Iowa Poultry
ASSOCIATION

December 20, 2004

Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203 and 2000N-0504, "Prevention of *Salmonella* Enteriditis in Shell Eggs During Production"

The Iowa Poultry Association is a voluntary statewide trade association composed of competing firms involved in all aspects of the poultry industry in Iowa. We offer the following comments relative to the proposed rule.

Recognition of Existing Efforts

FDA should recognize that many states and egg production and processing enterprises have already adopted egg quality assurance programs. If such programs are functionally equivalent to FDA requirements, then producers or processors following them should be considered in compliance with FDA's regulations.

We do not believe the creation of additional layers of bureaucracy will achieve the desired results. Programs should be outcome-based. The industry is working toward improved methods of reducing SE. If you are in the food business, safety is a top issue. Creating more programs, record keeping and paperwork is not the answer.

Identifying the common goals and allowing the industry to achieve the goal in the manner most efficient for them is the correct way to proceed. A producer should be provided the opportunity to first demonstrate their flock is of low-risk. In such a case, no further regulatory intervention is necessary. An approach like this accomplishes the goal of reducing exposure without creating an unnecessary burden of government intervention.

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Vaccination

We believe the option of using a vaccination program should be available for producers. It is our understanding data exists in the US and Europe which demonstrates the efficacy of vaccination programs. We are aware of very positive results from vaccination programs in Ohio and Pennsylvania.

Under a vaccination regimen, we do not believe egg producers should be required to do environmental testing at the 45-week and 22-week time periods but instead would do environmental testing at the time the flock is depopulated.

Cleaning and Manure Handling

Should an environmental positive be identified, the producer should then pursue a dry cleaning of the building. We do not believe wet cleaning should ever be used due to problems inherent in the process. Wet cleaning can wreak havoc on the metal equipment in a building and can substantially reduce the building's useful life. Requiring wet cleaning in Northern states in cold seasons would also prove quite problematic. And, wet cleaning may create environmental compliance issues relative to the cleaning water contaminated with disinfectants.

Some studies have shown increases in SE after wet cleaning. It is difficult to comprehend why the agency would propose to use a process that could actually increase the prevalence of SE in a proposed rule it says is necessary to decrease the incidence of the organism.

The handling of the manure will also be problematic and requirements must remain flexible enough to allow the removal of manure only during times when it can be transported and applied to fields in a short period of time.

The requirement that all visible manure be removed is unrealistic as some residue will likely remain in porous building materials. While the removal of all manure is a laudable goal, the regulation, must be realistic and practical.

Biosecurity

The use of biosecurity measures should be specific to farms and not buildings. The issue of clothing and footwear should also be farm-specific versus building-specific.

SE has been isolated from a number of organisms including horse, cattle, cats, dogs, pigeons, ducks, pigs, rats, mice and humans. The biosecurity definition used by the agency says, in part, such programs "ensure there is no introduction or transfer of SE

on to a farm or among poultry houses." No program can absolutely guarantee something does not happen. This is of particular relevance where, as with the present case, there is an organism with such a multi-host range. However, such programs *are* an important step in greatly *reducing* the likelihood that something would occur. The agency needs to be realistic in its nomenclature.

Pests

The agency's definition includes flies. It is our understanding that, on a practical basis, only rodents have been shown to have an effect on SE in chickens. In fact, soldier flies have been shown to reduce SE in manure. The definition of pests should only include those animals which truly have a practical impact on SE exposure.

Other Establishments

If food safety related to eggs is truly the purpose of this proposal, then FDA has the responsibility of ensuring all handlers of the eggs or egg products are storing, handling and cooking them in the appropriate manner. While the industry strives to improve the production side of the equation, egg producers and processors have no control over those who use the products. All the efforts on the production side of the equation can be for naught if improper food handling and cooking techniques are practiced on the consumption side of the equation.

FDA must recognize this fact and any regulatory path must also recognize the fact that production practices can be negated by improper handling at points beyond the control of the producer/processor. A food preparer can take a clean product, like pasteurized egg product, and contaminate it later through improper handling. Such action is not the fault of the producer/processor but you can be certain they will bear much of the negative perception as will the product.

Processing Issues

Egg processing facilities need to be able to recover as much liquid product as is possible from the eggs. Holding eggs at too cool a temperature greatly reduces the recovery of product. Where the egg product will be pasteurized in processing, FDA should allow the eggs to achieve an appropriate temperature prior to processing. FDA should also allow the storage of shell eggs on-farm and prior to processing at temperatures not to exceed 60° for a maximum time period of 5-days prior to processing. This will allow for the potential short-term storage and transportation of the shell eggs to the processing plant eggs and the slow cool down of the shell eggs to maintain shell strength and integrity.

The proposal's requirement that eggs held more than 36 hours be held at 45° F is unnecessary where processing will pasteurize the egg product. Eggs held at 45° F on the farm will have condensation issues, thermal checks during washing and reduced yield when processed.

Timing of Testing

The proposal's requirements for implementing testing after the discovery of an environmental positive are too short. If the proposal is to move forward, it should be changed to allow "up to 72-hours" time period between the finding of an environmental positive and the required egg testing. This allows for weekends or holiday weekends when laboratory facilities would most likely not be available to complete the test. In addition, has the agency even determined if lab capacity is adequate for the rule as proposed?

Husbandry Practices

We do not believe FDA has jurisdiction with regard to molting as a husbandry practice. It is our understanding there is a lack of field research in this area. A laboratory study where birds have been challenged with the bacteria is not the appropriate basis for a decision in this area. In addition, there is now more research into how to control the natural process of molting in the production setting with a variety of diets. It is premature to impose any regulatory scheme. FDA should rely only on peer-reviewed, duplicative, valid and sound science for making decisions that will affect an entire U.S. industry.

Program Administration

USDA - AMS already inspects egg packing facilities four times per year under the Shell Egg Surveillance Program. If the proposed rule is adopted, the AMS should be in charge of administering this program in since the vast majority of egg producers and processors have long histories of working with this agency and its associated state and federal employees. Utilizing existing resources avoids the diversion of FDA employees from important work like homeland security issues.

Application to All Producers

The current proposal exempts producers with fewer than 3,000 laying hens. However, again, if food safety is the purpose of the proposal, exempting hens based on the size of the operation eviscerates the alleged purpose. It is not the size of laying operation, but rather the practices followed, that create the safe food we enjoy in this country. To allow smaller producers to avoid food safety simply due to size exposes the entire

industry to issues of credibility. Should problems arise, "eggs" are going to be blamed regardless the nature of the operation involved.

More importantly, exemptions based on size expose people to food safety issues based on factors unrelated to food safety. Smaller flocks are more likely to be floor raised. In addition, organic flocks must have access to the outdoors. In either case that increases the exposure of the bird to sources of Salmonella. It has been documented that floor-raised or range chickens have more Salmonella.

Elimination of SE on Farm

On page 56832 of the proposal, the agency states, "Therefore, we have tentatively concluded that a proposal to require that producers of shell eggs for the table market, other than those producers whose eggs are treated or sold directly to consumers or who have fewer that 3,000 laying hens, comply with all of the proposed SE prevention measures would exclude SE on the farm and, thus, remove sources of SE contamination of shell eggs."

Do we understand this to mean the agency believes any federal rule will change the natural biologic processes that exist today? Mankind has never been able to totally control nature. The agency should change this thought toward a *reduction* of SE on the farm. And, this must further be modified to reflect the level of "farm" the agency will hold to the standard. Again, if the agency does not require floor-raised flocks whose eggs go directly to consumers to meet the proposed requirements how can the agency even remotely consider making such a statement? Some might view this with quite a cynical eye leading them to believe the agency's main goal is simply to increase the regulatory burden on producers.

Iowa's egg industry is firmly committed to producing the safe, readily available supply of eggs and egg products consumers' demand. We do, however, feel FDA needs to rethink the current proposal. We support more research in this area and the inclusion of industry experts in further FDA discussions regarding proposed regulation on SE in eggs. We stand ready to assist in any such effort.

Sincerely,

Kevin S. Vrichatto / for C.E.O.

Joe Laffoon
President