TO: FDA, Docket No. 00N-0504
FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

FROM: E.L. Knicely, President
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SUBJECT: FDA, Docket No. 00N-0504

The following comments are submitted on behalf of the National Egg Regulatory Officials (NERO). The membership of NERO consists of 30 State Department of Agriculture officials involved in shell egg and egg product regulations and programs. Examples of areas regulated by members include refrigeration of shell eggs, enforcement of quality standards, egg container labeling, record keeping for handlers of shell eggs, sanitation standards for shell egg processing plants and third party monitoring of Egg Quality Assurance Plans. Many members have cooperative agreements with USDA/AMS and USDA/FSIS for inspections conducted under the Egg Products Inspection Act and for the voluntary grading of shell eggs. The primary goal of the NERO organization is to promote uniform state, local and federal regulations concerning shell eggs and egg products that provide effective consumer protection in the areas of egg safety, quality and labeling.

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 overall Egg Safety Action Plan covers many of the areas related to the problem of SE in eggs and measures for reducing this hazard. Based on our regulatory experience, there are several areas where we believe additional measures or different regulatory strategies would be more effective. There are also several areas where gaps exist.

   Our organization foresees regulatory enforcement problems with the two strategy approach. Producers shift back and forth between sales to packers and further processors. Many eggs are sold through brokers rather than directly to packers or further processors. For these reasons, we think a single set of requirements for production would provide for more uniform enforcement and ensure that all eggs in the table egg market are produced under the same standards.

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With the exception of egg products and participants in AMS' voluntary grading program, the egg industry has not been subject to continuous inspection. Continuous inspection and specific regulations provide the regulated industry with guidelines for complying. The components in the Egg Safety Action Plan are for the most part very general statements of areas that need to be addressed in a HACCP like plan. If the regulations will be written with general components with performance measurements used to determine compliance, the industry will have to be provided with guidance by other methods (specific guidance documents, training sessions, etc.)

Production: Although The Egg Safety Action Plan outline of components for production (Page 22 from Report dated 12/10/99) covers the main areas necessary to reduce salmonella enteritidis, we would recommend the following changes:

1. SE environmental testing is presented as a component. Testing is a separate issue and should be evaluated for scientific basis as a method of determining if the components of the plan are working. If environmental testing will be conducted during the life of the flock, scientific data supporting the probability of positive eggs should be used to require diversion of the eggs from the table egg market.

2. Potable water supply should be added as a component.

3. There are several areas that have not been considered as part of production, however, these activities take place on the farm. Temperature abuse can occur at the farm level and needs to be addressed. Eggs should be gathered frequently to avoid time and temperature abuse. Additionally, eggs should be held at 55°F ambient temperature, if they are not to be shipped to the packer/processor within 24 hours. Our recommendation of 55°F is based on the recommended wash water temperature of a minimum of 90°F. If the wash water is more than 40°F warmer than the egg temperature, there is an increase in thermal cracks during the washing of shell eggs. 55°F would be the lowest temperature that could be maintained to slow the breakdown of the albumen protective properties and reduce growth of SE without creating additional cracks during processing. Another area of concern on farm is the washing and soaking of dirty eggs. Many packers/processors discount producers for excessive dirty eggs. Some producers will pull the dirty eggs to clean them prior to shipment to the packer/processor. The producers usually use small immersion washers to clean these eggs. This soaking of eggs in water that contains large amounts of manure results in high levels of contamination. The use of immersion washers or any type of soaking of dirty eggs needs to be prohibited at all levels. If on farm washing is done, the guidelines outlined for packers should be followed.

Packing/Processing of shell eggs: The components listed in the Egg Safety Action Plan would comprehensively cover the problems of SE in eggs and measures for reducing this hazard. The components that are listed cover all aspects, however, they are not very specific as to exactly what would be required. We recognize that regulations cannot address every detail but believe additional guidance should be offered so packers/processors understand what will be expected to comply with the regulations. The following are specific recommendations we would make based on available research, USDA/AMS' voluntary grading program and field experience.

Premises: The outside premises shall be clean and free of trash, debris, and unused equipment and materials. All unpaved areas surrounding the plant shall be free of tall grass, weeds and standing water due to improper drainage. The presence of any harborage, attractant, and/or breeding areas for insects, rodents, or birds is not permitted. A satisfactory system for the collection and removal of refuse and waste must be provided.

Buildings: Processing areas, egg storage areas, and storage areas for materials that will contact finished product - sound structure, secure openings (ex. Screened windows), well maintained, surfaces easily cleanable. The overall sanitation shall be sufficient to minimize contamination of product and packing materials.

Rodent/pest control: A documented rodent, pest and insect control program must be established. At a minimum, the documented program must include the use of indexing to verify program effectiveness. Records documenting results of inspections, showing locations of traps, and indicating that pesticides are used according to manufacturer's instructions must be maintained.

Chemical compounds: All cleaning and sanitizing compounds, insecticides, rodenticides, egg oils and inks, and any other chemical compound used in the plant must be approved for use in food processing and be used according to the manufacturer's instructions. All products must be labeled and separated from edible product and processing area. Product data sheets must be provided.

Toilet and hand washing facilities: Sufficient toilet and hand washing facilities are to be provided and conveniently located and maintained in a clean and sanitary condition. Hand washing facilities are to have hot and cold running water, soap, and sanitary hand drying methods. Separate facilities should be provided to prevent cross contamination in operations that have production and processing facilities in the same location. Signs should be posted directing employees to wash their hands before returning to work.

Health and cleanliness of employees: Employees must wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or otherwise soiling their hands. Employees in direct contact with shell eggs must wear clothing that prevents cross contamination of product. Only employees free from evidence of any communicable disease, open sores or other similar symptoms may work in processing areas. Employees working in production areas should not be allowed to work in processing areas without preventative measures in place to prevent cross contamination.

Washing, grading and packing operations and equipment: All washing, drying, oiling, grading, and packaging equipment must be maintained in a clean and sanitary condition during processing operations and thoroughly cleaned at the end of each processing day.

Water potability: Shell egg processing plants must test and provide documentation that the plant's water supply used in the egg washing operation is potable or that it contains less than one colony forming unit (CFU) of coliform bacteria per 100 milliliters of water. Additionally, the water supply is to be analyzed for iron content to assure that less than 2 parts per million is maintained. Water samples are to be analyzed at least every six months from wells and yearly from municipal sources. There should be no cross connections with non potable water supplies.

Washing and sanitizing: No immersible washers. All washing equipment must be sanitarily designed and constructed to facilitate cleaning. Washers, nozzles and brushes must be maintained in a clean and sanitary condition. Detergents that are approved for washing of shell eggs must be used. Wash water should be a minimum of 90°F and at least 20°F warmer than the internal temperature of the eggs to be washed. A pH of 10 or higher is to be continuously maintained in the wash water. Wastewater from the washing operation is to be discharged directly to a drain. Washed eggs are to be rinsed with water with a temperature that is equal to or greater than the wash water temperature and contains an approved sanitizer with a concentration of no less than 50ppm nor more than 200 ppm of chlorine or its equivalent. The washing requirements described would only fit the larger operations. Most of the small producer/packers do not have any type of washer. Guidelines need to be developed specifically for the small producer/packer. Research may also provide alternative methods of washing shell eggs that are effective in reducing bacterial load. Prior to use, all methods of washing and sanitizing should be evaluated and approved by the appropriate agency for effectiveness in preventing contamination and reducing bacterial load.

Drying: Washed eggs must be dry before packaging. The drying process and

equipment must be designed, constructed and maintained in a sanitary condition to prevent contamination of shell eggs.

Oiling: If oiling equipment is used, it must be kept clean and sanitary and the oil must be applied in a manner to avoid contamination of the eggs. The oil must be approved for this use and be free of off odors and contamination.

Packing and packaging: Primary containers must be new and free from dust, dirt, mold or any other contamination. Reusable packaging materials such as plastic filler flats must be cleaned before reusing. Shipping containers must be clean. Reusable shipping containers (wire or plastic baskets, bossies) must be clean before use. Packing and packaging operations must be conducted in a sanitary manner that avoids contamination of the eggs.

Refrigeration: Prior to washing, grading and packing, eggs must be kept at 55°F ambient temperature. (55°F reduces breakdown of albumen protective properties without cooling the egg enough to create thermal checks). After washing, grading and packaging eggs should be moved immediately into a cooler that maintains an ambient temperature of 45°F or less. Procedures must be in place to prevent cross contamination of processed shell eggs - need to address the storage of unprocessed eggs, inedible eggs, etc. Coolers must be maintained in a sanitary method (clean, no mold, etc.). The current FSIS policy on enforcement of the 45°F refrigeration requirement after processing should be revised. Currently, coolers can be between 45°F and 60°F during 3 out of 5 AMS conducted surveillance visits before it is reported as a violation to FSIS. Additionally, surveillance inspectors are not checking temperatures on follow up visits. We believe enforcement should be more proactive to encourage greater compliance.

There should be documentation of monitoring for compliance with plan and verification of effectiveness. There should be a national approval number issued for cases and cartons for use in verifying that companies are complying with the standards for production and packing. In addition to records verifying compliance with components of plan, records should be kept to assist in trace back situations.

Grading Issues:

Grade B issues: The practice of repackaging and older eggs in the marketplace has been an area of concern for consumers, industry and regulators. Research has indicated the breakdown in albumen quality caused by time and temperature allows bacteria to penetrate the yolk and multiply. USDA standards for egg quality include a tolerance for eggs that have albumen breakdown. They are classified as B quality based on the

thinning of the albumen. The current USDA standards allows 13% B quality at origin and 18% B quality at destination. These standards have not been revised since 1984. As changes in technology have reduced the amount of time between production and delivery to the consumer, the need for 13% and 18% tolerances for B interior quality eggs is no longer valid. A reduction in the tolerance would be effective in removing older and/or repackaged eggs from the market. Additionally, the tolerance for eggs labeled as Grade B should be changed. B exterior quality eggs are not a food safety risk, however, all eggs in a Grade B labeled pack can be old with significant albumen breakdown. B interior quality should not be sold in any of the consumer grades. A new tolerance would not incur any additional expenses for enforcement as the majority (34 states) of the States are actively enforcing USDA tolerances as part of their State egg law. (See Attachment A) The Egg Products Inspection Act prohibits the States from adopting tolerances or standards that are different from USDA's. A change in the USDA standards would automatically change the standards used in the enforcement of State egg laws. Another method of enforcement would be to revise the requirements of the Egg Products Inspection Act. AMS representatives currently check all consumer labeled product to ensure it does not exceed the tolerances established for Grade B even if the product is labeled Grade A or Grade AA. This requirement was established to prevent the sale of restricted (dirty, cracked, inedible) eggs to consumers. AMS representatives could verify that the product met Grade A or Grade AA standards in the same amount of time during the quarterly surveillance visits. This would prevent the sale of older eggs without incurring any additional inspection costs.

Restricted eggs issues: Research indicates cracked eggs are more likely to be contaminated. For this reason, the sale of restricted eggs at packer locations should be prohibited. The tolerance for cracked eggs should be evaluated to determine if a reduction in the number of cracked eggs allowed in consumer grades would improve egg safety.

Current production/expiration dates: 30 days current production is too long. Humphries research indicates that SE growth increases after 21 days at 60°F. With 30 days being current production, plus another 30 days of expiration date, the eggs would be 60 days old. Meaningful expiration dates would be beneficial to consumers, distributors, retailers and food service operations. An expiration date based on the date of lay would be the most meaningful, however, determining the accuracy of the expiration date would be impossible. The current interpretation of expiration dates is how long the eggs will still meet the tolerances for the labeled grade. The changes we recommend for the quality standards would also be effective in making the expiration date more meaningful. Current practice is to include expiration dates on consumer cartons but not on eggs packed for food service. A requirement for expiration dates on all eggs would assist distributors, retailers, and food service operations in rotating stock and disposing of old eggs.

In shell pasteurization facilities: The Egg Safety Action Plan does not specifically address in shell pasteurization facilities. This type of facility is new and to our knowledge there are only two operating currently. There exists a possibility for growth in the number of these facilities and we would recommend addressing requirements for these facilities in the Egg Safety Action Plan. The general areas that should be addressed are:

Controls for categories of eggs that can be pasteurized (Se positive, dirty, inedible, etc.)
Refrigeration prior to and post pasteurization
Plant and equipment sanitation
Pest control
Control of the pasteurization process

There should be records documenting compliance with plan and verification of effectiveness.

Hard Cooked Operations: The Egg Safety Action Plan does not specifically address hard cooked operations. We would recommend addressing requirements for these facilities in the Egg Safety Action Plan. The general areas that should be addressed are:

Controls for categories of eggs that can be hard cooked (Se positive, dirty, inedible, etc.)
Refrigeration prior to and post hard cooking
Plant and equipment sanitation
Pest control
Control of the cooking process

Egg Products:

The Egg Safety Action Plan covers several of the areas necessary for egg safety. In addition to those covered we would recommend adding:

Controls for categories of eggs that can be pasteurized (Se positive, dirty, inedible, etc.)
Refrigeration prior to and post pasteurization
Control of the pasteurization process

There should be records documenting compliance with plan and verification of effectiveness.

As FSIS implements HACCP in Egg Products, we would strongly recommend continuous inspection be continued. Comments have been made during the public meetings and in response to other dockets indicating a disproportionate share of FSIS' inspection force has been dedicated to egg products when egg products are not a risk. Although we agree that the pasteurization process reduces the risk of salmonella enteritidis in egg products, we believe some of the risk reduction can be attributed to careful monitoring by FSIS of facilities that are producing egg products to ensure compliance. As HACCP is implemented, FSIS should review each egg products facility to determine the level of compliance. This compliance record should be used to assess the level of inspection needed.

Transportation:

Transport units should be maintained in a sanitary condition and the unit should maintain a 45°F or less ambient temperature. The current enforcement procedures of FSIS should be reviewed. Currently, AMS surveillance inspectors conduct refrigeration checks during quarterly visits at egg packing facilities. These facilities often have transport vehicles present. At times, these transport vehicles are even used for storage. AMS inspectors are not authorized to monitor the temperature of these vehicles during the surveillance visit. To effectively enforce this component of the Egg Safety Action Plan and efficiently use existing resources, these surveillance inspectors should monitor the temperature of the transport vehicles.

Egg Handlers: There is a segment of the farm to table continuum that is not addressed in the Egg Safety Action Plan. Restricted eggs, nest run eggs, out of date graded eggs, damaged eggs and hatchery culls are picked up by egg handlers. Disposition of these eggs should be verified through inspection of records. If the records do not indicate the eggs were sold to an egg products plant, an inspection should be conducted at the buyer's location to determine the disposition of these eggs. Records to assist in a trace back should be maintained.

Wholesale:

The Egg Safety Action Plan does not address requirements at the wholesale level. At a minimum these facilities should ensure eggs are delivered in a unit that is sanitary and is maintaining a 45°F ambient temperature. Eggs should be moved immediately into a unit that is maintaining a 45°F ambient temperature. Records should be kept to assist in trace back situations. Procedures should be in place to ensure eggs are rotated.

There should be records documenting compliance with plan and verification of effectiveness.

Refrigeration at this level is currently enforced by both FSIS inspectors and State inspectors. FSIS has not explored the possibility of using the inspections conducted by the State inspectors. We would recommend that FSIS enter into agreements with States to conduct the temperature and refrigeration labeling checks being conducted by FSIS inspectors. In many locations, the FSIS inspector is making a trip to a facility just to check temperature and labeling. State inspectors not only check temperature and refrigeration labeling but also conduct a complete inspection of the eggs at the facility including other labeling requirements, invoice requirements, quality requirements, etc. Using the State inspectors to monitor compliance with FSIS' requirements for refrigeration and refrigeration labeling would appear to be a more effective use of resources.

Retail and Food Service:

The Egg Safety Action Plan addresses retail and food service by reference to the Food Code. At a minimum it should be required that these facilities ensure eggs are delivered in a unit that is sanitary and is maintaining a 45°F ambient temperature. Eggs should be moved immediately into a unit that is maintaining a 45°F ambient temperature. Egg pooling in high risk situations should be prohibited by federal law (similar to the FDA requirement for refrigeration). Food service should be required to have a certified safe food handler on each premise. There should be records documenting compliance with plan and verification of effectiveness.

Develop and distribute materials for the egg, retail, and foodservice industries using partnerships: The Egg Safety Action Plan outlines materials for egg producers and processors/packers, retailers and food service workers, etc. and recommends using egg industry, retail, and institutional organizations to distribute the materials. We would strongly encourage the agencies to also use State Departments of Agriculture and Health and the Cooperative Extension Service to assist in developing and distributing these materials. These organizations have extensive knowledge and numerous contacts with the target audiences.

2. What are the costs and benefits of implementing each risk reduction component in the Action Plan?

Our organization has a limited amount of information on the specific costs of changing industry practices, however, we do have some information on the extent certain practices are used. We also have information concerning the benefits of eliminating or changing certain practices.

The majority of eggs are delivered and processed within one to five days of lay. These eggs are usually Grade AA interior quality with the albumen having significant mechanical and chemical barriers to contamination. A small percentage (Based on our observations of State inspectors, we would estimate this would be approximately 5% of all eggs packaged for the table egg market) of eggs are processed after this interior quality breaks down. There are several reasons for not packaging all eggs immediately (low market demand, stock piling in anticipation of peak demand, store returns, reworking of eggs not sold, etc.). Frequently, these eggs are blended with fresh eggs in order to meet the tolerances allowed for B interior quality in AA and A labeled packs. The most effective method of removing these old eggs from the table market would be to reduce the tolerance for B interior quality. From September 20, 1999 to April 12, 2000, Maryland inspectors candled 1,843 lots of eggs (Lots are based on different size, pack date and/or packer) at destination locations (retailers, food service and wholesalers). These lots represented 193,883 dozens of shell eggs offered for sale in Maryland retail, food service and/or wholesale locations. Sixty percent or 1,123 of the lots inspected contained B interior quality eggs. Of the 1,123 lots with B interior quality eggs, 22 contained more than 18% B interior quality eggs. These eggs were removed from sale as they did not meet the USDA destination tolerances for the labeled grade. 31 of the lots contained from 11 to 18% B interior quality, 103 of the lots contained 6 to 10% B interior quality and 967 of the lots contained 1 to 5% B interior quality. These lots remained on sale as they met the USDA destination tolerances for the labeled grade. The information from Maryland's inspection records would not be conclusive as to the extent of the sale of B interior eggs in the United States. Maryland has a very active Egg Inspection program that conducts routine inspections to verify quality and handling of shell eggs. Additionally, Maryland does not allow the sale of eggs labeled as Grade B to consumers. For these reasons, the number of B interior eggs encountered in Maryland would probably be less than in some areas of the country. The actual costs to the industry would be the difference between selling the B interior quality eggs as AA or A and selling them to hard cooked or further processing operations. The primary benefit of implementing this change would be removing eggs with the potential for significant SE growth from the table market.

Our organization has some information that could be utilized to evaluate the impact of reducing the tolerance for cracks and eliminating the sale of cracks to consumers at the farm. The current tolerance allowed for cracks in a Grade A labeled pack is 7%. From September 20, 1999 to April 12, 2000, Maryland inspectors candled 1,843 lots of eggs (Lots are based on different size, pack date and/or packer) at destination locations. These lots represented 193,883 dozens of shell eggs offered for sale in Maryland retail, food service and/or wholesale locations. Of these lots 10 or .06% had 0% cracks, 100 or 5.5% has 1% cracks, 212 or 11.5% had 2% cracks, 249 or 13.6% had 3% cracks, 376 or 20.4% had 4% cracks, 265 or 14.4% had 5% cracks, 274 or 14.9% had 6% cracks, 201 or 10.9%

had 7% cracks and 156 or 8.5% had more than 7% cracks. According to a survey conducted by NERO, 10 states have already prohibited the sale of cracks at the farm level (See Attachment A). As the producers in these states are already prohibited from selling cracks, this would reduce the impact of a national regulation prohibiting this practice.

Twenty four states already have restrictions or have prohibited repacking at the retail level. This would significantly reduce the impact of any restrictions implemented at the federal level.

There are various types of repacking at the packer level. The total number of eggs that are repackaged is very small. A small percentage of the eggs that are repacked are store returns that are put back on the line. Another small percentage of eggs that are repacked are those that are either in the wrong packaging for the buyer or have neared an expiration date without being shipped. The majority of the eggs that are repacked are those that were retained by an inspector under the surveillance program or by the grader under the voluntary grading program. These eggs are repacked to remove the under grades that initiated the retention. Prohibiting the repackaging of store returns would not have a significant impact on the industry and would benefit consumers by preventing eggs that have been time and possibly temperature abused from returning to the table egg market. The other types of repacking should be evaluated based on research concerning the impact of rewashing and the age of the eggs.

Based on USDA/AMS records there are 687 packers (Grading Stations and producer/packers with more than 3,000 chickens) in the United States. Of these packers, 349 are monitored for compliance with USDA/AMS' sanitation requirements or state sanitation requirements either through the voluntary grading program or State regulations. (See Attachment A) The remaining 338 packers are not subject to compliance monitoring, however, many of these requirements are commonly accepted industry practice so many of the unmonitored would be using the same practices. The benefits of implementing the components outlined in the Egg Safety Action are obvious. Cross contamination or increase in SE growth can be prevented by implementing these sanitation requirements.

Ideally, implementation of production and packing/processing requirements would be at all levels with no exemptions. Realistically, the amount of funding necessary to monitor all producers and packers would be enormous. The current exemption in the EPIA is for producer/packers with less than 3,000 chickens. There is very little data available from the States on the number of producers with less than 3,000, however, what is available indicates there are very few producers in the 500 to 3,000 chicken category. There are a significant number in the under 500 chicken category. Maryland is one of the few states that requires registration of all producers. Based on Maryland Department of Agriculture records, there are 154 registered producers in the under 500 chicken category located in

Maryland. Maryland has no producer/packers in the 500 to 3,000 chicken range. Information from other states indicates these numbers are similar to what is found in other areas of the United States. This data would indicate there are thousands of producer/packers with less than 500 chickens located in the United States and a very limited number of producer/packers with 500 to 3,000 chickens. According to a recent NERO survey (See Attachment A) 24 states already regulate producer/packers with less than 3,000 chickens in some manner. There are several possibilities for the development of requirements for this group. The current exemption could be changed from producer/packers with less than 3,000 chickens to producer/packers with less than 500 chickens. Another option would be to exempt those with less than 3,000 that only sell at the production site. Anyone selling to retailers, food service or at farmers markets, etc. would be required to comply with all requirements of the Egg Safety Action Plan. Regardless of the exemption level, all exempt producer/packers should receive training in egg safety. Education would be the most cost effective method to improve egg safety with small producers. Guidelines that fit small operations should be developed. The Cooperative Extension Service, Universities and State Departments of Agriculture should be used to disseminate this information.

3. What training should be associated with respect to each component of the Action Plan?

Training should be conducted so that the regulated industry and the inspection force are trained together. This assists all interested parties in understanding the necessary actions to ensure egg safety and avoids potential problems with interpreting what is required. Industry and government have the opportunity to learn from each other.

All segments of the Farm to Wholesale continuum: Basic HACCP training, including specifics on the methods for monitoring and record keeping. Training will be particularly important to those segments of the industry that have not been subject to regulations regarding egg safety.

Production: Specific training in how to develop and implement a plan for their facility. Training should include rodent control and indexing, cleaning and disinfecting houses, methods of sampling (environmental drag swabs, etc.)

Packing/Processing: Specific training in maintaining plant sanitation, processing requirements.

Inspection Force: In addition to classroom training, all inspection personnel should receive on the job inspection training. A knowledge of how the industry works is essential to an effective program.

Training sources already available: The National Egg Quality School provides an intensive 3 day course that covers many of the areas the Egg Safety Action Plan addresses. FDA has provided excellent HACCP training to the National Egg Regulatory Officials at their annual meeting. USDA/AMS and State Egg Programs have many experienced inspectors that are in packing plants on a regular basis. These employees could be utilized to train additional personnel. State Animal Health programs and USDA/APHIS have many employees with expertise in the production area. Many of the Universities have experienced personnel and have already developed useful training programs.

4. Production: Are the following appropriate and adequate components for a nationwide SE reduction program: biosecurity, Se negative feed, chicks from SE monitored breeders, flock health monitoring program, cleaning and disinfection of houses, rodent/pest control, monitored water supply?

   Many of our members have been actively involved in the development and monitoring of Egg Quality Assurance Programs. Based on this experience and the research that is currently available we strongly support the listed components as an effective nationwide SE reduction program.

5. Production: How effective do you think each component would be? Which components do you think will provide the most risk reduction?

   Although we believe each component is necessary to maintain an effective program, the control of rodents and pests will provide the most risk reduction. If this is not accomplished, the other components will not be as effective.

6. Production: Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working and that the consumer is protected from consuming SE contaminated eggs?

   Environmental testing is the best method currently available for verifying that houses are SE negative.

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?

   The plan for that facility should be reviewed to attempt to identify the source of the SE contamination and determine areas of plan compliance needing improvement. Appropriate steps should be taken to improve the plan to reduce the risk of SE.

Additional testing to verify corrections should be taken.

8. 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?

   Based on our experience in diversion from the table egg market, the only method of ensuring pasteurization is shipping under seal. An inspector would be present when the eggs are placed on the truck to verify the number of eggs shipped. The eggs would be received by an inspector to verify the number received and ensure they are not resold into the table egg market. We feel this is the only method to ensure pasteurization, as many further processors resell nest run eggs into the table egg market.

   The use of hard cooked operations as an option for diversion of eggs from SE positive flocks should be included in the evaluation of this section. Hard cooked eggs have not been mentioned specifically in the action plan or egg quality assurance plans and we feel this is a gap.

9. What is the cost of maintaining refrigeration storage (maximum temperature 60°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?

   Our organization recommends 55°F. The most significant cost in this area will be for the producer who has no refrigerated storage at all and will be required to install a cooler.

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

    Candling of eggs and/or the use of a Haugh unit micrometer can be used to determine the breakdown of eggs associated with time and temperature. Based on these observations, the packer/processor can estimate how old the eggs are.

11. 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 reused?

    Although the use of only new primary packing materials will increase the marketing costs, our organization believes the benefits would justify the increased costs. Currently, the reuse of primary packing materials is not restricted at the federal level. USDA/AMS requires the use of good, used fiber filler flats for product bearing the USDA grade shield. Our organization is not aware of any other federal restrictions. The reuse of cartons is for the most part limited to very small producer/packers. In the larger operations, the used

primary packing materials are the primary packing materials that the nest run eggs are received on. Washed and sanitized eggs will be placed into previously used primary packing materials that had contained unwashed and unsanitized eggs. The possibility of cross contamination is significant and the benefits of washing and sanitizing are negated. The reuse of primary containers is a very small percentage of the total of primary containers used.

Plastic containers can be washed and sanitized making them acceptable for reuse. Metal bossies should also be cleaned. Frequently, plastic shipping containers are reused by retailers as trash cans, storage for other materials, etc. When they are finally returned to the packer/processors they can be a source of contamination.

There are plastic flat washers that can be used to clean plastic reusable primary containers. These are primarily used for transporting nest run eggs, not consumer product. Occasionally, plastic primary containers are used for consumer product.

12. 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?

    The proposed components cover the necessary areas but are very general. For these components to be appropriate and adequate to reduce the risk associated with SE, the guidelines we have outlined for Question 1 should be required.

13. Do the provisions in the 1999 Food Code which apply to shell eggs adequately protect at risk consumers in retail establishments?

    The provisions in the 1999 Food Code would provide for adequate protection if they were enacted nationwide. We would recommend FDA adopting those requirements relevant to shell egg safety in a manner similar to the proposed refrigeration at retail regulation. Many states have problems adopting all provisions of the Food Code within a reasonable time frame. We believe the importance of using pasteurized product for at risk populations would justify a federal mandate. Members of our organization conduct inspections at the food service level. During these inspections we have observed workers with little knowledge of safe handling procedures. We would recommend that each establishment have at least one person that has completed a Safe Food Handler certification course.

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

We have made recommendations concerning research in another section of this document. The economic effect would not be significant. There is a very small profit margin in the egg industry, but if a regulation prohibits everyone from certain practices the impact is reduced. The percentage of dirty eggs that are recycled and eventually are clean enough to be put into consumer packs is very small. If the eggs are not readily cleanable, they will usually end up breaking from the numerous trips through the washer, etc. Eggs that need to be reworked for various reasons (retained by inspectors, not sold to expected customer, wrong labeling, etc.), could be recandled and/or repackaged without going through the wash cycle.

15. 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?

Rewashing of eggs and recycling dirties through washer: Available research needs to be evaluated and additional research conducted to determine the cross contamination effect and albumen breakdown created by rewashing.

Research should be conducted to determine if eggs from a positive flock diverted to the production of liquid, frozen, or dried egg products need to be handled or processed differently to ensure the pasteurization process is adequate.

Research Interior quality

Additional research should be conducted concerning the correlation between environmentally positive flocks and the number of positive eggs. This research should also address determining if there are risk factors that increase the number of positive eggs.

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?

Our organization has little data on the actual store time and temperatures at the farm level. We have observed nest run eggs received at packing/processing plants that based on the interior quality have been stored somewhere for either a long period of time or a shorter period of time unrefrigerated. We would estimate that 5% of the eggs received have been stored under these conditions.

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?

It is common practice in the industry to reuse packing materials from the farm. Many producers are now using plastic flats for this purpose. The flats are returned to the farm for reuse. We have no information on the cost of sanitizing or using new packing materials, however, there are washers available for sanitizing the plastic flats.

Use of State personnel for enforcement of the plan: Various methods for implementing a national Egg Safety Action Plan have generated considerable discussion about the use of contracts or agreements with States to provide inspections and enforcement. Some of the comments have indicated that States cannot provide uniform enforcement. We believe this opinion is based on the differences that arise in State programs, not in the ability of State personnel to conduct uniform enforcement of a national program. In the absence of federal regulations states have developed programs for egg safety based on regional risks, industry practices, funding and legislative support. The impact of these factors on the development of these programs at the state level has created variations in programs and enforcement. A mandatory program with funding provided at the federal level will eliminate these variations. USDA and FDA have successfully used contracts and/or cooperative agreements with states for many federal programs - examples include seafood HACCP, Animal disease monitoring for APHIS, Poultry and Egg voluntary grading program and surveillance conducted for the Egg Products Inspection Act. For the most part these contracts are entered into to reduce duplication with State inspections and/or regulations, provide inspection in the most cost effective method and best use the specific knowledge and relationships the States have with the industry within their state.

FDA has utilized contracts with States to implement seafood HACCP. To ensure uniformity, FDA requires the inspectors be trained and pass an examination. Additional training is offered to update inspectors on changes and/or as a refreshed. Periodic audits are conducted on an unannounced basis to ensure the State is performing according to the agreement.

The majority of the inspections for surveillance under the EPIA are conducted by state employees. These employees are licensed by USDA. To obtain a license, the employee must be tested by a USDA representative after training. All inspectors are issued and required to follow USDA inspection guidelines. This program has been very successful. The state employees are highly qualified and their use in this program is very cost effective. The program has been uniformly enforced throughout the country. There are many State employees with years of experience in the enforcement of regulations related to egg safety. This expertise would be very valuable to the federal government as they enter a new regulatory area. For these reasons, we believe the use of contracts with states would be extremely effective.

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ALABAMA	YES	9		2		NO		YES	NO	YES	R	R
ALASKA	No	0	YES	4	YES	NO	NO	NO	NO	A	YES	R
ARIZONA	YES	1	YES	2	STATE TRUST	YES	NO	YES	NO	A	R	YES
ARKANSAS	YES	5	YES	3	STATE TRUST	YES	YES	NO	NO	A	NO	YES
CALIFORNIA	YES	47		18	NO	NO	NO	YES	NO	A	NO	R
COLORADO	YES	5	NO	3	NO	NO	NO	NO	NO	A	YES	YES
CONNECTICUT	YES	3	NO	4	NO	YES, NOT USDA	YES	YES	YES	NO	YES	NO
DELAWARE	NO	0	NO	1	FEDERAL TRUST	NO	NO	YES	YES	A	R	NO
FLORIDA	YES	16		10	STATE TRUST	YES	YES	YES	NO	YES	R	NO
GEORGIA	YES	12	YES	9	STATE TRUST	NO	NO	YES	NO	YES	NO	YES
HAWAII	YES	13	YES	1	STATE TRUST	NO	NO	YES	YES	A	YES	R
IDAHO		3		1								
ILLINOIS	YES	14	NO	2	FEDERAL TRUST	YES	YES	NO	NO	A	YES	YES
INDIANA	YES	27	NO	3	NO	YES	YES	YES	NO	A	YES	YES

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IOWA	YES	25	NO	6	NO	YES	YES	YES	NO	C	YES	R
KANSAS		4		1								
KENTUCKY	YES	1	YES	3	FEDERAL TRUST	NO	NO	NO	R	A	NO	R
LOUISIANA	YES	2	YES	2	STATE TRUST	NO	YES	YES	R	A	R	NO
MAINE	YES	1	NO	8	STATE TRUST	NO	NO	YES	NO	A	YES	NO
MARYLAND	YES	0	YES	4	STATE TRUST	NO	NO	NO	NO	A	R	YES
MASSACHUSETTS		8		1								
MICHIGAN	NO	10	NO	4	NO	YES, NOT USDA	YES, NOT USDA	NO	NO	A		
MINNESOTA		15		2								
MISSISSIPPI	NO	4	NO	2	NO	NO	NO	YES	NO	C	NO	NO
MISSOURI	NO	6	NO	1	NO	NO	NO		NO	A	R	
MONTANA	YES	33	NO	0	NO	NO	NO	NO	NO	C		
NEBRASKA	NO	2	NO	1	NO	YES	YES	YES	NO	A	YES	NO
NEVADA	YES	3	NO	0	FEDERAL TRUST	NO	NO	NO	NO	A	NO	

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NEW HAMPSHIRE	YES	4	NO	0	FEDERAL TRUST	NO	NO	YES	NO	A	YES	YES
NEW JERSEY	YES	9	YES	3	STATE TRUST	NO	NO	YES	YES	C	YES	
NEW MEXICO	YES	1	NO	2	NO	NO		YES	YES	A	YES	R
NEW YORK	YES	26	NO	2	FEDERAL TRUST	NO	NO	YES	NO	A	R	R
NORTH CAROLINA	YES	52	YES	3	STATE TRUST	NO	NO	YES	R	A	YES	R
NORTH DAKOTA	NO	3	NO	0	NO	NO	NO			NO		
OHIO	NO	23	NO	18	NO	YES	YES	NO		NO	NO	
OKLAHOMA	YES	3		2	FEDERAL TRUST	NO	YES	YES	NO	A	R	R
OREGON	NO	1	NO	4	NO	YES, NOT USDA	YES, NOT USDA	YES	NO	A	NO	
PENNSYLVANIA	YES	48	NO	9	NO	NO	NO	YES	R	A	YES	YES
RHODE ISLAND	YES	8	NO	0	FEDERAL TRUST	YES	YES	YES	NO	YES	NO	YES
SOUTH CAROLINA	YES	3	YES	4	STATE TRUST	NO	NO	YES	NO	A	R	R
SOUTH DAKOTA	NO	3	NO	1	NO	YES	YES	NO	NO	C	NO	
TENNESSEE	NO	3	NO	1	NO	YES	YES	YES	R	YES	R	NO

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TEXAS	NO	20	NO	11	NO	NO	NO	YES	YES	A	NO	R
UTAH	YES	2	NO	3	STATE TRUST	YES	YES					
VERMONT		3		1								
VIRGINIA	YES	3	YES	1	STATE TRUST	YES	NO	YES	R	YES	YES	NO
WASHINGTON		9		7		YES	YES					
WEST VIRGINIA	YES	0	NO	0	NO	YES, NOT USDA	YES, NOT USDA	YES	R	A	NO	YES
WISCONSIN	YES	21	NO	3	NO	YES, NOT USDA	YES, NOT USDA	YES	R	A	R	R
WYOMING	NO	0	NO	0	NO	N/A	N/A	N/A	NO	C	NO	N/A

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