BIOMUNE®

BIOMUNE CO.
8906 Rosehill Road
Lenexa, Kansas 66215

Phone: 913-894-0230
FAX: 913-894-0236

February 7, 2000

Dr. Lou Carson
Deputy Director for Food Safety Initiatives
Center for Food Safety & Applied Nutrition
200 C Street SW
Washington, D.C. 20204

This letter is intended as a comment to the President's Council on Food Safety Action Plan to Eliminate Salmonella Enteritidis Illnesses Due to Eggs, dated December 10, 1999: Egg Safety. From Production to Consumption.

The President's Action Plan for total elimination of Salmonella enteritidis illnesses due to eggs by the year 2010 represents a noble cause, however, the openly expressed opposition by certain segments of the table egg industry, specifically the egg producers themselves, is not only to be expected but also justified. It appears that not enough consideration has been given to the most important component of this particular farm-to-table continuum of food safety, the egg producer. In the current Plan the economic reality of contemporary farming in the United States has not been properly considered and will likely continue to face an antagonistic attitude by most farmers. One thing remains unequivocal, the Plan will probably not succeed without full cooperation from the egg producers, therefore, it must become more "producer-friendly" if is to be implemented by the egg industry.

The Plan's background statement of providing mandatory national standards for consistent egg safety standards across the U.S. and to provide egg producers and processors with a "level playing field" industry-wide seems to be welcome by most. The problems appear to arise with the recommendations that ... "offer industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution and to the consumer at an equivalent level of safety" (page 4). These two recommendations are equivalent in neither cost of implementation nor the achieved end result.

96P-0418

C 813

Strategy I: SE testing-egg diversion on farm will obviously reduce significantly the number of contaminated eggs reaching the shell market, however, this option does not have an actual provision that actively and directly achieves the objective of producing cleaner eggs. All the testing in the world will not reduce the incidence of SE in table eggs yet it will create a logistical nightmare. We do not have the capacity or the money to test the environment of every laying flock in the U.S. five or six times. Neither we have the capacity to test the eggs from every flock in an SE positive environment on a monthly basis. Additionally, the economic impact that egg diversion to pasteurization plants will have on every producer would be devastating. In the end there could be a shortage of shell eggs and an oversupply of liquid eggs. This will significantly affect the pricing structure of both commodities.

Strategy II: Lethal treatment, or "kill step" at packer/processor is hardly a choice. The lethal treatment that is being discussed, in-shell pasteurization of eggs, is literally cost-prohibitive since it practically doubles the cost of production. Besides, by putting most of the burden at the processor level, this strategy, if implemented, would likely hinder efforts made at the production level. Why spend more money at the farm if it is to be spent at the plant? This attitude from egg producers would be a likely scenario and will definitely contradict the Plan's broad base policy to use multiple interventions to achieve a more substantial reduction of SE. The Plan is trying to not direct efforts at one stage of the egg production to consumption continuum only (page 18).

There is an intervention step that has been surprisingly omitted from this plan and the only time that it is mentioned is on page 27, as "an on-farm intervention strategy or technology that needs to be developed or evaluated". Vaccination of laying pullets with an USDA approved SE bacterin is the single most effective method to reduce the production of SE-contaminated eggs and is already proven.

In the case of Biomune's Layermune SE, it was developed and licensed more than eight years ago and it has been thoroughly tested by independent researchers (Gast et al., 1993, Miyamoto et al., 1999). Also, Layermune SE has been used intensively and extensively in Germany since 1994, under the TAD label Talovac SE-109, when SE vaccination of laying birds became mandatory. The effects of chicken vaccination on reduction of SE outbreaks in Germany are clear. Also, during 1998 the British Egg Council, representing more than 70% of commercial layers in the United Kingdom, instituted the mandatory vaccination of birds from its members with two doses of an U.K. approved SE bacterin. Most of the rest of the layers, not represented by the Council, have followed this practice to not loose a marketing edge.

In Canada Layermune SE has been thoroughly evaluated in the field by industry for the past four years. As a result of these evaluations the government of the Province of Ontario, which represents more than half of all layers in Canada, modified its policy regarding SE in the egg industry more than two years ago. Vaccination of pullets is mandatory when they are to be housed in an environment that tested SE positive with the previous flock prior to depopulation or when the new chicks or pullets test SE positive. These two situations are regarded as high-risk. In addition, vaccinated layer flocks in an SE positive environment do not have to divert eggs to pasteurization plants. Only non-vaccinated flocks have to follow egg diversion after testing environmentally positive.

In the U.S. Layermune SE has also helped influence policy decisions by the Wisconsin Department of Agriculture. After a series of SE outbreaks more than two years ago that resulted in FDA traceback investigations, with the consequent findings of SE positive environments, the extensive application of Layermune SE in 90% of the birds intended for the shell egg market has significantly reduced the prevalence of SE. Today, vaccination of pullets is done in-lieu of pullet environmental testing and this is welcome by all producers.

In Pennsylvania use of Layermune SE has significantly improved the reduction in the prevalence of SE achieved by the Pennsylvania Egg Quality Assurance Program (PEQAP) from January 1997 to September, 1999. Data collected and summarized by the Pennsylvania Department of Agriculture and presented by Biomune Co. during the January 18, 2000, meeting in Atlanta showed a reduction in the number of SE positive environmental samples = 90% and, more importantly, a reduction in the number of flocks with SE positive eggs = 100% (see attachment). There have been no SE positive eggs detected by PEQAP in Layermune SE vaccinated flocks. The number of participating vaccinated flocks until September, 1999 = 93, representing 8.2 million layers. This figure, together with the standardization of management practices and testing protocol and intensity under PEQAP, make this a very significant reduction.

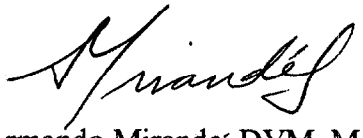
Vaccination should also be considered as a "kill step", implemented by the producer, since it provides a similar level of reduction in the prevalence of SE-contaminated eggs. It should also be recommended in-lieu of certain environmental testing, such as in the pullet house or during early lay, when the probabilities of detecting SE in the environment of a vaccinated flock are extremely low. This would provide an incentive to the egg producer. Flocks should be tested six to eight weeks prior to depopulation in order to determine the level of risk to which a new flock will be subjected. If a high-risk situation is encountered, additional interventions can be implemented with the incoming flock. This is the base for the recommendation on environmental testing presented by the US Animal Health Association's (USAHA) Committee on SE in Eggs.

Also, the effect attained from vaccination in reducing SE from the environment and, mainly from eggs, is accomplished with only a fraction of the cost of other interventions, such as in-shell pasteurization. In fact, the cost is 100 times less. Also, vaccination does not cause any of the side effects that pasteurization has on egg quality, such as increased mold from added humidity, increase in shell cracks, cloudiness of egg albumen, etc.

The benefits that vaccination with an SE bacterin has on reducing SE in eggs are not new. The Salmonella Enteritidis Pilot Project (SEPP) Progress Report, 1995, showed a very marked reduction of SE in eggs from fully vaccinated flocks (page 27). In a study designed to determine the correlation between blood spot egg (BSE) and nest run egg (NRE) SE positivity, vaccination in nine flocks showed a 22.4 X and 12.4 X reduction in the number of SE positive BSE and NRE, respectively, as compared with eggs from 17 non-vaccinated flocks. SE was found in 0.26 per 10,000 and 0.23 per 10,000 BSE and NRE of vaccinated flocks, respectively. The incidence for BSE and NRE in non-vaccinated flocks was 5.83 per 10,000 and 2.86 per 10,000, respectively. There were more than 50,000 BSE and more than 170,000 NRE tested. Unfortunately, the conclusions noted that although vaccination was suggestive of lowering the risk of a flock producing SE-contaminated eggs, insufficient houses were studied to draw a definite conclusion. One of the recommendations for future research included to "Conduct an adequately controlled field trial to determine the effectiveness of vaccines to prevent SE in egg layers" (page 76). Four years later, PEQAP has provided such field trial with the inclusion of 93 vaccinated flocks that validate SEPP's preliminary observations.

We propose that the current data on the use of Layermune SE available through PEQAP, be validated as one of the most extensive and controlled field trials ever conducted with commercial layers. We also propose that, based on such trial, the President's Plan consider the overwhelming evidence in favor of the efficacy of SE bacterin, specifically Layermune SE. Vaccination of chickens against SE is an already available intervention tool that should be recommended to egg producers by the Plan with an added incentive, such as a reduction in the intensity of environmental testing.

Sincerely,



Armando Mirande, DVM, MAM
Manager, Technical Services

Status Report on the Effect of SE Bacterin Vaccination in PEQAP Flocks (1997-1999)

Armando Mirandé
DVM, MPVM, MAM, ACPV
BIOMUNE CO.

SE Pilot Project 1992 - 1993

❑ Total flocks participating	134
❑ SE (+) manure or belt samples	16.1 %
❑ Flocks with SE (+) manure or belt samples	47.7 %
❑ Flocks with SE (+) eggs in (+) environment	37.2 %
❑ SE prevalence in eggs from flocks in SE (+) environment (per 10,000)	2.75

SE Status of PEQAP Flocks

	1997	1998	1999*
❑ Total flocks participating	261	316	315
❑ SE positive manure samples (%)	2.06	2.23	1.53
❑ Flocks with SE positive manure samples (%)	10.7	13.9	8.9
❑ Flocks with SE positive eggs (%)	7.3	10.1	4.4
❑ SE prevalence in eggs from flocks in SE (+) environment (per 10,000)	2.19	1.51	1.37
	29 / 132,240	53 / 350,613	25 / 182,379

* Jan. – Sept., 1999

Results of Environmental Testing in PEQAP Laying flocks (By Samples)

	1997	1998	1999*
Non-vaccinated Flocks			
No. Flocks	258	295	246
SE (+) samples / Total	82 / 3913	172 / 6975	54 / 2858
	2.1 %	2.47 %	1.89 %
SE Bacterin Vaccinated			
No. Flocks	3	21	69
SE (+) samples / Total	0 / 74	1 / 517	2 / 801
	0	0.19 %	0.25 %

* Jan.-Sept., 1999

Results of Environmental Testing in PEQAP Layers (By Flocks)

	1997	1998	1999*
Total No. of Flocks	n = 261	n = 316	n = 315
Non-vaccinated Flocks			
Flocks with SE (+) Manure	28 / 258	43 / 295	26 / 246
	10.9 %	14.6 %	10.6 %
SE Bacterin Vaccinated			
Flocks with SE (+) Manure	0 / 3	1 / 21	2 / 69
	0 %	4.8 %	2.9 %

* Jan.-Sept., 1999

Results of Egg Testing in PEQAP Laying Flocks with SE (+) Environment

	1997	1998	1999*
Non-vaccinated Flocks			
No. Flocks	258	295	246
Flocks SE (+) eggs / Total	19 / 258	32 / 295	14 / 246
	7.4 %	10.8 %	5.7 %
SE Bacterin Vaccinated			
No. Flocks	3	21	69
Flocks SE (+) eggs / Total	N.A.	0 / 1	0 / 2
	0	0	0

* Jan.-Sept., 1999

Cumulative Results of SE Prevalence in PEQAP Flocks Following Use of SE Bacterin (1997-1999*)

	Non-vaccinated	Vaccinated	Reduction
No. of Flocks	799	93	-
Birds represented (Millions)	45.6	8.2	-
Flocks SE (+) Environment	12.1 %	3.2 %	3.8 X
SE (+) Environmental Samples in all Flocks	2.2 %	0.22 %	10 X
Flocks with SE (+) Eggs	8.1 %	0	
Env. (+) Samples in (+) Flocks	21.4 %	8.3 %	2.6 X

* Jan.-Sept., 1999

Protective Effect of SE Bacterin Vaccination on Reducing SE (+) Environmental Samples

Combined Reduction Effect =

Reduction of Flocks with SE (+) Environment (3.8) X

Reduction of (+) Env. Samples in (+) Flocks (2.6) = 9.9 X

Combined Reduction Effect = 89.9 %

Conclusions

- Analysis of PEQAP data from January, 1997 to September, 1999, shows a 89.9 % reduction in environmental samples (manure swabs) in SE bacterin vaccinated flocks when compared to non-vaccinated flocks.

Conclusions

- Analysis of the same data bank shows that during the same time period there have been no SE positive eggs detected in SE bacterin vaccinated flocks

Conclusions

- The impressive SE reduction by the Pennsylvania Egg Quality Assurance Program (PEQAP) has improved with the increased use of a federally licensed SE bacterin.

Conclusions

- Use of SE bacterin vaccination against *Salmonella enteritidis* should be recognized by the President's Council on Food Safety (Objective No. 7) as an extremely cost-effective and already available tool to achieve its goal to minimize the risk of SE (+) table eggs.

Example: Cost of pasteurization = $ 0.35 / dozen eggs
Cost of vaccination with 2 doses of SE bacterin = $ 0.007 / dozen eggs (50 X less)

CROSS FILE SHEET

File Number: 98N-1230/ C F 1 3

See File Number: 97P-0197/ C 8 1 4

96P-0418/ C 8 1 3