Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504

Dear Sir or Madam:

I am writing on behalf of the layer company that I work for in regards of the Food and Drug Administration's proposed rule on *Salmonella enteritidis* in shell eggs. We have egg operations in Broadway, NJ, Galena, MD, Middletown, DE, and Lamar and Newberry, SC. It is our company goal to provide the best quality and safest commodity to our customers. Food safety is a very important part of our total quality program. The dockets listed above will have a direct impact on how we do business.

When considering the above mentioned dockets the FDA should take into consideration the progress the egg industry has made in the past decade. Egg quality assurance programs have had a positive impact on the level of *Salmonella enteritidis (SE)* infections from eggs or egg products. This is a tribute to the federal, state, and local programs that are already in place as well as the commitment from the egg producers.

If the FDA were to thoroughly review the data from the impact of existing state and private egg quality assurance programs you would find that the incidence of *SE* in states where formal programs are in place has decreased since their inception. These programs are there and are working. FDA could use these plans to establish a program that is known to work.

While the intent of the regulation is good, there are some points that the FDA should take into consideration. The egg industry is already regulated by federal and state agencies that could be used to carry out the regulations in these dockets. NPIP (National Poultry Improvement Plan) is already regulating *Salmonella Pullorum* and *typhimurium*, it would be logical to add *enteritidis* to the agency. USDA and AMS are already in the egg processing plants and could be used to insure the program is followed. FDA would have to add personnel to cover a program that would be in every corner of the United States pulling resources from national security.

FDA should look into the published data from experts in the field of egg and poultry science. Several parts of the proposal should be revised and reviewed by these experts. Many of the points are either impractical, unnecessarily costly, or in conflict with sound science.

- Vaccination is not considered as an effective tool in controlling *SE*. The bactrin that is used to vaccinate with colonizes the intestine preventing an infection with *SE*. A new product that is now available even has claims for colonizing the oviduct and ovaries. This would decrease the chance of an egg being infected with *SE* or having shell contamination. With proper vaccination the level of *SE* in the environment is decreased by 89% (Burns, K. E.). Since vaccination can control *SE* in a house then the amount of environmental testing should be reduced to just shortly before depopulation.

- The amount of testing that would be required is exorbitant. Has there been any survey to determine if the laboratories could handle the extra work load? State, university, and local laboratories have had cut back in the recent years. This usually means that personnel are spread thin as it is and adding the extra testing would be infeasible.
- Any cleaning, wet or dry, if done properly is effective in controlling any disease. If done improperly they can be disastrous. With wet cleaning is easier to have a problem if it not done perfectly. In an environment where there is a virtual cesspool of bacteria and viruses, adding water increases the population of these microorganisms logarithmically. Dry cleaning removes the moisture that the microorganisms need to survive as well as the substrate that they feed off of. Dry cleaning is a better way to clean an environment where the equipment is mostly metal. Adding water to this system is problematic. Rust and destruction will only add to the cost of the cleaning procedures. There also needs to be consideration of who will inspect the facilities to insure the cleaning has been done correctly.
- The requirement that eggs held more than 36 hours be refrigerated at 45˚F causes some problems. When eggs are produced in an in-line facility where none of the eggs are sent to another plant, this rule is fine in most cases. In situations where the eggs are produced on a farm and processed in another location, such as an off-line plant or a further processing plant, this rule would be very difficult to follow. In the off-line plant, eggs are usually picked up from the farm and processed during the week and not run on the week-ends. With this rule all of the small farms would have to increase there storage refrigeration. Then when the eggs are processed there would be an increase in the amount of thermal cracks which can sometimes go undetected. Thermal cracks happen when there is more than a 40˚F temperature difference between the internal egg temperature and the wash water temperature. Since the wash water has a minimum of temperature of 90˚F, there would be a 45˚F difference if the temperature could be kept to 90˚F. Most of the time the wash water is more like 100+˚F. When there is a crack in the shell of an egg there is an increase in the chance of contamination of the interior of the egg. For the further processing plants, this would mean an increase in refrigeration and capacity for a process that is ultimately going to kill the bacteria. When looking at the amount of time it takes and the temperature required for a logarithmic growth of *SE*, the temperature and time requirement is unnecessary. The amount of time it takes for *SE* to grow in shell eggs is dependant on the temperature. When holding inoculated eggs at 54˚F it takes 35 days before *SE* can be detected in more than 25% of the eggs tested. In the same situation, in order for SE to be detected in more than 25% of the eggs within the 36 hour limit the temperature would have to be more than 99˚F (Humphrey et al.).
- In the section for biosecurity there are some issues that would be impractical to implement. Most of the industry is integrated and have in-line facilities where houses are connected by more than the egg belt. The steps suggested in this section refer to production in areas (i.e. Swiss) where they are smaller farms with more control within individual houses. Cross contamination becomes a concern in situations where there is a problem. If *SE* is not in one house, it can not be carried to another house. Every situation is different. It is unrealistic to implement the same biosecurity policies in every operation. Programs need to be tailored to fit the individual operation. The other question is who is qualified to review the biosecurity programs for these operations?

Would there be someone devoted to reviewing the program and the implementation? This would take a tremendous amount of time and man power.

- In today's liquid egg production operations have worked to streamline there operations like the shell egg production. Most of the liquid plants are set up to run in-line from the chicken houses into the breaking facility. They have eliminated the need for nest run eggs. The liquid plants that still use nest run eggs are quickly becoming a thing of the past. If FDA required the amount of eggs to be sent to a braking plant as suggested there would be an over load on the few plants that are not in-line. Has there been any investigation into the availability of these types of plants and there willingness to accept eggs from positive farms? If the industry is not able to go to a braking plant with there eggs, will all of the eggs be destroyed? Will this lead to the ultimate depopulation of a farm? Where would we be able to dispose of the positive hens? Have there been any thoughts about indemnification? In an industry that could not withstand depopulation without indemnification this is a valid question. When looking at indemnification the industry would need the potential income as well as the cost of the birds.

When reviewing dockets 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504, I urge FDA to consider these points. Personnel to cover the program as well as enforce compliance are an area of concern. The program needs to consider the use of vaccination and realize the effectiveness of including this in the total control methods. A survey of the laboratories needs to be done to find out if there is the capacity to handle all of the testing required. The way a house is cleaned should be revised to include dry cleaning with wet cleaning as an option. There should be more investigation into the time/temperature relationship with the growth of *SE*. When regulating biosecurity, we can not compare US production with production in other countries nor can we have a cookie cutter program. There also needs to be a survey of the liquid plants to determine the capacity and ability to accept the eggs from positive farms. We have come a long way from where we were 10 years ago with the control of *SE*. Farms practicing Best Management techniques developed from within the industry have been effective and continue to improve. When the FDA is finalizing these dockets they should look to the industry where proven success has already occurred and has not negatively impacted producers.

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