M.G. WALDBAUM Innovative Egg Products
A MICHAEL FOODS COMPANY

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April 19, 2000

USDA/FSIS Hearing Clerk
300 12th Street SW
Room 102 – Cotton Annex Building
Washington, DC 20250-3700

Re: USDA, FSIS Docket No. 98-045N3
HHS, FDA Docket No. 00N-0504
Federal Register, vol. 65, pp. 15119-15122 (March 21, 2000)

Dear Sir or Madam:

Michael Foods, Inc. submits the following information regarding the "Egg Safety Action Plan" being developed by the Food Safety and Inspection Service and the Food and Drug Administration. The Michael Foods Egg Products Company (M.G. Waldbaum and Papetti's brand names) is a supplier of pasteurized egg products and also maintains egg production flocks. The vast majority of the eggs we produce are nest-run eggs sent to our processing plants for production of a wide variety of pasteurized liquid, frozen, dried, pre-cooked and in-shell pasteurized eggs. The remaining smaller percentage of our egg production is used to supply a portion of the retail table egg market. We also purchase eggs for breaking from a group of outside suppliers. The Michael Foods Egg Products Company has been involved in a *Salmonella* Enteritidis (SE) flock monitoring program since 1991. Our program has been aggressive, self-administered and self-tested, and our experiences have given us a wealth of information on the relative value of various SE intervention strategies.

Michael Foods is pleased to submit the following information in response to questions posed by the Agencies in the recent *Federal Register* announcement:

1. **Does the Egg Safety Action Plan comprehensively cover the problem of SE in eggs and measures for reducing this hazard? If not, what should the Plan include to be more complete?**
   - The Plan outlined by the President's Council on Food Safety is certainly comprehensive in its attempt to address all key aspects of the farm-to-table continuum relevant to the public health problems associated with SE in shell eggs. The greater challenge is the need to properly prioritize the various elements of the plan and to assure that the national standards called for in the Plan are effectively implemented and enforced across the entire industry. Certain key details in the Plan, such as the frequency of flock environmental testing, need to be determined by applying the best available science and the learning experiences of the more proactive producers in the industry. In order to achieve the ambitious SE illness reduction targets summarized in the Overarching Goal of the "Egg Safety Action Plan", Michael Foods believes that there must be greater utilization of pasteurized eggs and egg products, which have an outstanding food safety record. In order to provide the public with a uniform level of protection/risk reduction, we contend that the "Action Plan" must be implemented uniformly across the industry without exception for smaller egg producers or processors.

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I. Shell Egg Production:

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?**
   - In order of priority (highest priority item listed first): Flock environmental SE testing program (pullet at 12+ weeks, peak lay, peak molt, and end-of- lay), vaccination program, NPIP program, rodent control program, biosecurity, health monitoring, cleaning and disinfection, SE-negative feed and monitored water supply.

5. **How effective do you think each component would be? Which components do you think will provide the most risk reduction?**
   - The key components of the program are: Environmental testing, vaccination and an effective rodent control program. One without the other will result in a program failure. The greatest SE risk reduction for the least cost is the killed vaccination program. Live vaccination approaches do not have an adequate track record to be recommended across-the-board at this time.

6. **Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? If so, how often and when should testing be performed to ensure that the plan is working and that the consumer is protected from consuming SE-contaminated eggs?**
   - To be effective, verification programs must include testing. Pullet testing at 12 to 14 weeks, peak lay, molt peak and end-of-lay are a *minimum*. Testing of eggs should be reduced to a one-time negative test following a positive environmental isolation. The number of eggs to be tested should be determined by flock size; for example: 2,000 eggs from flocks over 50,000 hens; 1,000 eggs for 20,000-50,000 bird flocks; and 500 eggs for flocks consisting of fewer than 20,000 birds, etc. SE-positive eggs will require diversion until a single, subsequent egg test yields a negative result.

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?**
   - In the event of an environmentally-positive flock, the next pullets placed in the house should be vaccinated. A possible program would include two live vaccines at 2 and 4 weeks, followed by administration of a killed vaccine at 12 to 14 weeks. Pullet flocks should be culture-negative prior to placement into a layer house.

8. **Where vaccines have been used, is there a correlation between vaccine use and reduction of SE in eggs?**
   - Vaccines use will result in a reduction in environmental and egg positives when combined with a rodent program. However, vaccines alone cannot be relied upon to eliminate the SE problem in houses without an adequate rodent program, biosecurity, health monitoring, cleaning and disinfection, etc.

II. Shell Egg Packing and Egg Products Processing:

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?**
   - Diverted eggs will simply need to be paper tracked to the breaking facility and monitored by a USDA employee on a follow-back to the egg producer.

10. In the event eggs from an SE-positive flock are diverted to the production of liquid, frozen, or dried egg products, should the eggs be handled or processed differently? Indicate the cost associated with the described process.

- The eggs intended for further processing must be stored and shipped under acceptable time-temperature conditions. The egg shipments must be clearly labeled as coming from SE-positive flocks, along with the date of egg collection. USDA documentation, as noted in the answer to question (9) above, should be required to accompany each shipment of diverted eggs. In general, as long as the facility is using approved pasteurization procedures and finished product tracking systems, then no additional requirements are needed. The only exception to this would involve shell eggs from which the albumen is collected during breaking for the production of pasteurized *liquid egg white* products. Published research has demonstrated that the lethality of certain liquid egg white pasteurization processes against *Salmonella* spp. is not as great as that for other liquid egg products (whole egg, yolk, various blends, and dried egg whites). Additional research on this subject is needed, and is currently being conducted in a research program sponsored by the United Egg Association and designed in conjunction with the USDA, FSIS.

11. Do customer specifications exist that prohibit the processing of SE-positive eggs for egg products? Considering your production volume and available market for egg products, will this influence the price for SE-positive eggs?

- Yes, a relatively small number of our egg products customers have made it clear (either verbally or in written specifications) that they do not want their products to be made from eggs obtained from known SE-positive flocks. As customers become more aware of the mandatory diversion requirements included in the Action Plan, it is possible that the number of concerned customers will increase to some extent. Uncertainty about the impact of diversion exists because the true prevalence of SE-positive flocks in the U.S. is not known. This issue should be clarified when the results of the environmental testing portion of the NAHMS Layers '99 survey are made public. Ultimately, the price of (potentially) SE-positive eggs will be a product of supply and demand coupled with the actual number of egg products customers who do, in fact prohibit the use of these eggs in their products. If the initial wave of testing turns up large numbers of positive flocks and consequently, large volumes of eggs, there could be a significant decrease in value for these eggs to move through breaking channels, depending on how many of the larger egg products customers prohibit the use of these eggs in their products. If there is some economic loss to the affected producers, then corrective measures would likely be taken rapidly, suggesting that the long-term impact would be minimal since the supply of SE-positive eggs would ultimately diminish. If the SE-positive egg shipments were to be sealed and handled by the USDA in a manner similar to eggs from Avian Influenza-infected flocks, we would expect the eggs to be de-valued by at least $0.02 to 0.04 per dozen, depending on supply and demand. In summary, if a strong customer bias *against* potentially SE-positive eggs develops, then the economic impact on affected producers could be significant due to the added burden placed on the egg further processor to segregate these eggs during breaking and to preserve lot identity of the finished products with respect to the SE "status" of the eggs.

12. What is an estimated cost to implement the proposed components of a HACCP-based system, including adequate good manufacturing practices to minimize the growth of SE and prevent cross contamination, for each of the following processing operations (include only the new costs incurred such as record keeping, company verification on a continuing basis, and revised processing procedures for conformance):

a. Packer of shell eggs for the consumer?

- The answer to this question, along with parts (b) and (c) will depend on the exact program requirements in the finalized Action Plan. Maintaining an effective egg washing system (washwater temperature, pH, detergent concentration, etc.) will be critical for reducing risks of external-source microbial contamination. If the focus of the Egg Safety Action Plan is indeed SE, then it should be noted that the packer/processing stage can reduce the growth rate of SE (through refrigeration, for example), but not eliminate this risk. An in-line pH control system will cost approximately $4,000 per unit. Continuous recording devices may be necessary in certain operations (cost estimates not available at this time). The documentation required to monitor HACCP "Control Points" will average 3 person hours per day at $12 per hour, or approximately $13,140 per year.

b. In-shell pasteurization of eggs?

- The Michael Foods Egg Products Company is the exclusive licensee of a patented In-shell Egg Pasteurization process developed by researchers at the University of Missouri. The Company has been offering this product for sale in selected retail and foodservice markets since 1996. Michael Foods Inc. offers sub-licensing agreements for the use of this technology to interested egg processors at reasonable rates. Specific capital and incremental costs can be discussed with individual processors upon request and execution of appropriate non-disclosure agreements. A convenient means to summarize the costs involved in using this technology is to note the current typical selling price of Michael Foods' in-shell pasteurized eggs (size Large): $1.59 to $1.89/dozen at retail (one-dozen, tamper-evident packages). Because of the proven effectiveness of in-shell pasteurization in addressing *Salmonella* food safety concerns in shell eggs, this technology is compatible with the HACCP system of food safety assurance described in part (c) below for traditional pasteurized egg products.

c. HACCP in egg products establishments?

- The Michael Foods Egg products Company has already implemented HACCP systems in each of its egg further processing plants. Depending on program requirements, it is possible that our current HACCP plans may differ to an extent from the "regulatory" HACCP requirements under development by the USDA. Essential to the success of an egg further processing HACCP program will be the availability of a full-time HACCP Coordinator at each production facility (approximately $32,000 per year plus benefits). It is typically required that the HACCP Coordinator attend a certified HACCP training or refresher course once per year (approximately $1,500 to $2,000/year). The use of a third-party consultant to initially review company HACCP programs will cost approximately $1,000 per production facility. HACCP training costs will average $4,000 to 5,000 per year for a plant with 300 employees. A HACCP program software CD will average $700 per plant location. If experimental validation of the efficacy of a given Critical Control Point is required, then research costs (which will vary on a case-by-case basis) will have to be taken into account.

13. For the development of performance standards for the thermal processing of liquid eggs and other egg products, we are requesting information regarding the enumeration of SE in liquid eggs prior to pasteurization.

- Unfortunately, it very unlikely that this information exists. Current testing methods for salmonellae in foods typically focus on the presence or absence of the pathogen (*Salmonella* genus only, not specific serovars) in a given sample size. Experimental methods such as modified MPN procedures have been used on a limited research project basis to estimate the numbers of salmonellae (genus only) in poultry carcass rinse samples and various meat products. We are aware of no recent data on the numbers of *Salmonella* spp. or SE in raw liquid egg prior to pasteurization. The only published research on this topic (Garibaldi *et al.*, 1969) was conducted more than 30 years ago and

is not reflective of current egg industry conditions and practices. Additional survey research using a statistically-sound sample from across the U.S. will be necessary to obtain an accurate estimate of this important parameter.

14. What is the cost of maintaining refrigerated storage (maximum temperature 60 deg. F) for eggs received that are destined for grading and packaging or in-shell pasteurization, when time to processing will exceed 24 hours from time of lay?

- We currently do not have operations in which the energy cost for running the shell egg coolers is separated from the rest of the operation. If there are significant delays beyond approximately 48 hours, then loss-of-capacity issues may represent an added expense.

15. Are there any methods by which a packer/processor can determine how old eggs are when they are received?

- A logical approach would be to require each egg producer to label the eggs with a "produced on" date that would stay with the eggs until the point of processing.

16. When packing shell eggs for the consumer, will the use of only new primary packing materials increase your marketing costs? If so, what is the estimated cost? Is there a way to clean plastic containers to prevent cross contamination so they can be re-used?

- The only material that should be allowed to be re-used are plastic baskets. Used cartons, flats or cases should not be allowed for shipment of eggs to the consumer. If most packers have been following this practice, there should be no significant increase in packaging costs. Plastic baskets have to be either washed with high pressure or a machine specifically designed for this purpose.

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?

- As a part of national standards, ECI and other purchased eggs should have a "from tested flocks" label or other requirement for the protection of the purchaser.

III. Retail Distribution and SE Research:

18. Do the provisions in the 1999 Food Code which apply to shell eggs adequately protect at-risk consumers in retail establishments? If not, what other provisions are necessary for their protection?

- Yes, the provisions of the 1999 Food Code are science-based and do provide adequate information necessary to protect at-risk consumers. The larger challenge is for the FDA to identify and address barriers to more widespread adoption of all egg-relevant provisions of the Food Code to uniformly protect all U.S. consumers who enjoy eating eggs in restaurants and other foodservice settings. Another important need is for food safety certification of retail food managers and training of food handlers to be more widely adopted.

19. Re-washing of shell eggs is a wide-spread industry practice. Are there data or research to support it? If it is disallowed, what economic effect will it have on the shell egg industry?

- In order to address this question, it will be necessary to clarify which specific types of re-washing procedures are being considered.

20. What research on SE in eggs is already underway and what additional research is needed to assist producers, packer/processors, and retailers in proper practices?

- Based on the Egg Safety Action Plan issued December 10, 1999, research items 7.1 through 7.4 should definitely be explored, including an independent review of scientific data available from companies that develop and market vaccines, immunomodulators, competitive exclusion products, etc. Additional publicly-funded research on in-shell pasteurization is not necessary, since the science is now well understood and has been published in peer-reviewed scientific journals. Michael Foods has implemented the technology in commercial practice and understands the logistics and costs of operation. Research item 7.2.5 (pasteurization of egg products with additives) is being explored in the projects sponsored by the United Egg Association. Research items 7.4.1, 7.4.2, 7.4.3, 7.4.4 and 7.4.7 are important, practical and ambitious areas for further study. A thorough review of the available scientific literature (which is significant in volume) should be conducted to identify the relevant information gaps before proposing and funding new research projects. Studies conducted under realistic U.S. commercial production conditions should be given the greatest emphasis in the analysis of the scientific literature.

IV. Economics Information Requested by the FDA:

21. To what extent are you already engaging in the following practices:

a. Use of chicks from National Poultry Improvement Plan (NPIP) SE-monitored breeders?

- Yes, for all of our production flocks.

b. Rodent/pest control?

- Yes, for all of our production flocks.

c. Bio-security?

- Yes, for all of our production flocks.

d. Cleaning and disinfecting?

- Yes, but only for pullets (not for layers due to the expense compared to the short-term duration of the benefits).

e. Use of monitored water supply?

- Yes, for all of our production flocks.

f. Use of SE-controlled feed?

- Yes. Over several years of testing, we have never isolated SE from a feed or feed ingredient sample from our suppliers.

22. Testing for verification on the on-farm plan. We are interested in your answers to the following questions for both environmental testing and egg testing:

a. To what extent are you currently testing?

- Our current environmental program is: pullet test before moving to layer farm, peak , molt peak, end-of-lay. Since we are a primarily a breaking operation, we usually test only at the end of lay.

b. What is the sampling plan for the tests you conduct?

- In pullets test two swabs in one bag for each row plus one fan sample per house on routine, and double this number for "suspect" farms. Layers are tested by egg belts: 2 swabs in one bag per row on routine. If a problem is suspected the numbers will double. We prefer to have 8 to 10 samples per house for routine testing. At end of lay, we typically test both egg and manure (2 swabs in one bag per row).

c. What tests do you use? Do you test for the presence of Salmonella, SE, SE serotypes, etc.?

- We test for the presence of *Salmonella* by standard cultural enrichment procedures and identify *Salmonella* spp. by plate test from TSI slants using a minimum of 5 isolates from the BG and XLT4 agar plates. Serogroup "D" isolates are sent to the National Veterinary Services Laboratory for complete serotyping.

d. How much do these tests cost (include separately both lab costs and on-farm labor costs)?

- Lab costs are $7 to $10 per test. Egg cultures cost approximately $10 per test If 50 pools of 20 eggs are tested the cost is about $500 and at outside lab tests would cost approximately $1000. The labor cost to collect the samples must be added to the above figures.

23. How much would it cost you to implement each of the proposed components of the risk reduction plan? (Note: The costs you estimate should be the new costs you will bear in excess of what you are already spending on risk reduction.)

- We currently estimate that lab costs account for $7,500 per year per 1 million birds. This was and is a direct increase since we have voluntarily made the choice to test.

24. What are the current market prices or costs you pay or get for the following:

a. Chicks from NPIP SE-monitored breeders versus chicks from noncertified sources?

- NPIP chicks cost approximately $0.50 each and are the only chicks we purchase.

b. Grade A/B eggs versus breaker eggs?

- This information is updated regularly and is readily available from the Egg Clearinghouse (ECI) and the Urner-Barry organization.

c. Dry cleaning versus dry, wet disinfecting poultry houses.

- If dry cleaning costs $1000 per house, then wet cleaning will cost 3x to 5x more.

d. SE-controlled feed versus noncontrolled feed?

- No comparisons are available as you cannot test every sample of feed to make sure it is negative. The most reliable means to assure an SE-free feed supply would be to heat treat all feed which costs $20 per ton, or formaldehyde treat the feed which costs only $2 to $4 per ton. It should be noted however that poultry feed does not appear to be a major vector for SE. We have never isolated the serotype SE from a feed ingredient.

25. Can you get replacement chicks/pullets at a time different from your usual lay cycle? If so, what price premium, if any, would you have to pay to get these birds?

- Yes, replacements are available, however most hatcheries establish breeder schedules 1 to 2 years in advance. Proper scheduling is essential to maximizing the efficiency of egg production.

26. Do you currently vaccinate your layers for SE? At what time(s)? What does it cost?

- Pullets are vaccinated if the layer house they are to be placed in is environmentally SE-positive or if the complex is positive. SE is not a single house problem but is a complex problem. It is nearly impossible to clean up a complex without having both a good rodent control program and a vaccination program for all birds in the complex. This does not mean that all birds should be routinely vaccinated. The houses need to be tested first and a program established. A single killed vaccination will cost about $0.10 per bird. In the case of a more severe problem, the suggestion is to use two live vaccines at 2 and 4 weeks and the killed at 13 weeks with a cost of about $0.115 to $0.12 per bird. Live vaccines are available and appear promising, but the track record has not been proven sufficiently over time. Live vaccines would be more economical and would cost about $0.015 to $0.02 per bird. We currently have no information as to the long-term benefits of the live vaccine approach, especially under challenging conditions.

27. Before processing or shipping for processing, are your eggs stored on the farm in an environment that is not temperature controlled? For how long? If so, what temperatures are the eggs stored at and how long do they stay in storage?

- The eggs are stored at the farm at 60 to 65 degrees F. These eggs are used only for breaking and further processing. Storage is usually only 1 to 3 days total, with part of that time being spent at the processing plant.

28. When you ship your eggs from the farm to the processor/ packer, do you reuse packing materials? What steps are taken to minimize any bio-security hazards that may arise from such a practice? How much would it cost to sanitize or use new packing materials for each egg shipment?

- Yes. Washing and sanitizing costs an average of $0.35 per 100 flats, using automated flat washing equipment.

V. Requested Background information on the Michael Foods Egg Products Company:

a. In what State(s) do you currently operate?
- NE, MN, IA, NJ, and PA

b. How many layer houses do you have?
- 60 to 70 layer houses

c. What style of house(s) is typical for your operation?
- Stacked deck with manure belts

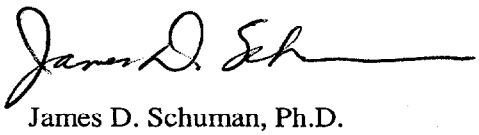
d. What is the average number of layers in each house?
- 80,000 to 130,000 per house

e. Is yours an in-line or an off-line operation?
- Primarily an in-line operation

f. Do you currently molt your layers? If molting is used, when is it used?
- Yes, typically at 65 to 70 weeks.

We respectfully submit these comments for your consideration and appreciate the opportunity to provide input on the development of the Egg Safety Action Plan.

Sincerely,



James D. Schuman, Ph.D.
Director of Food Safety

cc: Bill Goucher
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