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Federal Drug Administration
Dockets Management Branch HFA-305
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 00N-0504 (HFA-305)

Greetings:

The Sparboe Companies is pleased to comment on the President's Council on Food Safety/Egg Safety Action Plan, hereafter referred to as the Plan. The Sparboe Companies, headquartered in Litchfield, Minnesota is among the largest producers of fresh shell table eggs in the United States. We also rank among the largest producers of whole liquid egg products in the United States. Our operations are located in Minnesota, Iowa and Colorado. We also have several family farm egg producers on contract with us throughout Minnesota and Iowa.

The three general questions inviting comments to the docket were:

1) Does the Plan comprehensively cover the problem of SE in eggs and measure for reducing this hazard?
2) What are the costs in implementing the risk reduction components?
3) What training is needed?

These comments will respond to each of these general questions, detail areas of the Plan that need more emphasis, and highlight those steps in the Plan that do not contribute materially to the stated objectives.

Sparboe Companies considers food safety of paramount importance and supports the goal of the President's Council to protect the public health from all foodborne hazards through science-based objectives and action steps. The Plan's strategic policies must continually ask if the action steps will actually stop someone from getting ill.
Protecting the food supply is an ongoing challenge because, although the risk associated with eating will never be eliminated, the hazards can be minimized.

Overall, the Plan is comprehensive. However, the Plan is over ambitious and will not meet the objectives of the Plan for reasons discussed herein.

Question No. 1. Does the Plan comprehensively cover the problem of SE in eggs and measure for reducing this hazard?

Science-based objectives and action steps in any regulation must be founded on accurate data

Any science-based objectives and action steps need to be truly rooted in scientific data and accurate information so that there is valid information for making informed decisions. Broadening the participation in quality assurance programs by establishing a national uniform program of grading and inspection for all egg producers will assist with the collection of accurate data and the further decline in the incidences of SE related illnesses.

The Plan has numerous examples of misinformation and misunderstanding which could lead to erroneous decisions. Even before the Plan's introduction, numerous quality assurance programs developed by the egg industry have contributed to a 48% decline in the rate of culture-confirmed SE cases reported to the Centers for Disease Control and Prevention (CDC) between the years of 1996 to 1999, and a 7% decline between 1998 and 1999[1]. In the 1999 National Animal Health Monitoring Study[2] it was reported that 56.1% of farm sites were conducting a quality assurance program.

Misinformation with misleading results

When President Clinton made his radio address on December 11, 1999, he stated that there were 3.3 million infected eggs that could lead to human illness. This risk is overstated. The figure 3.3 million is based on the risk model of 1 egg in 20,000 or 0.005%. This percentage of the nation's total egg production yields 3.3 million eggs, but the President's advisors neglected to point out to the President that nearly 30% of all eggs are broken into liquid form and pasteurized. Overstating the potential risk by 30% is a serious misstatement that has damaged the reputation of the egg and thus the egg industry this past year.

The media coverage of the President's comments stated that foodborne illness accounted for 76 million people becoming ill every year, 300,000 would be hospitalized and 5,000 reported deaths. It was not pointed out that this is a combined figure for all foodborne illness, not just Salmonella or Salmonella Enteritidis associated with eggs. We must take extreme care as both the

[1] CDC Mortality and Morbidity Weekly Report, February 17, 2000.
[2] USDA/APHIS/US National Animal Health Monitoring System.

Government and the Industry are faced with making critical decisions based on information. Accordingly, we need accurate information.

It is vital to recognize that the most important priority for any Federal food safety strategic plan is credible information. Real, not hypothetical, numbers need to be used in making decisions leading to policy.

The MMWR of February 4, 2000 provides the number of outbreaks and number of deaths attributed to Salmonella Enteritidis infection associated with eating raw or undercooked eggs. The deaths reported during that 14-year period was 79 (less than 6 per year . . . nowhere near the 5,000 deaths reported), of which 64 or 81% occurred in health-care facilities. The MMWR of March 17, 2000, also shows a decline in illnesses attributed to SE. The information about the majority of deaths occurring in health-care facilities were not included in the Plan, with the net effect that major newspapers and other forms of media attributed the 5,000 deaths annually to eating SE-contaminated eggs. Any loss of life is unacceptable. However, risk communication must be accurate to prevent the continued disparaging of any commodity. Greater efforts need to be directed toward accurate risk communication.

Cited epidemiology must be current and accurate

In reporting the rate of isolation of SE from infected humans, the Plan cited the years from 1976-1994 to acknowledge an increase in the rate from 0.5 to 3.9 per 100,000 population. It also reported regional trends for the years 1990-1994, indicating a decrease in the Northeast with increases elsewhere. This is correct information for that time period. However, this information is misleading as the more current information from CDC shows a decline in every region of the country. The MMWR reported from 1996-1998, the rate of culture-confirmed SE cases reported declined from 3.6 to 2.2 per 100,000. Every effort should be made in reporting accurate and up-to-date epidemiology information so that action steps can be solidly based.

Industry demographics must be accurate
Every egg producer must be included in the plan

In reporting the demographics of the US egg industry, the Plan noted the estimated value of layers at nearly $1 billion. In 1999 the value of the laying flock would be more accurately reported at $1 per bird. With an average flock size nationwide of 269 million layers, this would have yielded a value of less than one-third of the reported value in the Plan. Additionally, the demographics represented the egg industry as 5,000 producers with 3,000 or more hens and another 65,000 farms having less than 3,000 egg-laying hens. The USDA, in cooperation with the

American Egg Board collects the most current statistics on the number of egg-producing farms with 3,000 or more hens showing this total at less than 700 farms. The actual number of farms is, therefore, only 14% of the number referenced in the Plan.

Accurate industry demographics are imperative for accurate decision-making. Because the Plan will exclude farms with 3,000 or fewer layer hens and because it is reported that these farms can produce up to three-quarters of a million eggs annually for each farm, the potential exists for millions of eggs to be produced each year by farms excluded by the Plan. This creates a significant opportunity for potential foodborne disease problems with a large number of eggs entering the marketplace without any quality assurance surveillance. The grading and inspection program must be uniform and apply to every egg-producing farm in the country irrespective of the number of laying chickens on that farm.

What is the Risk?

Are eggs less safe than other protein-rich foods? This is the implication in the FDA's proposed safe handling label. The President's Council on Egg Safety has identified egg safety as one component of this public health issue that warrants immediate federal, interagency action. The risk assessment has been determined by the SE Risk Assessment Final Report prepared by the Food Safety and Inspection Service as one SE-contaminated egg from the production of 20,000 eggs[3]. The risk assessment is 0.005% which is several orders of magnitude lower than most animal products. Statistically, the likelihood of becoming ill from a contaminated egg is once in 84 years. This risk is very, very low. The Plan's action steps in developing labeling for egg cartons must be adjusted from its proposed discriminatory message. United Egg Producers (UEP and others) has suggested that the Partnership for Food Safety Education's *Fight Bac!* Campaign will further educate consumers in the proper way to handle all foods rather than wan against eating such products. Sparboe Companies supports such a campaign.

Importance of educating consumers demands immediate implementation

A broadly based policy is more likely to be effective in decreasing/controlling egg-associated SE illnesses than a policy directed solely at one stage of the farm-to-table continuum. In the Plan the burdens of immediacy are placed on the egg industry through a comprehensive testing program (Section 1.1.1) while federal responsibilities provide for more generous timelines.

Objective 8 provides for the education of individuals using science-based materials. This must be a high priority item with a more aggressive action step. Based on data from the Centers for Disease Control and Prevention (CDC), most SE

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[3] FSIS Salmonella Enteriditis Risk Assessment, Shell Eggs and Egg Products, June 12, 1998.

outbreaks occur in commercial venues. The Plan under the subheading Egg-Handling Practices provides the basis for the urgency in the immediate implementation of science-based educational material by stating, "the presence of SE bacteria in a raw egg, alone, does not guarantee illness upon consumption." Thus, control measures directed against egg contamination per se are not critical for control of SE illnesses in humans. If one applies the HACCP approach to the whole food chain, the only real critical control point is at the handling and food preparation point. Focus on this point, as an alternative to the strategies the Plan offers of either diversion or pasteurization, will significantly and with more certainty and lower cost, reduce the incidence of SE illness in humans. However, the likelihood of developing SE infection increases when the egg is not handled safely by permitting the bacteria to multiply and a greater number of bacteria to be ingested with the food. In 1997, seventy-one percent of the SE outbreaks were in food service or institutional settings. Clearly, food service establishments need additional education on how to store and prepare food. The sooner this is developed, the sooner we will reap the rewards of meaningful reductions in the incidence of Salmonella associated with eggs and other foods.

We can and must work together on educating consumers. Without a clearly focused timeline on this vitally important step of educating the consumers and handlers we are undermining the efforts of the Plan. Although not the only line of defense, educating the consumer in proper food handling and preparation is the final line of defense.

Flaws in the objectives and action steps of the Egg Safety Action Plan

The Overarching goal calls for the elimination of SE illnesses associated with the consumption of eggs by 2010. The Plan has set an interim goal of a 50% reduction in egg associated SE illnesses by 2005. These are surely commendable goals. However, is there a consensus among epidemiologists that complete elimination of Salmonella is possible? In the Plan it states, "Salmonella of various serotypes are commonly found in the digestive tracts of animals and frequently contaminate our environment." Salmonella is also found in domestic animals, insects, lizards, amphibians, fish, wild mammals and wild birds. If Salmonella is commonly found in the digestive tracts of animals and these other sources, how can any amount of effort totally eliminate it? To establish a goal that will not succeed is to plan to fail. It will only result in further damaging consequences and reduce the credibility of both egg industry and the Government.

Objective 1 calls for the reduction of the number of SE-containing eggs marketed to the consumer. In subsection 1 of the nationwide SE reduction program it details a rigorous testing program and diversion of eggs to pasteurization upon discover of a positive. Is this diversion the result of a positive SE test? This is an important

factor as other vectors can contribute to the presence of SE in the environment. For example, science has shown that mice may be carriers with each fecal pellet possibly containing 25,000 SE organisms. One mouse may deposit 100 pellets in a single night. Testing can help verify that a good quality assurance program is working and that should be the goal rather than **testing** be the goal. We can control rodents, but we cannot eliminate them. The egg industry in the United States does not and cannot operate in a vacuum.

Section 1.2 establishes a HACCP-based system for shell processing with the specifics being founded in quality assurance programs. This action step should precede Section 1.1.1 on environmental testing. Testing should be the validation of the effectiveness of a quality assurance program. You cannot "test" your way to safety, but you can manage those hazards that will reduce the incidence of Salmonella associated with eggs through a good quality assurance program.

Question No. 2. What are the costs in implementing the risk reduction components?

Economic Impact of Testing

Basically, the Plan is an attempt to first control, and then eliminate SE in eggs and egg products. As referenced, it is our position that SE infections in humans can be controlled better (completely) and in a more cost efficient manner at the food preparation level rather than on the farm. The fact is, SE eradication on the farm is not necessary for effective control of SE infections in humans.

If a flock tests positive for SE, the measures that need to be implemented to divert those eggs to pasteurization and/or make the flock SE negative will cost the producer significantly.

It is difficult to place a number on the cost associated with a positive SE test result. However, if a flock tests positive for SE, sooner or later the economics will force the producer to attempt to make it SE negative. This cannot be achieved without depopulation of the farm. If the Plan is truly comprehensive (arguably the Plan is), depopulation of one positive barn on a complex cannot be expected to eliminate SE from the entire complex. Thus, the whole complex will have to be considered SE positive, all eggs will have to be diverted, and depopulation of the whole complex will be necessary. Even with that, there is no guarantee that you can repopulate without another positive test result which, as you can see, leads to a "catch 22" and could result in having to continue to divert eggs while you start the cycle all over again. Do you understand the implications?

Under a serious Plan, once a flock tests positive for SE, it is considered positive for life. Thus, eggs are diverted for life. It cannot be argued that a SE positive flock can

suddenly become an SE negative flock. We should not propose a Plan that ignores this and call it serious. Again, we suggest that the most cost effective method to control SE infections in humans is at the food preparation link in the food chain and not, as the Plan emphasizes, at the farm level.

For instance, if 81% of the SE related deaths reported occurred in the "at risk" populace (see Page 3, supra) it would be much easier, cheaper and more effective if control measures are directed toward food handling and preparation to these at risk individuals rather than at the farm environment. Indeed, alternative pasteurized products available to the populace as a whole, and mandatory use of pasteurized egg products in elementary schools and nursing homes would reduce the incidence of SE illnesses tremendously and create much less of an economic hardship to egg producers.

One can argue with and tweak the numbers to support a vast array of all kinds of costs in implementing the Plan and the risk reductions associated therewith. However, one thing is certain: the economic impact of the egg industry of following the protocols of testing under the Plan to their logical conclusions would be significant. The economics of SE eradication would be huge.

Question No. 3: What training is needed?

Inconsistent Enforcement

Objective 1.1.8 specifies the training of an inspection force. Implementation of inspection services would be conducted through the state agencies. The President's Council on Food Safety sought in its risk management goals the identification of gaps in the food safety system. The egg industry in general, and Sparboe Companies in particular, is supportive of focused and comprehensive objectives that will reduce the rate of foodborne disease, but the Plan is producing more gaps in its organizational structure by its plans to train State agencies to provide oversight and enforcement. The development of an organizational structure for enforcing egg safety programs through training fifty State agencies will create more and larger inconsistencies and pave the way for wider gaps in the current food safety system. The Plan is setting itself up for failure unless the organizational structure can be verified and enforced by a Federal system that has proven results in consistent enforcement. Because the USDA Agricultural Marketing Service and USDA Animal & Plant Health Inspection Service; both of which have written agreements to audit UEP's 5-Star Quality Assurance Program with already trained USDA employees, the Sparboe Companies would support an organizational structure of enforcing of egg safety standards through those entities.

AMS in cooperation with the National Egg Regulatory Officials currently utilize a work force representing 50% of USDA's AMS workforce who already have

experience in processing, sanitation inspection, refrigeration enforcement, monitoring quality assurance plans, enforcing the Egg Products Inspection Act and determining the quality of eggs through hand candling. This proven track record for enforcing consistent grading standards through the AMS voluntary shell egg grading service demonstrates the degree of effective communication necessary between industry and government to achieve success. To develop a training program through State agencies is not a good utilization of taxpayer funds when a proven system is already in place. This would duplicate what is already done daily. This recommendation is the most efficient, most effective and the least expensive in achieving this objective.

HACCP, Vaccines and New Technologies

Objective 1.2 establishes a HACCP-based system for shell egg processing. The Sparboe Companies is supportive of policies and procedures that are HACCP-like in their implementation. Reductions in the incidence of Salmonella have resulted from HACCP-like quality assurance programs and public health surveillance systems. To see the rate of disease decrease four years in a row is heartening to agencies, egg producers and consumers. The Sparboe Companies is optimistic about continuing this trend as it further develops stringent quality assurance plans. Practical techniques that are economically feasible, such as the use of vaccines for controlling Salmonella, are eagerly sought by the Sparboe Companies. Every effort should be made to facilitate the sharing of technologies that will contribute to a decrease in a foodborne disease. The egg industry and private vaccine manufacturers have submitted data and information on the use of vaccines in preventing the shed of SE organisms in the egg to the Food and Drug Administration with no response. European countries have added the use of vaccines in effective SE control programs. The interagency coordination necessitates that this lack of response be addressed and corrected so that transfer of technology be facilitated.

Labeling should educate consumers, not frighten them

Objective 1.4 notes the finalization and implementation of refrigeration and labeling regulations for eggs from processor to consumer. The Sparboe Companies supports providing safe handling labels that reflect science-based education of consumers into proper food handling and preparation. What is the rationale for the development of the FDA proposed safe handling label that uses language substantially more alarmist than the language required by the FSIS for labeling meat and poultry?

The sterner warning proposed by FDA and the use of additional inflammatory adjectives and other wording not required for meat and poultry may have the effect of implying to consumers that eggs are less safe than meat and poultry.

Funding

No mention is made in the Plan as to how this program is to be funded. Will the egg industry find itself in a position of enforcing an unfunded mandate? To be consistent with every inspection program calling for Salmonella-testing presently enforced by federal statute; public funds are used to pay the cost of inspection. To segregate the egg industry from every other inspection program by insisting on an unfunded mandate is discriminatory. Whatever program is enforced by federal regulatory authority, it should embrace the consistent practice of public funding. To do otherwise would be construed a tax, be discriminatory, and would further contribute to the consolidations and further decline in the number of farms already taking place in the egg industry.

The egg industry is supportive of indemnifying egg producers who must divert their eggs to a breaker. The level of indemnity would be based on the market value during the time of diversion less what the egg producer receives from the breaker for those eggs to be pasteurized.

Answers to Specifically Numbered Questions Posed in the Federal Register Notice

4.) Are the following appropriate and adequate components for a nationwide SE reduction program: Bio-security, SE-negative feed, chicks from SE-monitored breeders, flock health monitoring program, cleaning and disinfection of houses, rodent/pest control, monitored water supply? Yes, these components are important in the validation procedure but not sufficient to control or eliminate SE. However, cleaning and disinfecting, for example, is not practical for producers in colder climates during the winter months. Therefore, although appropriate, it may not be practical. Providing SE negative feed would be highly cost prohibitive. Again, many of these components would be cost prohibitive as control components under the Plan and, therefore, can only act as a monitoring component which, by the time a positive test result is obtained, will only lead to the vicious diversion and depopulation cycle referenced earlier.

Many quality assurance programs presently in operation call for these components. An additional provision should be comprehensive training in the program addressing the implementation of each segment on a consistent basis, nationwide.

5.) How effective do you think each component would be? Which component(s) do you think will provide the most risk reduction? Each component is a link in the chain for preventing the introduction of *Salmonella* into the egg laying complex. We believe the best risk reduction component is emphasis on the food preparation and "at risk" populace consumption. The components listed are adequate for monitoring

the effectiveness of quality assurance programs but actually do little to reduce/eliminate the risks of SE illnesses.

6.) Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? In the event an environmental test proves positive, additional testing would occur, as specified in the UEP 5-Star Quality Assurance Program. Sparboe's follows the UEP 5-Start Quality Assurance Program. Environmental testing is an appropriate step in determining whether the program is working and thus monitors the risk of reduction but does not effectively control such.

7.) In the event that an environmental sample for SE is positive, what, if any, additional steps should a producer be required to take with the positive flock/house and with the next flock that will be placed in that house? Two series of steps are recommended; one calling for the use of vaccines and the other if vaccines are not used. If vaccines are used, and the environmental tests are SE positive, then extra cleaning and disinfecting procedures (formaldehyde) should begin immediately upon depopulation. The replacement flock would be vaccinated with an approved live or killed SE vaccine prior to the onset of lay. Next, environmental testing of the facilities would be conducted at 30 weeks of age and again, if and, when the flock is molted. Environmental testing of molted flocks should be tested once hens have been returned to production. If environmental tests are positive, then eggs must be diverted to pasteurization until egg tests of 480 egg samples have indicated a negative test. Environmental testing will be conducted 6-10 weeks prior to depopulation.

8.) Where vaccines have been used, is there a correlation between vaccine use and reduction of SE in eggs? Yes. [See answer to number 7 above.]

9.) In the event eggs from an SE-positive layer flock are diverted from the table egg market, what measures should be implemented to ensure those eggs are pasteurized? Any eggs diverted to the breakers will be pasteurized. Loads destined for the breakers are tagged so that any loads determined to be positive will be identifiable and will be pasteurized. This requires uniform enforcement by the USDA.

10.) In the event eggs from an SE-positive layer flock are diverted to the production of liquid, frozen, or dried egg products, should the eggs be handled or processed differently? *No. Salmonella* is heat sensitive so the process of pasteurization will kill the pathogens.

11.) Do customer specifications exist that prohibit the processing of SE-positive eggs for egg products? There exist some breaking facilities that may not accept SE-positive eggs for pasteurization even though the heat process kills the pathogens.

This would cause serious consequences for those egg producers who are in a position where they must divert their production to the breakers due to the identification of *Salmonella*-positives. Diverting those eggs to a landfill may also require a moisture-absorbing additive prior to acceptance at a landfill. The losses for a producer in this predicament is substantial.

The series of questions relating to specific costs for various components in the quality assurance programs were answered during the public meetings in differing areas of the country. These costs are significant.

15.) Are there any methods by which a packer/processor can determine how old eggs are when they are received? No. While we may not be able to determine the exact day each egg is laid, AMS has been operating a grading service that serves as a barometer of both age and quality of shell eggs. Also, nest run eggs are more commonly graded than farm packed if those eggs are destined for the table egg market. Those eggs would commonly have lot numbers which could help ascertain how old the eggs are when graded.

16.) When packing shell eggs for the consumer, will the use of only new primary packing materials increase marketing costs? Only new material is used when packing shell eggs for the consumer.

17.) Are the proposed components of the national standards for packing and processing of shell eggs and egg products appropriate and adequate to reduce the risk associated with SE? No. The Plan is comprehensive enough as it relates to these areas but emphasis at the packing and processing stages is misplaced. For example, the Plan indicates that research should be conducted on the practice of repackaging and re-selling of eggs that have been returned unsold from grocery stores. We should not study the practice. <u>We should ban the practice!</u>

The Plan should also provide stronger incentives to implement the promising vaccination programs. For example, if a human illness outbreak should warrant an FDA traceback to the farm, then those layer houses using a vaccination program as a component of the total Quality Assurance Program would be exempt from environmental tests and only egg tests would be conducted. The Plan requires much more testing than is necessary. Diversion of eggs should only occur if *Salmonella* is determined in egg samples. Afterall, it is the eggs that are sold to the consumer and hence that is the ultimate product to be sampled as is true in other commodities such as meat and poultry. The Plan does not address the ongoing practice of egg centrifugation at restaurants and bakeries in those States that have not banned the process or the machinery. This process of centrifugation at the bakeries and restaurants must be prohibited to stop the commingling of the shell's surface with the internal contents of the egg.

The remainder of the questions in the Federal Register notice call for answers that would vary from farm operation to farm operation.

Conclusion

The Sparboe Companies considers food safety of paramount importance and supports the reasonable goals outlined in the Plan aimed at protecting the public health. The Plan is meant to be a salmonella enteriditis control program, not a salmonella enteriditis monitoring program. The very core of the Plan's problem is that, on the farm SE control is extremely difficult, is uncertain, is not cost effective and is basically a failed approach.

Whereas we agree that we need to attack the problem at each link in the food chain, not enough emphasis is being placed upon those areas where control is less difficult, more certain, more cost effective and a proven approach in controlling SE illnesses.

Therefore, with the suggested strategies listed herein, together with informed input from other stakeholders the Plan effects, we believe a workable and reasonable Plan can be arrived at and put into operation.

Thank you for the opportunity to present these comments. Please call with any questions.

Sincerely,

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