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**RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, 2000N-0504 and RIN number 0910-AC14**

Dear Sir or Madam:

**GENERAL COMMENTS**

The overall goal of this proposed FDA rule is certainly admirable. No responsible member of the egg industry will argue with the aim of reducing the likelihood of foodborne illness related to eggs containing *Salmonella enteritidis* (SE). While it is probably an unrealistic expectation with our current knowledge, it would be beneficial to all if the goal of never having another egg internally contaminated with SE could be achieved. The SE-egg issue has been of great concern to the egg industry since it became evident in 1986-87, worldwide. We still do not understand how such a problem could emerge around the globe within the same time frame with so many distinctly different SE phage types but it is a matter of public health that must be corrected. The industry has had to proceed to try to deal with the problem as best it could without having all the answers of where SE came from, how to get rid of it and how it could be absolutely avoided. One thing is certain: the internal contamination of eggs with SE had to end and the industry has had to do whatever was necessary to try to accomplish that goal.

This proposed rule has been on the shelf and /or in different stages of revision since it was first prepared about eight years ago. As a result, it includes many data that do not accurately reflect the very significant progress made by the egg industry with help from USDA and their respective state government agencies in reducing SE in layer flocks through voluntary Egg Quality Assurance Programs. Neither does the proposed rule include much emphasis on either the live or inactivated vaccines that have been extensively used in Europe and the USA with very positive results. Unfortunately, it is difficult to conduct research on vaccine efficacy in preventing egg contamination because the acknowledged SE incidence rate in eggs laid by unvaccinated infected hens is so low. Therefore, third party research papers on field layer flocks in refereed journals are not as available and not as informative as we wish. Based on their experiences, vaccine users in this country have come to rely upon them as an important weapon in combating SE. Some countries in Europe require vaccine use in egg layers, yet vaccines are not presented in the proposed rule as being that important to achieving the overall goal of the rule.

Because of the long delay in getting to this comment stage, the proposed rule does not include the latest numbers on human illness. Reports issued by the CDC give a much more encouraging picture than is presented in this proposed rule. They show a decline in SE illnesses from a peak in 1995 of 3.88/100,000 population to the latest numbers given in 2002 of 1.8/100,000 population. When examining the SE illness data from the three most severely affected regions in the US, the Mid-Atlantic region declined from their peak rate per 100,000 population in 1989 of 10.52 down to 3.3 in 2002. The New England region declined from their peak of 10.1 per 100,000 in 1995 down to 3 in 2002. The Pacific region declined from their peak in 1994 of 6.7 down to 1.55/100,000 in 2002. SE outbreaks (an outbreak being defined as two or more ill individuals related to the same occurrence) declined from the peak of 85 outbreaks in 1990 to the latest numbers provided which was 29 outbreaks for 2002. When they reported on the causes of the outbreak illnesses in 1998, 443 were egg-related as compared to only 86 in 2002, 114 were non-egg related in 1998 and 566 were non-egg related in 2002, and unknown causes accounted for 109 cases in 1998 and 188 in 2002. It appears clear that other foodborne causes of SE illnesses are emerging even though past egg related history encourages foodborne illness investigators to check out the role of eggs before proceeding to look for other sources of the illness.

The “50% reduction in SE by 2010” goal presented in [www.healthypeople.gov](http://www.healthypeople.gov) is used to justify more stringent and more comprehensive egg production regulations even though SE is now being demonstrated to also coming from numerous other foods. Regardless of meeting or not meeting the 50% reduction goal from 44 outbreaks in 1997 down to the goal of 22 in 2010, it should be clear to all that the data provided by CDC already show a marked decrease in SE illnesses from any source and an obvious decline in the number of illnesses related to eggs since the SE in eggs problem became known. It is increasingly clear that more and more SE illnesses are related to foods other than eggs.

These general statements support the position that the voluntary SE prevention and control efforts have been successful and are still working well to resolve the problem. There does not appear to be adequate justification to proceed with a mandatory, prescriptive regulation that dictates the step-by-step procedures for producing safe eggs. The goal should be to continue to decrease the likelihood of SE contaminated eggs and that process is well underway as evidenced by the data presented above. Setting aside the voluntary SE programs because they are “not always uniformly administered or uniformly comprehensive” is inadequate justification to implement such a costly and potentially damaging rule for many egg producers. Private enterprise, consumer/user education, mandatory implementation of the FDA Food Code related to institutional use of eggs, research on SE prevention and control methods and actual SE prevention experience will allow the egg producers to meet the year 2010-50% reduction in SE goal, even though the starting baseline was set late in the control efforts (1997) after much progress had already been made.

## **SPECIFIC COMMENTS**

### **Exclusion of <3,000 layer flocks**

The exclusion from the proposed rule of the more than 33,000 farms with fewer than 3,000 layers is certainly understandable from a political and compliance enforcement standpoint. The proposed regulation clearly supports the concern that this group of small producers will be the producers that will likely be deficient in areas of rodent control, biosecurity, egg cleaning/sanitizing, egg refrigeration and SE testing. They will also be less likely to obtain replacement pullets or chicks from breeders who participate in the SE prevention programs. Although they may produce only 1% of the eggs produced and most would be sold to individual

consumers and not to commercial users, they may be the cause of a disproportionate share of individual sporadic illnesses and some “church supper” type outbreaks related to egg pooling and temperature abuse. Egg-related human illness statistics will be used as an important measure of the effectiveness of any egg safety program and to exclude over 33,000 producers would appear to predetermine a more limited demonstrable public health benefit of the regulation.

### **Prescriptive versus outcome regulations**

The prescribing of step-by-step procedures for egg producers to follow to be in regulatory compliance is an inappropriate and inefficient way to achieve the goal of SE-free eggs. It is virtually impossible to draft a set of prescriptive regulations that are suitable for all types and sizes of houses, for all climates, for the different types of cages and equipment, for the different contractual arrangements or even more important, for the range of SE risk level presented to the flocks. Procedures appropriate for one area, based on the historically proven level of SE risk, may be inappropriate for another area. It does not appear to be sound policy to require the most stringent operational requirements where they are not needed, simply to “level the playing field” for all egg producers.

### **The FDA Food Code**

Consideration should be given to making some features of the FDA Food Code mandatory and not advisory, especially those parts related to the pooling of eggs in institutions. Many of the large outbreaks are related to commercial or government institutions that misuse eggs, especially when they break and pool large numbers of eggs. The hand breaking assignment usually goes to the lowest paid, less educated, less trained staff member in many kitchens. Even if the eggs are delivered SE-free, the hand breaking and pooling of eggs can result in a contaminated pool due to inadequate hand washing, unclean utensils, temperature abuse during the breaking process and cross contamination from other raw foods. The requirement that only pasteurized egg product be used for large egg pools will help alleviate this problem which is especially important in hospitals and nursing homes. The first major outbreak in NY that exposed the SE-egg and illness connection reported in 1988 was said to be due to low-salt raw egg mayonnaise being made using outdated eggs for elderly patients. Pasteurized product substitution would have likely avoided that lethal outbreak. Based on the past events, the mandatory compliance with this provision of the Food Code will likely yield an immediate benefit in the form of a reduction in SE illnesses.

### **Hold eggs at 45F within 36 hours of laying**

There does not appear to be adequate scientific justification for the provision in the proposed rule that eggs must be held at 45F within 36 hours of laying. There are two concerns: I know of no data that show storage on the farm for several days at 45F is acceptable whereas 55-60F is not acceptable. If 45F eggs are transported from a contract grower’s layer house to the humid environment of the egg processing plant, the moisture from the air will condense on the cold eggs and they will “sweat” before they are washed/sanitized, increasing the chances of surface contamination penetrating the eggs. When eggs that cold are moved into the egg washer which must utilize hot water, checks or cracks can develop in the shell, lowering the quality of the egg and increasing the chances of future surface bacterial or fungal contamination getting into the interior of the eggs.

The other issue is the over 36 hour time requirement. I know that there is ample evidence that SE contaminated eggs contain extremely low numbers of SE cells in the albumen when laid.

The inhibitors within the albumen keep those numbers in check along with the lack of appropriate nutrients and iron needed for bacterial multiplication. If eggs are held at high temperatures or for periods in excess of three weeks, the integrity of the yolk membrane deteriorates and yolk contents can leak into the albumen and bacterial multiplication can occur. Humphrey, based on laboratory studies, places that temperature-dependant time at about three weeks, not 36 hours. It seems unreasonable to set the temperature at 45F instead of a more egg washing process-acceptable 55-60F and to require refrigeration if the eggs are 36 hours old instead of 48-72 hours which would be very helpful in remote contract grower situations where eggs must be trucked to the plant for processing. Unless you can support the proposed 36 hour/45F requirements with data acquired from naturally contaminated eggs, you should reconsider and adjust this portion of the proposed rule.

I might add that you have frequently referenced SE research done in the UK in this proposed rule. I have found that when you shop in the major chain grocery stores in the UK, you will find the cartons of unwashed, unsanitized eggs, often exhibiting feather pieces and bits of feces, at room temperature on the shelf alongside the dry breakfast cereals. I prefer that my eggs are clean, sanitized and refrigerated as they are in the US but the 36hour/45F rule is not justified, in my opinion, and can negatively affect the final outcome you are seeking: a safe egg.

### **Begin egg testing within 24 hours of a positive environment notification**

The simple logistics of this aspect of the proposed regulation needs clarification and probably reconsideration. If notification of a positive environmental test arrives on a Friday or on the day before a holiday when the testing lab is closed, when does “egg testing” begin? When the 1,000 eggs are randomly collected for testing or when they arrive at the lab for testing? There should be some flexibility built into this portion of the rule to allow for unexpected complications as mentioned here. This time-sensitive requirement should be carefully spelled out so that a producer will not be found in unintentional violation of this part of the rule.

### **Producer training**

It is proposed that at least one individual at each farm receive standardized FDA-curriculum or equivalent training of up to 2 to 3 days. This is certainly not an unreasonable requirement for a large in-line, multi-house operation but it could present a significant challenge and hardship for a one-person contract producer setup. There needs to be consideration given to some sort of home-based study system to allow such small, independent producers to get training without having to travel away from their base of operation. Care should be exercised to not impose deadlines for such training that could be difficult for such a producer to meet.

### **Adulteration of Eggs**

The infection of hens with *Salmonella enteritidis*, leading to the infrequent natural deposition of that bacterium within the normal egg should not be termed “egg adulteration”. To the uninformed, that term implies that the egg producer or processor has purposely caused the bacterial adulteration of the egg which is not only an inaccurate interpretation, it is an unfair accusation. I can understand if FDA needs to use “egg adulteration” instead of “egg contamination” for legal reasons to try to avoid making any compensation for producer losses due to SE control programs, however, it is an inappropriate term to describe an unfortunate but naturally occurring phenomenon and should be avoided if possible. One thing is clear: the contamination of eggs is not a willful, intentional act by producers and use of the term “egg adulteration” by FDA could inaccurately imply that was the case.

## **Enforcement of on-farm measures**

The proposed regulation states that any person who violates a regulation prescribed under Section 361 of the PHS Act may be punished by imprisonment for up to one year and may be fined, up to \$100,000 if no deaths resulted and up to \$250,000 if death has resulted. It is not clear who the “any person” could be but if it is the individual required to be named to be responsible for the administration of the SE prevention programs on each farm, those positions may be very difficult to fill, considering the severity of punishment for being found “in violation” of the Act.

## **Wet cleaning requirement of environmentally positive houses**

It could create serious problems for the industry if the final rule includes the requirement that environmentally positive layer houses, even with negative egg results, be “wet cleaned”. You even cite a published report in the proposed rule that found that only half of the SE-positive layer houses were SE-negative after cleaning /disinfection which included wet cleaning. The requirement of the proposed rule is the “removal of all visible manure”. After dry cleaning to remove dust, feathers and old feed, “you must wet clean the poultry house” followed by disinfection. Based on these directions, the present day, commercial in-line multi-tiered cage layer house with related accessories and equipment for watering, feeding, egg collection, manure deflection, storage and removal will likely be impossible to bring into compliance so as to pass inspection by an overzealous inspector who has never personally tried to accomplish the required tasks. Careful thought should be given to how you would enforce a requirement such as “removal of all visible manure”. The complex machinery (some electrical) is very difficult to clean at best and is just not compatible with wet cleaning. Consideration should be given to dropping that requirement. It would also be very difficult to accomplish in very cold climates because of freezing in that the layers were an important source of house heat until they were removed for replacement.

## **Egg diversion provision**

The main feature of the proposed regulation is that eggs from a SE-positive layer house environment will be diverted to pasteurization unless testing of four pools of 1,000 eggs each yields SE negative results. That provision seems to be justified and is a reasonable way to keep eggs of a greater risk out of the table egg market. Unfortunately, it could be very damaging to some egg producers who do not have their own egg pasteurization capabilities. They will be subject to the pricing practices of the breakers who know the producer must sell to breakers who are likely to already have all the eggs they need to fill their orders. There may also be resistance by egg product buyers, not wanting to purchase product known to have come from eggs diverted because of SE. A large egg company that has a breaking plant can simply decide which of their eggs are used to supply their breaking plant and which eggs are packaged in cartons or cases for shell egg sale, based on their environmental culture results. That has been a common practice in recent years and is a good way to help assure no SE-positive eggs reach the consumer.

There needs to be consideration of some way to deal with the economic impact of this egg diversion provision for those companies that don't have their own egg breaking capabilities. As it appears now, the regulatory requirement to divert eggs for those companies is essentially an order to destroy the layers because they will not likely be able to market eggs to breakers at a price that will make it economically feasible to retain the flock. Reducing the financial impact on the producer is the one positive feature of waiting until late in the production cycle to test the layer house environment. Spent fowl are essentially worthless so if flock environments are

tested earlier in the interest of trying to improve egg safety, there may be some egg producers, especially the small producers, going out of business in a disastrous way if their hens have been used as collateral for operating loans. The solution may be very difficult but it seems that some type of federal compensation package may be needed in the interest of improving public health to help smaller producers that lack pasteurization capability to at least partially offset the very negative aspects of the egg testing and egg diversion provisions of the proposed regulation.

**Recommendation:**

Do not implement the proposed regulation as it is presented for comment. Instead, allow the current voluntary SE reduction programs to continue, follow the SE illness rates to assure steady progress in declining human illnesses continues and make it clear to the egg industry that this regulation will be implemented unless egg-related SE human illnesses continue to decline. This will allow the industry to use vaccines, pasteurization, rodent control, and any other approved practices, including diversion to breaking, to meet the challenge. The public health goals of this regulation (50% reduction by 2010) will be met with much less negative economic impact and hardship.

Thank you for having the opportunity to make comments and to suggest alternative approaches to the resolution of the problem related to SE in eggs. The egg industry certainly looks forward to the day when SE in eggs is no longer a problem and will do whatever is necessary to achieve that goal, hopefully while being able to continue to provide consumers with wholesome and safe eggs.



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