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

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

Dear Sir or Madam,

We are writing to comment on the Food and Drug Administration's proposed rule on *Salmonella enteritidis* (SE) in shell eggs. After reviewing your proposal we have noticed that Salmonella vaccines and bacterins are not emphasized as part of the total control program. Salmonella vaccines and bacterins have had a tremendous impact in helping to reduce the incidence of SE in shell eggs and poultry environments both in the United States and throughout the world.

Nowhere is this more evident than in Pennsylvania where they have implemented the Pennsylvania Egg Quality Assurance Program (PEQAP) to reduce SE in shell eggs. The success of PEQAP has led to national and international recognition as the current standard for SE reduction in shell eggs. Vaccination against SE is an integral part of PEQAP. Data collected from PEQAP show consistent and overwhelming reduction of SE isolations for both poultry environments and shell eggs as a result of SE bacterin use. The summaries of two and four years of PEQAP results compiled by Dr. Armando Mirandé (References 1 and 2) show that SE vaccinated laying flocks had a 93% reduction in SE positive eggs. Additionally, the data show that there was an overall 89% reduction in environmental positive samples in vaccinated vs. non-vaccinated flocks. The PEQAP study represented the largest known sampling of its kind and the number of birds in this study total more than 70 million (57.4 million unvaccinated and 15.9 million vaccinated commercial laying chickens). This study was the result of a cooperative effort between the Pennsylvania Poultry Industry and Pennsylvania Department of Agriculture.

In addition to field surveillance data from PEQAP, numerous clinical studies and trials also support SE bacterin use as a very efficacious tool in controlling SE. In a research study conducted by USDA-ARS Southeastern Poultry Research Laboratory, Holt,

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Gast. Et al. (Reference 3) demonstrated that antibodies in table eggs laid by hens vaccinated with an SE bacterin had a dramatic effect in inhibiting growth of SE when SE was artificially inoculated into those eggs. As we are all aware, SE contamination of eggs has frequently occurred from mishandling or contamination of product after eggs have left the farm. Unlike pasteurization which is a point kill process that still would allow for easy recontamination, the presence of maternal antibody protection from vaccination of hens would help to protect the product all the way to the doorstep of the consumer. Essentially this study indicates that salmonella prevention through the use of bacterins has the ability to significantly prevent infection at two very critical places (i.e.; the laying hen and its end product the egg).

As with any commercial USDA licensed vaccine, salmonella bacterins are put through rigorous tests to prove both safety and efficacy. Some of these test results can be viewed in *New Era in SE Control* (Reference 4) and in *The Dawn of a New Age in Food Safety* (Reference 5), publications made available to industry to help introduce the benefits of vaccination.

In Japan, the use of salmonella bacterins is an integral part of the vaccination program and has proven to be a very effective tool in helping to reduce the incidence of food-borne illnesses associated with Salmonella contamination of table eggs. This has proven to be a tremendous accomplishment in a country of such high egg consumption many of which are eaten in a raw or semi-cooked form. Numerous studies conducted in Japan have continuously supported the use of SE bacterins to ensure the safety of this food resource. Two of these studies have been included for your review (References 6 and 7.)

The Lion Quality Code of Practice from the United Kingdom (Reference 8) is another example where the use of salmonella bacterins has been acknowledged and instituted as an effective tool to prevent colonization of the hen by SE to protect the consumer from egg-borne salmonellosis. The goal of this program is very similar to the goals of the PEQAP previously cited: to reduce the risk of salmonella through the production chain and ensure that eggs are held and distributed under the best possible conditions and produced to the highest quality standards of food safety in the world. Vaccination is an integral element of PEQAP and is recognized as the most important "on-farm prevention measure". More than 80% of UK eggs are currently produced under the Lion Code of Practice that includes vaccination against SE and a "best before" date stamped on every egg as part of it.

Data from leading egg-producing countries support the use of SE bacterins as an effective tool for "on-farm prevention". Vaccination should be integral part of the on farm SE prevention program and should be the focal point of the SE prevention



measures. The successful use of SE vaccination for the past 12 years in commercial laying flocks has demonstrated that vaccination can significantly reduce the incidence of SE positive eggs. SE vaccination should be required for a replacement flock following depopulation of a previously positive premises.

Similarly, the use of vaccination should be accepted as an alternative replacement to wet wash down, a process that is difficult if not impossible to accomplish in many areas of the country during the winter months. Recent studies on water wash down show conflicting information as to its effectiveness, as reported by Dr. Eric Gingrich PEQAP Executive Committee and USAHA Salmonella subcommittee Chairman (Reference 9).

Today's costs associated with SE vaccination are significantly lower than those mentioned in the Proposed Rule released in September. On average, the most common vaccination program costs between \$.05 and \$.07 per bird. Wet washing during winter can cost three to four times more than vaccination of replacement pullets. A freshly washed house is only clean until new birds are put in, whereas vaccinated replacement pullets will continue to be protected against SE colonization during lay. Vaccination has been shown to reduce SE re-isolation in the feces and eggs by 89% and 93%, respectively (Reference 2.)

In closing, we support FDA's efforts in protecting the consumer and its attempt to effectively reduce food-borne illnesses associated with SE in eggs. Similarly, we are aware that the egg industry is very conscientious in their efforts to produce a safe and high quality product. Many have already taken it upon themselves to vaccinate flocks against SE, and the results have been very beneficial. We strongly urge you to incorporate vaccination into the program as an effective tool for prevention of SE in poultry.

Sincerely,

A handwritten signature in black ink that reads "Ron Plylar". The signature is written in a cursive, flowing style.

Ronald Plylar
President

A handwritten signature in black ink that reads "Joan Leonard". The signature is written in a cursive, flowing style.

Joan Leonard, Ph.D.
Executive Vice President