, the requirement should be for biosecurity appropriate for the farm, for salmonella and for egg production: pullet movement, spent hen movement, people and equipment and eggs, flats, shells, etc. movement.

FDA suggests that biosecurity will "ensure" that SE is not introduced and will not spread. It is generally recognized in the veterinary community that biosecurity alone will not totally control a pathogen with multiple hosts.

3. A pest and rodent control program. There are both research and anecdotal reports to indicate that rodent control is practical, effective and economical in the overall effort to reduce SE on a layer farm. That part should stay.

FDA has defined "pest" as any objectionable animal and has stated that pests shouldn't be "on the grounds." There are state and federal laws regarding which animals may be treated as pests. For example, the only birds that can be treated as pests are English sparrows, European starlings and pigeons. There are laws that protect mammals, reptiles, amphibians and fish as well. In addition it is one thing to keep animals out of the chicken house but quite another thing to keep them "off the grounds."

PEQAP does not have a requirement for control of pests other than rodents. There is no information, research or otherwise, to indicate that other potential pests play a role in SE introduction or maintenance on a farm. SE has been isolated from flies (as it has from hogs, cattle, horses, dogs, cats, pigeons and ducks)(USAHA Proceedings), but that doesn't mean flies (or these other species) play a role in infecting layers. That part should go.

4. Cleaning and disinfection. Science and experience tell us that wet cleaning a poultry house may either reduce or may increase the isolation rate of SE. That may be because addition of water contributes to biofilm formation whereas absence of available water is associated with death of SE. There is significant question about whether wet cleaning is effective, practical or economical. There is anecdotal evidence that environments can be made SE negative without such drastic measures. Consequently, wet cleaning requirements are not appropriate for a rule.

In the Proposal it is stated that no Environmental Impact Study or Environmental Assessment is needed, but this ignores the quantity of water and disinfectant required for washing and disinfecting. It is inconceivable that EPA will not have stringent requirements for water and disinfectant use in wet washing chicken houses.

The requirement for wet washing has been dropped from the PEQAP as a result of positive experience of cleaning houses without washing.

Under some environmental conditions it is not possible to totally clean out a high rise poultry house at the same time a flock is removed (mid-summer when crops occupy the land or mid-winter when snow covers the ground) because manure cannot be spread on fields. Further, under cold conditions (< 32 F), water changes form which can result in significant problems with ice. Layer houses have no furnace and rely on hens for heat.

The producer with a positive house knows that if he doesn't do everything possible he is likely to get a positive environmental test on his next flock. The economic penalty for a positive environmental test is at least $8,000 and probably much more than that just for sampling and testing eggs, to say nothing about costs of diverting eggs. That is motivation enough for the producer to try to clean up the environment.

5. Refrigeration. Science and experience have clearly shown that maintaining eggs at cool temperatures results in less SE multiplication than at warm temperatures. What has not been demonstrated is just exactly what rate of cooling is important, and thus the proposed 36 hour rule is lacking in both scientific and anecdotal evidence for effectiveness, practicality and economics.

As stated in the proposal, if SE is in the egg it is in the albumen where there are effective inhibitors of salmonella multiplication for seven days or longer.

Certainly it is important to evaluate the potential for significant unintended consequences with this proposal. Processing cool eggs in warm wash water will result in thermal checks. Allowing cool eggs to contact warm moist air during transfer or before washing will result in condensation which contributes to bacterial problems. People who understand the positive and negative aspects of cooling eggs need to be consulted to make the egg cooling rule most effective.

FDA asks, "Should eggs be held at 45 F prior to heat treatment?" I am unaware of any scientific or anecdotal information to indicate that pasteurized eggs have been involved in a SE outbreak. There are many issues here that will be no doubt be addressed by others, but one thing that must be acknowledged is that many of the eggs that are sent to an egg breaking plant are unsettable hatching eggs and generally such eggs could not be and would not have been held at 45 F.

6. Monitoring.

Environmental sampling. Obviously one must monitor for SE in order to detect it. The question of what is a scientific sampling method cannot be answered in an FDA office. Whether sampling every cage row is more effective than sampling 32 random sites in a laying house is a researchable question. Such research could be completed in a short period of time. Research has shown that pooling environmental samples sacrifices little sensitivity and reduces costs by 75% (Kinde, et al, Avian Diseases, 48:590-594. 2004).

FDA says common labor can take environmental samples. Management is going to be held responsible for the samples being taken in a "scientifically valid" manner. That means management will collect the samples. Consequently sampling the environment <u>will cost more</u> than stated in the FDA proposal.

FDA asks about appropriate different methods of drag swabbing. There are different styles of chicken houses that make it impossible to compare drag swabs from one type of house to another.

It seems that the only way to test different types of houses in a comparable manner would be to drag swab the aisles or swab a certain number of feet of egg belt since few houses are hand gathered.

Environmental sample testing. The estimated laboratory costs of $37.50 per sample come from the California EQAP, not from the FDA proposed requirement of 2 enrichments, 6 plates times as many as 5 picked colonies to 2 differential media. Testing environmental samples under this proposal will cost more than the estimate. The salmonella antiserum alone may cost more than $37.50 per sample in the FDA proposed requirement. There is no provision for immunoassays, advances in technology or PCR tests.

Response to positive environmental test. There is no evidence that egg testing and diversion reduce human illness. The costs of egg testing and diversion are simply incentives for the industry to reduce environmental contamination. There is experience that vaccination reduces environmental and egg contamination. FDA should consider changing the focus from testing and diversion of eggs to vaccination, because it would be more apt to prevent human illness.

The 24 hour requirement for initiating egg testing is impossible. Even collecting the eggs within 24 hours might be difficult at times. To arrange testing for 1000 eggs requires scheduling people, labs, media, etc. and cannot be done is 24 hours. More thought needs to go into this requirement.

Egg sampling. FDA says common labor can take egg samples. This is unlikely, again because management is going to be held responsible for the adequacy and records of egg collection. Sampling eggs will cost more than stated in the FDA proposal.

Egg sample testing. FDA says lab costs are estimated at $30 (from a 1999 reference which in turn references the pilot project) but the pilot project lab costs are for direct plating from the egg pool onto 2 plates not for the testing proposed of one pre-enrichment followed by two enrichments followed by 5 plates for each enrichment broth and then inoculation onto 2 differential media! This cost of testing eggs is grossly underestimated. There is no provision for immunoassays or PCR tests.

Response to positive egg test. FDA has failed to consider that for marketing and political reasons an egg breaking establishment may decline to accept eggs from a positive flock. Niche marketers will suffer a far greater differential between there usual price and breaker price. For these reasons their estimate of costs of diversion are inadequate.

Reasonable estimate of sampling and testing costs. The University of Minnesota Veterinary Diagnostic Laboratory estimates that actual testing costs in the proposal would be at least 50% greater than stated. (Dr Andre Ziegler, personal communication)

7. What's missing? Vaccination is known to reduce egg contamination and to contribute to reducing environmental contamination. Why it is not a part of the proposal is a mystery to all egg layer veterinarians.

Other issues

Inconsistencies The proposal is voluminous and that might explain the amusing inconsistencies and oddities found throughout. The suggestions that the industry uses wild birds for fly control, that there is such a thing as a one row chicken house and that the egg industry could develop a plan for

the same cost as the juice industry could be taken as evidence of FDA's ignorance of the egg industry.

> "There's no sense being exact about something if you don't even know what you're talking about." John von Neumann

FDA estimated cost of total program. The FDA's unreasonably low estimate of $83M is more than 25% of the egg industry's net in 2002 (most recent data, ERS Poultry Yearbook). This is about $.01 per dozen if spread equally over the whole industry.

However, there is a much greater impact on small producers than large producers. When much of the cost is "house-based" the small producers will pay 10 or more times more than large producers. For example, the environmental samples will likely cost over $50 each and the cost for each house will be over $600 to $1600. Thus, environmental testing alone may cost a producer with 3,000 hens $0.20 to 0.53 per bird ($0.01 to 0.026 per dozen). Of course if the small producer has his 3000 hens in two or three houses his costs will double or triple for the same number of hens. I have been on a layer farm with 20,000 layers that were housed in six houses! (The FDA proposal assumes all the hens on a small farm are in one house.)

FDA's own estimate of $1.01 per hen ($.05 per dozen) for a small producer exceeds the net return per dozen reported for the industry in 2002.

The producer with 200,000 layers per house will incur a cost of $0.003 to 0.008 per bird ($0.00015 to 0.0004 per dozen). If egg testing is needed, a conservative estimate of $8000 to test eggs from a flock of 4000 layers would be $2 per bird or approximately $0.10 per dozen. The cost of the same test for a flock of 200,000 layers would be $0.04 per bird or $0.002 per dozen. Such a disproportionate differential will unfairly force small producers out of business.

The "house-based" approach ignores that it is the egg that causes human infection not the chicken house. For all the mathematical gyrations FDA has gone through, this simple fact seems to elude them

FDA estimates that 9.7% of environments will be positive and 26% of them will result in at least one egg sample positive. If so, 2.5% of the flocks in the U.S. will be affected.

FDA asks, "Should safe egg handling be mandated and should high risk people be protected?"

Here is what FDA has said, "In establishments where eggs are combined to make food items, one SE-contaminated egg can contaminate a dish that will served to many people. Thus, it is necessary for you to use SE prevention measures on your farm to prevent SE contamination of your eggs and illness in consumers."

They could also more appropriately say, "Thus, it is important to use pasteurized eggs when eggs are mishandled, combined or undercooked."

In the proposal FDA is suggesting that a producer with 3000 hens should spend $3030 ($1.01 per hen) to reduce the risk of SE. The producer's hens will produce approximately 750,000 eggs in a

year. If one in 20,000 of those eggs is contaminated, the producer is spending $3030 to prevent 37.5 contaminated eggs from reaching the market. An institution can pool and mishandle thousands of eggs and infect say 3,750 people. If a small producer can be asked to spend $3030 to prevent 37.5 contaminated eggs (which we agree cause no illness if cooked properly), what is the appropriate amount to ask a large institution to spend to prevent 3,750 illnesses?

If FDA mandates farm worker training, why not mandate food preparation worker training? For FDA to focus on farmers and omit large food service corporation, hospitals, nursing homes and restaurants shows what a political document the proposal is.

FDA asks, "Is performance-based preferable to rule-based?" The program as proposed is a combination of results-based and rules-based. FDA has to decide for itself whether it wants to set the goal and let industry try to reach it or if it wants to set the rules and accept the results no matter what they turn out to be. The risk to the industry if FDA decides on a rule-based program is that when it fails FDA will take its frustration out on the producer. This essentially returns FDA to the situation it created shortly after 1988. It would be wise for the FDA to set goals or standards for the industry to reach and then step back.

FDA asks, "Should we expand the record keeping?" This is directly related to the point above. Records don't accomplish anything. It's results that are needed and records of results are sufficient.

FDA asks, "Should producers with <3000 hens be exempt?" Very small farms are likely to have the hens on the floor or range where they contact their own manure. Research has shown Salmonella to be a bigger problem in such management systems. Exempting small farms from the testing and refrigeration requirements when such farms are more apt to have problems is not rational. If such farms cause a problem it is the egg industry that is blamed.

Excluding the very small producer will also make him/her vulnerable to marketing efforts of larger producers. Conversely, the exempt very small producer has a significant marketing advantage over the small (>3000 hens) producer.

Definition of consumer. FDA does not state whether it is using the USDA definition of consumer or not. This is a critical piece of information.

Conclusion. Not credible best describes the justification. Disappointing describes the one-size-fits-all proposal which is both cumbersome and punitive. Its impacts are disproportionate and unfair to small producers caught between large efficient farms and very small exempt producers. Fortunately the proposal is not law yet. To improve the proposal FDA should seek facts and experience rather than comments. FDA has overlooked the role of veterinarians in the success that has been achieved to this point in the reduction of SE in the egg and in the environment.

Sincerely

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