**DEPARTMENT OF FOOD AND AGRICULTURE**
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April 19, 2000

TO: **FDA/Dockets Management Branch (HFA-305)**
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: **Docket No. 00N- 0504**

Recent public hearings were recently held in Columbus, OH and Sacramento, CA sponsored by FDA and USDA pertaining to the *Egg Safety Action Plan.* Comments made at these meetings illustrate to regulators, consumers and egg producers that the success of the plan and public confidence in government officials responsible for developing and implementing the plan rests upon a sound, defensible science-based approach. The term 'pathogen reduction' was used repeatedly by participants and re-emphasizes the framework established by the President's Food Safety Council whose goal is to assure the safety of food through *Risk Assessment, Risk Management and Risk Communication*. In order to obtain support from all parties, the development of the *Egg Safety Action Plan* must rest on the principles of transparency and objectiveness. Ninety-one percent of all known California layer premises voluntarily participated in a statewide SE prevalence study recently, largely based on acknowledgement of these principles.

The *SE Risk Assessment Report,* published by FSIS in 1997-98 illustrates that reduction of *Salmonella enterica* Serotype Enteritidis (SE) in humans requires a deliberate commitment at all points in the food chain in order to reduce the risk of SE in humans. Question 5 of the Federal Register/Vol. 65, No. 55 is fully addressed by the findings of the *SE Risk Assessment Report* just mentioned. The following practical comments are offered with this perspective in mind.

**ON-FARM PRODUCTION**

1. Producer education must be the foundation for changing current production behaviors and practices to continually implement principles of Good Agricultural Practices (GAP's), obtaining support for research and developing practical and economical risk reduction strategies for SE. With the assistance of qualified scientists, producers need to understand how to develop and implement a risk management plan appropriate for their facility.
2. Risk management plans for SE promote general guidelines but should be flexible enough to accommodate regional variability in climate and geography, SE prevalence, management systems, marketing and economics (the reader will find many instances of regional differences in the National Animal Health Monitoring System - NAHMS report, *Layers '99*). Existing Quality Assurance Programs (QAP's) already address this issue. Regional accommodation must be considered in regions without existing QAP's.

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3. The 1/20,000 egg prevalence for SE is based on an environmental prevalence in Pennsylvania of 37 % (Se Risk Assessment Report - p. 36 Production Module). The California SE survey has found the prevalence of SE in manure of layer premises to be approximately 10 %. Could California's low environmental prevalence rate be reflected in lower egg prevalence?
4. Under a process control paradigm, testing as well as recordkeeping assists the producer or processor to assess and adjust the process. Process control must have intrinsic value to the producer and it must include impartial third-party verification of records.
5. Testing must be risk-based and producers must demonstrate *'Due Diligence'*. Testing all premises a predetermined number of times during a production cycle may overestimate or underestimate risks in certain situations. In addition, the SE Pilot Project demonstrated that, *"Repeated environmental testing of a house did not give consistent results"* (Schlosser et. al.). SE is clustered spatially and is intermittent temporally. The philosophy of process control dictates that the need for additional research focused on the ecology of SE and that testing be based on risk as defined by such research. To do otherwise would be scientifically and economically untenable. Preliminary annual cost estimates for California on-farm testing could reach $2 million.
6. Random selection of manure rows to be tested is scientifically valid, especially in light of economic and mandatory testing of every flock currently in production in some states.
7. On-farm GAP's and processor Hazard Analysis Critical Control Points (HACCP) are not fully equivalent in structure, function and effect. The *Egg Safety Action Plan* does not fully recognize this inherent difference between GAP's and HACCP.

## PACKER SHELL EGG PROCESSING

1. Since a larger percentage of eggs are sold as shell eggs in California, the economic implications of in-shell pasteurization will be substantial in specific regions such as the western U.S. Current egg-processing practices should be improved with the goal of developing the best available performance standards for shell eggs.

## EGG PRODUCTS PROCESSING

1. Current State laws governing the use of egg breaker centrifuges require review and analysis since they contribute to the risks of amplifying the number of SE organisms in baking goods and other egg products prepared at the retail level.

## RETAIL, FOOD SERVICE AND CONSUMER

1. Pathogen reduction is achievable at the farm level. Pathogen elimination in final food products is predicated upon preventing amplification of SE and the final kill step – cooking. Human food handlers still account for 20 - 30 % of all SE contaminated food (Guzewich, Bryan).
2. The CDC should assess the relative risks of the following variables in human SE due to food borne contamination: time-temperature abuse, inadequate cooking, inadequate cooling, inadequate holding, cross-contamination from objects, secondary human infections in institutions, strategies for high-risk individuals (elderly, young, immune-compromised).
3. County and State environmental health specialists require additional training in performing timely and thorough foodborne illness outbreak investigations focusing on the following three areas: epidemiological, environmental and laboratory data collection and analysis (Guzewich, Bryan).
4. Education is crucial for successful control of SE at this point of the food chain. Turnover of institutional food handlers is a challenge that needs to be met. Children need to be educated early concerning personal hygiene and food handling. Promoting protective behaviors once reinforced through mandatory school health curricula is also indicated.

## RESEARCH

1. The development of performance standards must be based on a sound understanding of the ecology of SE.
2. The presently accepted rate of trans-ovarian transmission of SE may be overestimated. SE, which reach the shell membrane from external contamination, are not likely to multiply as much as eggs internally contaminated with SE by the trans-ovarian route. The route of SE multiplication is important in prioritizing risk reduction strategies in the farm-to-table continuum.
3. Longitudinal epidemiological field studies are needed to complement cross-sectional studies completed in Pennsylvania and California. The risk for SE at various stages of production is really unknown since no such field study has yet been done in the U.S.
4. A recent SE survey conducted in California indicates that for most "positive" premises, fewer than 25% of individual swabs were SE-positive. Risk-based performance standards are needed to determine what adjustments will be effective in reducing the risk of SE in eggs. The relationship between positive environment and positive eggs has yet to be determined. This is important from the point of view of end product testing, however, undertaking environmental testing to validate the "process" should require different responses depending on the level of risk (see attached flow diagram for an example of one possible approach).

**CONCLUSION**

Environmental monitoring should be used to validate core components of the QAP. A recommended protocol for environmental monitoring is attached with this docket submission. Thank you for your attention to this submission.

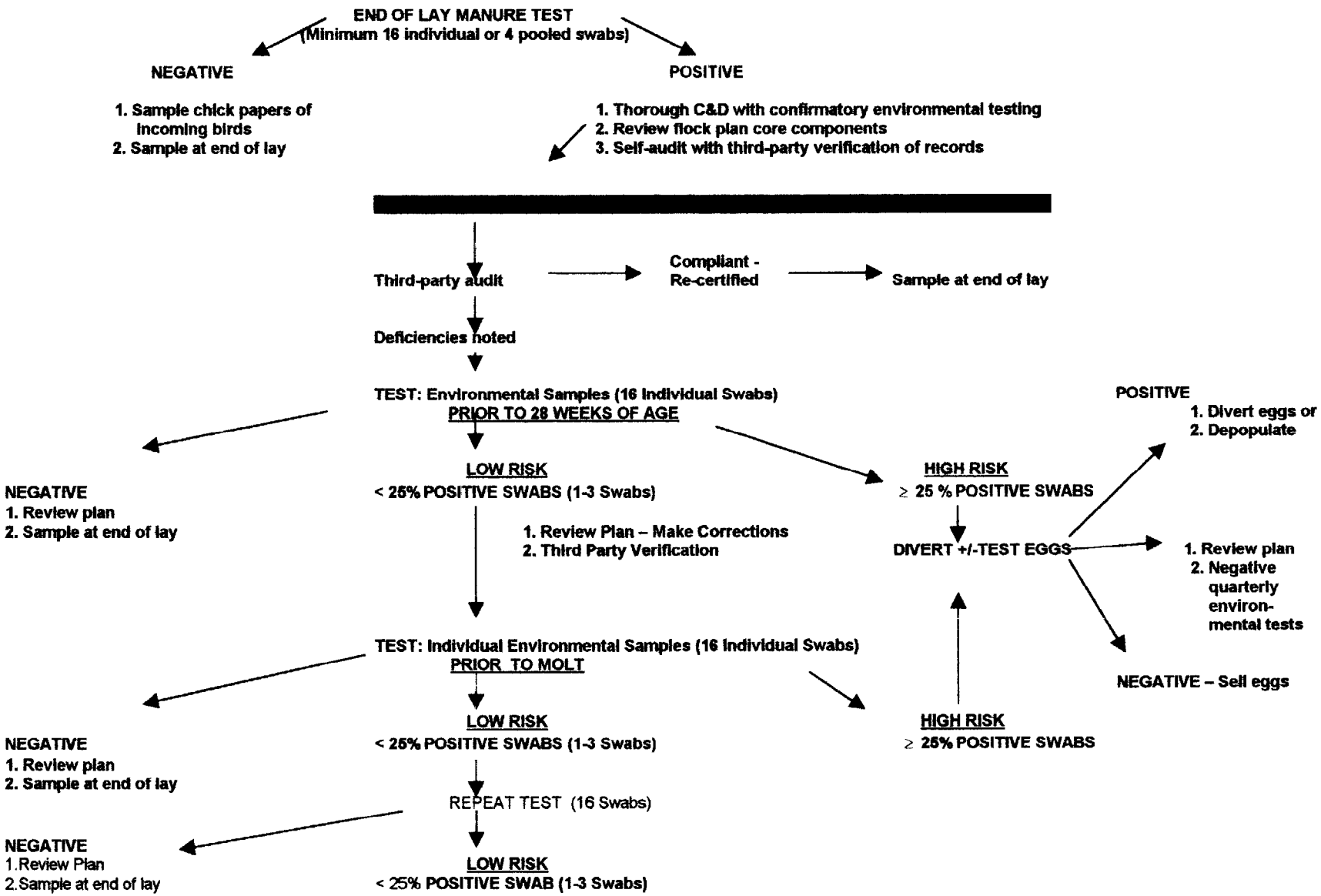
Sincerely,

Richard E. Breitmeyer, DVM, MPVM
State Veterinarian and Director
Animal Health and Food Safety Services

Attachment

** If action is required based on environmental monitoring, the concept of high versus low risk flocks illustrated below, is recommended.

## EXAMPLE OF A RISK-BASED FLOW DIAGRAM FOR ON-FARM SE RISK REDUCTION



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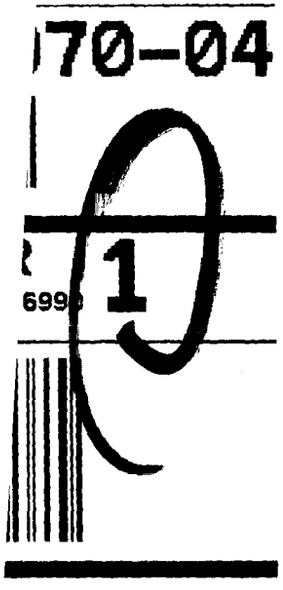




meter breaststroke and 100-meter/200-meter freestyle, Klenz is training for a spot on the German National Swim Team
Games in Sydney, Australia. He has worked at UPS for three years and is currently a part-time preloader in Leipzig, Germany. He is a member of the
Training Assistance Program (ATAP), which provides employee-athletes with the support they need to pursue their Olympic dreams.