



# United Egg Producers

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**[Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504 and RIN number 0910-AC14]**

Dear Sir or Madam:

These comments are submitted on behalf of United Egg Producers (UEP) in response to the Food and Drug Administration's (FDA) proposed rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule." UEP is a cooperative whose member farms account for about 90% of shell egg production in the United States. We have members in 42 of the 50 states, including every state where eggs are produced in commercially significant quantities.

UEP has been a leader in promoting food safety. UEP was an early supporter of the pilot project in Pennsylvania that performed seminal work on SE control measures – work that was subsequently incorporated into the Pennsylvania Egg Quality Assurance Program and similar programs (EQAPs) in other states. UEP also has developed and provided to its members the 5-Star Quality Assurance Program, whose features are similar to those of state EQAPs. The 5-Star program was one of only two privately-developed EQAPs singled out by FDA in its discussion of the proposed rule, the other being a program designed by the U.S. Animal Health Association (FR p. 56831). Decades ago, egg producers supported enactment of the Egg Products Inspection Act (EPIA), requiring pasteurization of processed egg products and inspection of shell egg packing facilities, to address foodborne illness concerns.

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Egg producers have an obvious self-interest in providing a safe product to their customers. All EQAP participants today are voluntary participants, and the widespread adoption of EQAPs shows that producers and their customers want to do everything possible to assure food safety.

UEP members have been encouraged by the decline in *Salmonella* Enteritidis (SE) illness rates, in the number of SE-related outbreaks and in the proportion of outbreak cases attributed to eggs. We will discuss these trends in more detail later in these comments. Nevertheless, one foodborne illness is one too many, and UEP recognizes the need for continued cooperation between the private sector and the government to further reduce the problem of SE. This proposed rule is intended as one means to meet that goal.

When FDA in 1999 first discussed an Egg Safety Action Plan – the term then used to describe a variety of SE-related measures, the centerpiece of which was the proposed rule now published – UEP objected strongly to certain aspects of the plan as it was initially described. In particular, we felt that science did not justify a requirement to divert eggs into processing solely because of a positive environmental test. We also believed that the number of tests initially described would have been excessively costly and not justified by the balance of scientific work on the subject.

FDA was responsive to our concerns, and in July 2000 published documents entitled “Current Thinking Papers on the National Standards for Egg Safety” (the “current thinking” papers). UEP and other interested groups accepted the broad outlines of the policies laid out in the “current thinking” papers.

UEP continues to honor this commitment. We also find upon reviewing the proposed rule that FDA has been faithful to the spirit of the “current thinking” papers, with respect to the on-farm measures which are now proposed. As we will note later in these comments, we are somewhat surprised that the proposed rule does not include any new initiatives to protect consumers through retail regulation, since such a step was clearly intended in the “current thinking” papers. Moreover, we cannot help noting that FDA has issued a proposed rule on which we must comment without any knowledge of what the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture will propose in a related rule which is not expected until sometime in 2005 at the earliest. UEP has consistently requested that FDA and FSIS coordinate the issuance of their proposed rules, since the same producers may be affected by both. It is difficult to evaluate the FDA proposed rule with confidence when one does not know how FSIS’s proposed rule may interact with FDA oversight.

To repeat, however, UEP honors the commitment we made in 2000 and feels that the proposed rule is a fair and reasonable reflection of what FDA stated in the “current thinking” papers. This does not mean that the proposed rule is perfect. It is not. As described in detail in these comments, UEP feels strongly that the proposed rule can be improved through modifications that would not change its underlying principles but would result in more cost-effective administration and closer conformity with the most current science. We have tried, in these comments, to

provide specific suggestions for improvements in the proposed rule, and to explain in some detail why we believe these improvements are necessary.

**Notes on References and Format:** We have listed some relevant sources at the end of these comments, and parenthetical references in the text refer to these sources. However, because these comments quote so frequently from the *Federal Register* of September 22, 2004, in which the proposed rule was published, we have referred to this document as “FR,” and where we quote from it, have noted the relevant page number in that day’s issue – e.g., “(FR p. 56874).” In addition, where we believe a provision of the rule raises a specific issue that requires an FDA response, we have numbered the issues sequentially throughout this document.

### **The Problem in Perspective**

FDA states that “[t]he incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern” (FR, p. 56832). FDA also states that “SE illnesses have essentially remained steady for the past several years” (FR, p. 56825). While acknowledging public health gains from egg quality assurance programs (EQAPs), education and refrigeration requirements, FDA says that “these gains are still far short of the public health and foodborne illness gains required to meet Healthy People 2010 goals.” Further, the agency notes that “[t]he incidence of SE in the United States remains much higher than in the 1970s” despite significant improvement from the higher levels of the 1990s (FR, p. 56826).

UEP does not dispute the seriousness of Salmonellosis, the need to further reduce SE illness, or the responsibility of producers to sell a safe product. Indeed, UEP has taken the lead in developing the most widely used industry EQAP, the 5-Star Program; was instrumental in encouraging early research into SE prevention through the Pennsylvania pilot project and other initiatives (Schlosser et al, 1999); and has supported the basic thrust of FDA’s present rulemaking since 2000.

We also believe, however, that an objective look at the SE problem provides substantial grounds for optimism and hope. This is not a problem without a solution. Egg producers and the states have made significant progress with no federal mandates, and the situation is improving.

Consider these facts:

- **The number of SE-related outbreaks has steadily declined.** FDA notes that from 26 such outbreaks in 1985, the number increased rapidly to a peak of 85 in 1990 (FR p. 56826). The agency then notes the declining pattern of 56 outbreaks in 1995, 50 in 2000 and 32 in 2002 (*ibid.*). **This means that the number of SE-related outbreaks is returning to levels that prevailed at the beginning of public concern over SE. The number of outbreaks in 2002 was 62% lower than in 1990 (CDC outbreak report 2002).**

- Of the 14,319 actual illnesses attributed to SE from shell eggs during 1990-2001, **72.7% occurred before 1996**, according to FDA's supplementary information published with the proposed rule (FR p. 56826).
- **SE illnesses per 100,000 persons were 1.8 in 2003, the lowest rate since 1999, according to CDC FoodNet and *Salmonella* Surveillance Systems data.** Meanwhile, the percentage of SE outbreaks attributed to eggs fell to only about 10% of all outbreaks in 2002 (CDC outbreak report 2002). Some 67% were specifically attributed to non-egg sources. Although this result could be anomalous, it is important if it heralds a trend. (The low percentage of egg-attributed outbreaks was *not* due simply to an increase in the number of outbreaks from other sources. The total number of cases in these outbreaks fell significantly from 2001 to 2002, and the absolute number of egg-related cases was lower than in any year in the 1998-2002 period, while the absolute number of non-egg-related cases was substantially higher than any year in the period and the number of unknown cases was relatively stable.)
- **SE is not the most common cause of Salmonellosis.** According to the Centers for Disease Control's *Salmonella Annual Summary 2002 (Table 1)*, the most common serotype identified was S. Typhimurium, causing 21.9% of all human salmonellosis illnesses, while S. Enteritidis was the second most common at 15.8%.
- **Only a minuscule portion of all shell eggs in the United States contain SE.** FDA estimates that 2.3 million eggs out of 47 billion table eggs may be SE-positive (FR p. 56827). This number is 0.00489% of the nation's table egg supply – **less than five one-thousandths of one percent.**

The Egg Nutrition Center has analyzed these and other SE-related statistics in an industry update which is attached to these comments (Egg Nutrition Center, 2004).

We do not adduce these statistics to argue that SE is not a problem. SE is a problem. Nor do we cite improvements to justify inaction.

Rather, we ask FDA to consider SE as a serious problem which is nevertheless being gradually mitigated through industry and government efforts. In light of continuing progress, FDA should give due consideration to the additional costs being imposed on an industry that has provided food-safety leadership and embraced best practices for safe food production. Moreover, FDA should examine with a critical eye any of its proposals that might disrupt or duplicate successful current efforts, such as state and industry EQAPs.

Throughout these comments, UEP will cite considerations of cost and practicality. We do not do so out of insensitivity to human health. Rather, we recognize that all public policy development requires a balancing of interests and due consideration of costs and benefits.

### **Program Administration**

Like many federal agencies, FDA has been given a variety of new tasks by Congress in recent years, and may sometimes find its personnel resources strained. Now FDA has proposed a rule that, by the agency's own count, will require annual inspections at more than 4,000 farm sites (FR p. 56827). By contrast, during fiscal 2005, FDA reportedly plans to audit approximately five egg producing operations.

It is natural to ask where FDA will get the personnel and related resources to conduct these inspections and carry out other functions associated with the proposed rule. Fundamentally, the agency would appear to have four options:

1. Utilize exclusively federal FDA employees for inspections;
2. Contract with other federal and state agencies to carry out inspections;
3. Rely on a combination of producer self-audits and existing inspections or audits by state agencies, coupled with enhanced FDA scrutiny through tracebacks of illness outbreaks; or
4. Conduct no regular annual inspections, but require submission of environmental and egg test data, and spot-check the accuracy of test reports and producer compliance.

Options 3 and 4 might become viable if FDA determines to require only environmental and egg testing, while leaving specific SE control measures up to producers. That is not what the agency has proposed, but FDA has asked for comment on such an approach. Should FDA adopt that approach, its need to conduct annual inspections would change dramatically.

However, for the purposes of this discussion, UEP notes FDA's comment that it intends to provide for annual inspections (FR p. 56842), and assumes that specific on-farm control measures will be required (though we comment on alternatives elsewhere in this document).

Under that assumption, UEP would expect that FDA's primary options are those identified as 1 and 2 above – direct inspections by FDA personnel, or a contract with other responsible agencies.

#### **Issue 1: Should FDA carry out inspections of egg production facilities directly, or delegate the responsibility to other federal or state agencies?**

*Discussion: Inspections serve several purposes, in UEP's view. These purposes include:*

1. *To identify instances of non-compliance and take appropriate action;*
2. *To encourage compliance through the knowledge that enforcement actions are possible;*

3. *To apply consistent and uniform inspection standards to all producers, so that the entire industry operates under conditions of fair and even competition; and*
4. *To identify common problems or areas for improvement in the regulations.*

*The underlying purpose of all inspections, of course, is to further the public health goals embodied in the on-farm regulations. What is being inspected, however, is an agricultural facility – a farm. Inspectors therefore need agricultural expertise in order to carry out their responsibilities thoroughly, consistently and fairly.*

*UEP suggests that producers, FDA and the public should all agree on the desirability of the following attributes of an ideal inspection system:*

- *It should make the most efficient use of limited federal personnel resources.*
- *It should ensure that inspections are carried out by persons knowledgeable of the agricultural sector and the egg industry in particular.*
- *It should provide for an arm's-length regulatory relationship.*
- *While obtaining all necessary information, it should minimize the additional burden on producers, taking into account other regulatory activities which already affect their business operations.*

*USDA's Agricultural Marketing Service (AMS) presently carries out an inspection program at all shell egg packing sites, the Shell Egg Surveillance Program. It should be noted that this surveillance is not the same as quality grading, which is voluntary and involves different personnel. Rather, the surveillance program is carried out under the Egg Products Inspection Act, which "provides for inspections of shell egg handlers to control the disposition of certain types of loss and undergrade eggs," according to an official USDA summary. "It also mandates that shell eggs sold to consumers contain no more restricted eggs than permitted in U.S. Consumer Grade B and that restricted eggs be disposed of properly."*

*The Shell Egg Surveillance Program is conducted quarterly, and covers "firms with over 3,000 layers that grade and pack their own eggs, firms that grade and pack eggs from production sources other than their own (grading station), and firms that are hatcheries." Inspections are carried out either by AMS employees or, in a few cases, by state agency personnel under contract with AMS. (USDA, 2004)*

*FDA could – subject to agreement with AMS – enter into a contractual arrangement whereby one of the quarterly inspections under the Shell Egg Surveillance Program would be expanded to include an inspection related to FDA's on-farm SE regulations, with additional visits to farm sites scheduled so that each site would be visited at least once a year. Under such a contractual arrangement –*

- *FDA would instruct AMS on the records and practices to be inspected, and AMS would carry out the inspection in accordance with FDA's rules and any guidance that may subsequently be published; and*
- *FDA would specify the circumstances under which it wished to be notified of any apparent violations of the regulations so that FDA could take appropriate enforcement action.*

*In UEP's view, there would be several advantages to such an arrangement.*

1. *The additional regulatory burden on producers would be somewhat reduced, because they would not face an inspection by a federal agency that does not regularly visit their operations – rather, they would be dealing with an agency with which they are already familiar.*
2. *An arm's-length inspection would be assured because (a) AMS would carry out inspections under FDA's directed procedures, and (b) AMS personnel utilized in the Shell Egg Surveillance Program are different from grading personnel who are resident at the facility.*
3. *AMS's supervisory and management infrastructure is designed to ensure uniform application of standards, avoiding the problem of uneven or arbitrary enforcement.*
4. *AMS has longstanding relationships with state egg regulatory authorities, including contractual relationships in some cases.*
5. *Net federal government costs would likely be less than if FDA performed inspections itself, since (a) the use of AMS would minimize the need for any new federal hires, and (b) AMS personnel are already knowledgeable of egg industry practices, so training costs should be less.*
6. *From FDA's standpoint, the use of pre-identified federal personnel in AMS should provide greater assurance that inspections will really occur on an annual basis, especially if this is specified in a contractual arrangement. By contrast, if FDA relies solely on its own personnel, it risks the diversion of these personnel into other tasks in the event of unforeseen developments, budgetary problems or security-related problems.*
7. *An arrangement with AMS would follow a successful precedent: USDA's Food Safety and Inspection Service already utilizes AMS personnel to monitor compliance with egg refrigeration requirements – and this monitoring is part of the Shell Egg Surveillance Program, as suggested here for the FDA's on-farm SE regulations.*

*This is a subject on which Congress has also spoken. In the FDA's appropriation bill for fiscal 2001, the agency is required to "[s]olicit comments on appropriate options for implementing a Salmonella Enteritidis reduction plan in shell eggs, including comments on conducting and funding testing, through state and federal programs." (Emphasis added.) (P.L. 106-387, Sec. 753.) Accompanying legislative history states that the agency is to "[c]onsider the appropriate utilization of existing federal, state, or local government agencies charged with poultry or egg safety responsibilities (including such aspects of grading as are related to egg safety), in implementing the regulations." (H. Rpt. 106-948.)*

*It is clear from this language that Congress intended for FDA to give strong consideration to an administrative role for other agencies, both state and federal. Thus, an arrangement with AMS and the state agencies with which it cooperates would not only have the advantages listed above, but would also be consistent with the expressed desire of Congress.*

***UEP Comment: UEP strongly urges FDA to delegate inspection responsibilities to USDA's Agricultural Marketing Service, with inspections to be carried out according to procedures specified by FDA, in conjunction with the existing Shell Egg Surveillance Program. UEP believes this arrangement will minimize additional regulatory burdens on producers; promote consistent and fair regulation by utilizing personnel with expertise in the egg industry; make the most efficient use of scarce federal resources; and provide assurance of arm's-length, annual inspections.***

### **The Role of Existing State and Industry Programs**

It remains somewhat unclear, even 20 years into the era of public concern over SE, just why the organism became such a problem so quickly in the early 1980s. There is strong scientific consensus, however, about one factor which has helped reduce SE incidence since then: the adoption of egg quality assurance programs (EQAPs) by industry and the states.

FDA's supplementary information on its proposed rule acknowledges the positive role of EQAPs (FR p. 56832). Just after publication of the proposed rule, the Centers for Disease Control and Prevention published a paper in *Emerging Infectious Diseases* which quantified and strengthened the claim of EQAPs to have made a real, measurable and positive difference.

The article, entitled "Egg Quality Assurance Programs and Egg-associated *Salmonella* Enteritidis Infections, United States," (Mumma, 2004) examined data from states that had implemented EQAPs. The plans included not only those developed by a particular state (e.g., California, Pennsylvania), but also UEP's 5-Star Program, which has been officially adopted by several states (e.g., Indiana). In all, 15 states reported having official EQAPs: Connecticut, Pennsylvania, California, South Carolina, Maryland, Ohio, Michigan, Utah, New York, Alabama, Louisiana, Indiana, Oregon, Florida and Georgia.

In 2003, according to USDA data, these states accounted for 43.967 billion eggs, or more than 50% of total U.S. egg production. (Taking into account producer participation in UEP's 5-Star

Program nationwide, of course, a significantly higher percentage of eggs are actually produced under an EQAP, since this program may be adopted by any producer regardless of his or her state of residence.) Six of the top 11 egg-producing states have EQAPs.

Although existing EQAPs are voluntary, they have enjoyed a high level of participation by producers. For example, the Pennsylvania Department of Agriculture states that flocks representing 85% of that state's egg production participate in the Pennsylvania Egg Quality Assurance Program. California's Department of Food and Agriculture reports an even higher rate of compliance – 95% -- with that state's EQAP.

The CDC paper demonstrates the effectiveness of EQAPs, and its conclusion is “that EQAPs probably played a major role in reducing *S. Enteritidis* illness in these states [that adopted them].” In particular, the CDC found “a connection between the introduction of EQAPs at the state level and significant reductions in *S. Enteritidis* incidence in humans. The regression analysis found that *increasing the quantity of eggs produced under EQAPs was associated with reducing S. Enteritidis incidence.*” (Mumma, 2004, p. 1788, emphasis added.) CDC also stated that “flock-based interventions have had a positive effect on health by reducing *S. Enteritidis* incidence in humans. These data further indicate that EQAPs probably played a major role in reducing *S. Enteritidis* illness in the United States.”

This paper lends quantified support to a well-established consensus that EQAPs (whether state or industry-led) are beneficial in controlling SE. Indeed, that consensus appears to be a major part of FDA's rationale for its proposed rule. Of course, the fact that EQAPs are effective need not imply that states without EQAPs are producing unsafe eggs. Rather, in several cases EQAPs have been established in states with pre-existing SE problems – reflecting the fact that SE has not been equally common in all regions of the United States, for reasons that are not completely known.

However, a basic principle of medicine is also applicable to regulation: First, do no harm. The proposed rule leaves unclear the relationship between new federal SE-control requirements and the existing voluntary EQAPs. In doing so, FDA has inadvertently raised questions about the future viability of the very programs that have been largely responsible for progress in fighting SE since the mid-1990s.

If existing state programs are working, it makes little sense to change them for change's sake, or suddenly replace them with federal regulations that may or may not be equally effective. UEP does not think this is FDA's intent. Yet the reader of the proposed rule could be forgiven for wondering just how state EQAPs relate to the highly detailed, prescriptive federal regulations.

**Issue 2: Should FDA take account of state and industry EQAPs in its final rule, and if so, how?**

*Discussion: In assessing state and industry EQAPs generally, FDA will find several points of contrast between the existing EQAPs, on the one hand, and the proposed federal rule, on the other. In general (and with exceptions), these contrasts include that –*

- *Existing EQAPs are voluntary, but the federal rules will be mandatory;*
- *Some but not all existing EQAPs have egg testing and diversion programs similar to what FDA has proposed;*
- *Existing EQAPs may differ in their particulars from the on-farm measures and methods prescribed by FDA in its rule; and*
- *In some cases, existing EQAPs feature a greater role for producer input or administration than is found in the FDA's proposed rule.*

*However, these differences are not as great as they appear at first. For example –*

- *Though EQAPs are voluntary, the extremely high degree of participation in some states suggests that customers are requiring participation by their suppliers. Nor would it be necessary to make the existing EQAPs mandatory if FDA sought to make them an integral part of its own regulations. Instead, producers could simply choose between the existing EQAP and adoption of measures in FDA's rules.*
- *The inconsistency in testing or diversion requirements among various EQAPs need not imply any deficiency in these EQAPs, but rather may suggest a common federal component that would apply nationwide in any system which endeavored to allow for both federal rules and existing EQAPs.*
- *FDA's proposed rule, when taken at face value, is more flexible on individual SE control components than some commenters have believed. In most cases, the rule lays out a standard but also permits for an equivalent practice, thus providing for flexible administration.*
- *FDA's regulatory structure may be less amenable to direct producer participation than are state programs, but the agency could – and arguably should – provide for regular, formalized producer advice, e.g., through the creation of a producer advisory committee.*

*Egg producers do not want society to lose any of the benefits from existing EQAPs. At the same time, the industry also values the consistent, fair and evenhanded application of similar rules to all producers, regardless of where they reside. For example, producers have expressed genuine concerns about the economic impact of a diversion requirement (see separate section of these comments). But if diversion is to be required – with all its attendant economic burdens – then the rules should be the same for all producers.*

*Moreover, the industry also understands that all EQAPs are not necessarily created equal. FDA would not be likely to grant a blanket exemption from its rules to any producer participating in an EQAP, nor is it clear that such an approach would be sound public policy.*

*And yet state EQAP administrators are sincerely concerned about how FDA's proposal will affect them. State EQAP officials, and participating producers, have invested time and money in building the credibility of their plans. Moreover, as we have seen, no less an authority than CDC believes strongly that these EQAPs work and have made a difference in public health.*

**UEP Comment:** *FDA should modify its proposed rule to take account of the highly positive contributions made to public health through existing state and industry EQAPs.*

**Issue 3:** **How could FDA ensure that the public continues to enjoy the benefits of existing EQAPs, without sacrificing the agency's fundamental goal of evenhanded nationwide standards for SE control?**

*Discussion:* *To preserve the role of state and industry EQAPs while ensuring that FDA's fundamental goals are met, several approaches are possible. One is suggested by FDA itself in the supplementary information on the proposed rule (FR p. 56830): "We are soliciting comment and data on alternative regulatory schemes ... [including] a requirement for a specified frequency of environmental testing for all producers, followed, if necessary, by egg testing and diversion. As long as producers were maintaining poultry houses that tested negative for SE, the SE prevention measures would be recommended but not required." Under this approach, testing would be mandatory for everyone, but producers in a state or industry EQAP could continue to use the provisions of that plan to guide their on-farm SE control measures. Producers who did not wish to participate in any plan would not have to do so, although they would be required to test and, if necessary, divert eggs.*

*A similar but distinct approach would also feature flexibility and preserve the core requirements for testing and diversion, but provide additional support to state and industry EQAPs. This approach could be described as a "recognition regime," since FDA would recognize EQAPs that met a standard of equivalence to the agency's own requirements. Producers who participated in recognized EQAPs would be considered to be in compliance with FDA's regulations (subject to inspection by the agency administering the EQAP), but would still have to carry out environmental and, as necessary, egg testing and diversion.*

*Under a "recognition regime," FDA would establish in the final rule a procedure by which states and industry groups could request recognition of an Egg Quality Assurance Program. In the final rule, FDA would establish a standard by which such programs would be judged – e.g., a standard of equivalence but not a requirement for absolutely identical provisions. EQAPs seeking recognition would also need to provide detailed information on inspections, audits or other means of verification. However, FDA would stipulate that if the EQAP does not have testing and diversion provisions virtually identical to those in the proposed rule, then producers participating in that EQAP would nevertheless remain subject to FDA's testing and diversion requirements.*

*UEP notes that this proposal has the potential to further reduce federal taxpayer costs. Elsewhere in these comments, UEP has strongly urged FDA to utilize the services of the Agricultural Marketing Service for inspections under the proposed rule, and has noted that*

*because of possible savings in training and other costs, the use of AMS should be marginally less costly to taxpayers than if FDA attempted to utilize its own personnel to perform all inspections.*

*But under a recognition regime, further savings to the federal budget could accrue because state EQAPs already feature an audit or inspection component, typically carried out by the state department of agriculture. Part of recognizing a state EQAP would be the recognition of that EQAP's administrators as competent to assess compliance with on-farm measures. Since these administrators carry out these tasks already, and would merely continue their current role, no additional federal expenditures should be necessary.*

*Hence, in these states, it might not be necessary for either FDA or AMS to conduct on-farm inspections – and so federal costs might be less than in the alternative case. (However, it might still be necessary for AMS to inspect testing and diversion records and practices, since in many cases these would be additive to the existing EQAP. In the alternative, administrators of the existing EQAP might perform these functions, but in that instance one would expect some additional cost.)*

***UEP Comment: UEP urges FDA to recognize the positive contributions of existing state and industry EQAPs by instituting a “recognition regime” in its final rule, whereby the agency would assess EQAPs and recognize those that are equivalent to FDA’s own regulations. All producers would be subject to common testing and diversion requirements, but on-farm SE control measures would be governed by the EQAP in which each producer participated. Producers who did not wish to participate in a recognized EQAP would then be subject to FDA’s on-farm SE control measures.***

**Issue 4: To allow the FDA sufficient time to develop and carry out procedures for recognizing existing EQAPs, should the implementation period for the final rule be modified?**

*Discussion: UEP believes that the complexity of several issues involved in the proposed rule strongly suggests that FDA should consider making its regulations effective two years rather than one year after the publication of a final rule. Elsewhere in these comments, UEP has discussed several such issues in detail, e.g., the need to obtain better information on the adequacy of the current public and private laboratory system.*

*Although FDA is probably familiar with some EQAPs – especially the best-known, such as the Pennsylvania EQAP – the agency likely has not performed a detailed comparison of each EQAP to FDA’s own proposed regulations. Moreover, some time would be necessary to permit state and industry groups to submit their EQAPs for recognition – including time to modify these EQAPs if necessary to attain FDA recognition. Finally, it would take some additional time for FDA to review all applications for recognition, make decisions and officially inform the public and producers of approved plans.*

*It seems reasonable that FDA might be able to perform these tasks in the year following publication of a final rule. At that point, all producers would know their options clearly and*

*could assess their own readiness for either a state or industry EQAP, or FDA's regulations. A phase-in period of a year after that point would permit producers to make any necessary changes in their own operations.*

***UEP Comment:*** *For a variety of reasons cited elsewhere in these comments, but primarily because of the desirability of assessing and recognizing existing state and industry EQAPs, UEP supports a two-year phase-in of the FDA's regulations, with the first year following publication of a final rule devoted to promulgation and implementation of a recognition regime, and the second year constituting a phase-in period for industry. (UEP does not object to a third year during which smaller operations would have an additional opportunity to phase in changes, which would be consistent with the differential phase-ins proposed by FDA. However, UEP believes strongly that the first year following publication of a final rule should be devoted to development of a recognition regime and the accomplishment of certain other tasks identified throughout these comments. This year would not constitute a phase-in period because the precise terms of requirements on producers would not be fully known until the end of the year.)*

### **Retail Regulations**

FDA has requested comments on whether certain sections of the Food Code should be incorporated into federal regulations. It appears from FDA's comments that the agency would be inclined to apply these regulations to food service institutions that predominantly serve vulnerable populations (chiefly immunocompromised persons, preschool age children or senior citizens), rather than to all food service providers (e.g., schools, restaurants).

UEP commends FDA's earlier leadership in requiring refrigeration of all shell eggs received by retail institutions, as provided in a final rule published December 5, 2000. UEP also commends FDA for requesting comments on this important subject. At the same time, UEP is somewhat puzzled why FDA included no retail provisions in the proposed rule. As FDA itself notes (FR p. 56850), the July 2000 "current thinking" papers circulated by FDA included provisions for both on-farm and retail measures. However, now the proposed rule has been published with no retail provisions whatever. On-farm regulations are presented in great detail, and FDA estimates that the production sector will bear some \$82 million in costs because of them (FR p. 56885). Yet under the proposed rule as published, *no costs at all would be imposed on the retail sector.*

Egg producers acknowledge their responsibility in the total effort to deliver a safe product to consumers. They not only accept this responsibility, they have acted on it. The Centers for Disease Control and Prevention found a clear pattern of improvement in public health outcomes when egg quality assurance programs were implemented. Because all these programs have been voluntary, they have contributed to public health only because egg producers themselves voluntarily decided to implement the programs (Mumma, 2004).

But egg producers also believe that responsibility for safe food is shared throughout the chain from farm to table. Some agricultural products are potentially hazardous in their raw form. Eggs are not the only such product. As people should not eat raw meat or poultry, they should not eat raw eggs either. Whoever is preparing meat, poultry or eggs for others bears some responsibility for taking common-sense steps to avoid any hazard to the ultimate consumers. Raw animal products pose certain risks by their nature, risks that cannot be completely eliminated by the producer – and therefore people who handle and prepare these foods also must assume some responsibility for controlling their risks.

In responding to comments received earlier in the rulemaking process, FDA wrote (FR p. 56850): “We do not believe that a greater emphasis should be placed on any one segment of the farm-to-table continuum, i.e., producer, packer, processor, or retail establishment.” The fact is, however, that FDA itself *is* placing a greater emphasis on the producer sector in the proposed rule: After publishing in writing its intent to propose retail standards more than four years ago (FDA Current Thinking Papers), the agency has issued a proposed rule which contains no provisions affecting retail establishments. Asking for comments on this subject is highly commendable, but the agency is surely aware of the obstacles which arise when an agency seeks a final rule with provisions that were not in the proposed rule.

Despite these concerns, UEP again commends the agency for seeking public comment on this important subject. In this regard, FDA’s Food Code is the logical and accepted reference point for safe egg handling at retail, including institutional food service. The Food Code sections cited by FDA (FR p. 56828) are those which require that –

- Eggs be received in refrigerated equipment that maintains an ambient temperature of 45° F or less, and when cooked and received hot, be held at 135° F (2001 Food Code [as modified 2003] section 3-202.11);
- Eggs be received clean and sound, and not exceed the restricted egg tolerances for U.S. Consumer Grade B (3-202.13);
- Liquid, frozen and dry eggs and egg products be obtained pasteurized (3-202.14);
- Pasteurized eggs or egg products be substituted for raw shell eggs in foods that call for raw eggs and are not cooked (3-302.13);
- Raw shell eggs be cooked to 145° F or above for 15 seconds when prepared to a consumer’s order for immediate service, but soft cooked eggs may be served under specified conditions (3-401.11);
- Consumers at food service establishments be notified of the increased risk of consuming raw or undercooked foods, if such foods (including eggs) are offered in ready-to-eat form (3-603.11); and
- Pasteurized eggs or egg products be used in recipes prepared at establishments serving highly susceptible populations, where more than one egg is broken and combined, with exceptions for single-meal servings such as scrambled eggs, situations where eggs are cooked thoroughly, or the food establishment uses a HACCP plan with several specified egg-related elements (3-801.11).

The Food Code provisions are based on sound science and have been adopted by many states. UEP believes several issues require consideration and a response by FDA as the agency determines whether to apply some of the provisions as formal federal regulations.

**Issue 5: Does codifying only Food Code provisions pertaining to eggs imply that eggs are less safe than meat, poultry or other raw animal products?**

*Discussion: UEP believes all federal agencies involved in food safety have a responsibility to convey information about different foods in a balanced manner, ensuring that consumers receive an objective view of safety and risk in various foods. Thus, we argued strenuously in 2000 that FDA had proposed a warning label for eggs which, when compared with the warning labels for meat and poultry, incorrectly implied that eggs posed a greater danger. (FDA made appropriate changes to the label language in its final rule, changes which UEP commended at the time and continues to appreciate.)*

*The question here is whether the act of codifying certain Food Code provisions, but not others, may unintentionally convey the message that eggs are more dangerous than other potentially hazardous foods that are specifically mentioned in the Food Code. UEP has no reason to believe that such an invidious comparison is FDA's intention. Rather, the issue is whether the codification in itself, regardless of intention, might send an inappropriate message – a message of more alarm than is justified by the totality of risks involved.*

*On balance, UEP does not feel that codification is likely to convey a prejudicial message as long as the agency is clear about what it is doing. FDA can – and should – communicate to the public that –*

- *Many Salmonellosis outbreaks occur in institutional settings, so that regulatory action aimed at the food-service sector is an appropriate and targeted means of directly combating a public health problem;*
- *Because food safety is affected by actions throughout the farm-to-table chain, it is appropriate that the responsibility for egg safety be shared, not borne solely by producers;*
- *Adequate precautions in institutional settings may substantially enhance the reduction in illness which could be expected from the on-farm measures in FDA's rule; and*
- *The fact that the measures would generally apply when vulnerable populations are served is an additional justification for regulatory action, since –*
  - *Precedents already support the need for additional regulations to protect the health of children, the elderly, and immunocompromised individuals; and*
  - *It may be less appropriate to depend solely on consumer education and responsibility for these populations, since they may be less well-suited than the general public to assimilate and apply food safety information because of age, health condition or other factors, and are less likely than the general public to prepare their own food.*

***UEP Comment:*** *UEP does not believe that FDA should be dissuaded from codifying certain sections of the Food Code merely because of concern over singling out eggs. Rather, FDA should communicate in a positive manner the benefits of the codification, and avoid any implication that eggs are less safe than other potentially hazardous foods.*

**Issue 6: Should Food Code provisions be codified for all retail establishments, not merely those that serve vulnerable populations?**

*Discussion:* *The public policy case for codification is strongest for vulnerable populations, as noted in the discussion above. On the other hand, FDA is not applying its on-farm regulations only to producers who sell eggs to institutions serving vulnerable populations. Indeed, FDA's "current thinking" documents stated that the agency intended (in 2000) to apply certain standards to all retail establishments, others to those that serve at-risk consumers, and still others to establishments serving the general public.*

*One relevant consideration is whether some provisions are already required by law. For example, the "current thinking" document said that all retail establishments would be required to receive eggs that had been transported at 45° F or less, and to receive egg products in pasteurized form. However, it is not clear what practical change such a requirement would effect. The Egg Products Inspection Act (EPIA) and FDA regulations already require refrigeration of shell eggs from the time they are packaged for the final consumer through storage and sale in retail establishments. The EPIA also requires the pasteurization of all egg products. UEP and the Further Processors Division of United Egg Association (UEA) have supported and continue to support these requirements. UEA will provide additional perspective in comments to be filed separately.*

*UEP is aware of no evidence that retailers are receiving unrefrigerated eggs or unpasteurized egg products. Imposing a new requirement of this type would be unlikely to have a material impact on public health, simply because the problems in institutional settings tend to occur after eggs have been received rather than before. For example, numerous outbreaks have occurred because of mishandling, undercooking or inadequate personal hygiene by food service workers.*

*If FDA sought to affect health outcomes through interventions in food service establishments generally, the agency would be well advised to look at areas other than those already covered by existing laws and regulations. In particular, a case could be made to require the use of pasteurized liquid eggs, rather than individually broken unpasteurized shell eggs, in many recipes where eggs are pooled for cooking. The improper cooling and cross-contamination that may be associated with such uses of raw shell eggs have been associated with some Salmonellosis outbreaks, and not just among vulnerable populations.*

*On the other hand, FDA must also be cognizant of its enforcement capabilities, personnel resources and other responsibilities. A regulation that would apply to every food service establishment in the United States would beg the question how FDA would enforce it. The agency may be better advised to begin with institutions serving vulnerable populations. By*

*common consent, the greatest risk of hospitalization and serious complications is found in these populations.*

***UEP Comment:*** *For the time being, UEP's view is that FDA should codify egg-related Food Code provisions only for those establishments serving high-risk populations, generally along the lines specified in FDA's supplementary information to the proposed rule (FR, p. 56850; but see discussion of following issue). Should the present rulemaking not result in a decrease in Salmonellosis consistent with FDA's goals, the agency should consider further retail regulation as a second step.*

**Issue 7: How should FDA define the institutions covered by the codified Food Code provisions?**

*Discussion:* *UEP has noted above its general agreement with FDA's focus on high-risk populations, which FDA deems to be those who are both members of a vulnerable population (preschool age children, older adults or immunocompromised individuals), and exposed to congregate feeding environments such as a hospital, day care center or other institution.*

*However, FDA will need to come to grips with several questions if the agency does move forward (as UEP recommends) with a codification.*

- *Will any restaurants fit into the definition of covered facilities? Preschool children would constitute a substantial portion of the customer base at many fast-food restaurants, but these establishments generally do not fit the "institutional" concept that FDA seems to be pursuing.*
- *Will schools that offer the National School Lunch Program or the School Breakfast Program be covered? Although preschool children are by definition not part of their clientele, the school feeding programs serve millions of children just above preschool age.*
- *Could institutions that do not primarily serve vulnerable populations but nevertheless have a history of Salmonellosis outbreaks (e.g., prisons) be covered in some alternate fashion? For example, could FDA work with federal corrections authorities to ensure that proper food handling practices are used at all federal correctional facilities?*

*Despite these questions, UEP feels that a workable definition of covered facilities is readily attainable, particularly since according to FDA, 41 of 50 states have already adopted some form of the Food Code. In these states (particularly in those that have adopted the more recent versions of the Food Code), all food service establishments may already be covered by the provisions under discussion here. UEP encourages state and local authorities to adopt the most current Food Code where they have not already done so.*

*The best definition for covered facilities would simply list those institutions that are most obvious, and that will account for the vast majority of meals served in congregate settings to*

*vulnerable populations: hospitals, nursing homes, child and adult day care centers, and similar institutions; and then add a category such as “any other institution that regularly serves group meals to vulnerable populations.”*

***UEP Comment:*** *UEP suggests that FDA apply egg-related Food Code provisions to a list of congregate settings that serve vulnerable populations, including but not limited to hospitals, nursing homes, child and adult day care centers, and any other institution that regularly serves group meals to vulnerable populations. UEP does not believe that institutions whose service to vulnerable populations is only incidental to their primary mission – including schools and restaurants – should be covered at this time. UEP believes the Food Code provisions cited in FDA’s supplementary information to the proposed rule (FR p. 56850) are the appropriate sections for codification.*

### **Diversion and Other Costs**

FDA estimates that under its proposed rule, the eventual annual costs to the egg industry will be \$81,834,000 (FR p. 56885). These are estimated to be the incremental or additional costs of complying with the proposed rule, not total industry costs for quality assurance programs, which would be substantially greater.

On average, there were 278,550,000 table egg type layers in the egg industry during 2003, according to USDA statistics. On this basis, the FDA estimate of more than \$81 million in costs implies that the SE rule will involve new costs of slightly over \$0.29 per bird.

The 278,550,000 table egg type layers produced 74,404,000,000 eggs during 2003. Thus, each hen produced an average of 267 eggs in 2003, or approximately 22 dozen eggs. Spreading the \$0.29 per bird cost over the eggs produced implies that the proposed rule will increase costs by about \$0.013 per dozen.

At FDA’s public meeting in California, Don Bell, the University of California’s poultry specialist emeritus, noted that a profit margin of 5 cents a dozen would equate to just over \$1 per bird per year ( $\$0.05/\text{dozen} \times 22 \text{ dozen/year} = \$1.10$ ). New costs of \$0.29 per bird would reduce this annual per-bird margin by 26%. **Thus, if FDA’s own estimates are correct, the proposed rule appears to involve substantial ongoing costs for the egg industry which would lead to a significant reduction in profitability.** Of course, the egg industry is marked by frequent periods when income is below production costs for most farms. In these circumstances – which the industry experienced for several months earlier this year – an already unprofitable enterprise becomes even more so.

A potentially more serious concern is the fate of eggs from flocks with a positive egg test. Under the proposed rule, these eggs must be diverted to further processing. (In theory, they could be pasteurized in the shell, but in-shell pasteurized eggs have not become popular with consumers and are simply not an option for the vast majority of egg producers because of the extremely high capital investment required for in-shell pasteurization equipment. Many operations would

go out of business if compelled to make this level of capital expenditure. So if a producer must divert eggs, his or her only real option is to sell them to an egg products plant.)

There is little doubt that these eggs would be sold at a deep discount. First, there is the normal discount which the market places on eggs sold for breaking rather than for the table market. In its Preliminary Regulatory Impact Analysis, FDA estimates this discount at \$0.13, a figure derived from regional discounts weighted on the basis of relative production. However, respondents to an egg industry SE prevention survey estimated this normal discount at over \$0.20 (Bell, 2004). Their response is more consistent with recent market experience than FDA's estimate. In 2003, the average Umer Barry Midwest Large quote for table eggs was 92.1 cents per dozen, with the average Umer Barry Central Breaking Stock quote averaging 54.4 cents per dozen in the same period. The difference of 37.7 cents needs to be adjusted to reflect the fact that producers sell table eggs to major retail customers at around a 15-cent-per-dozen discount to the Umer Barry Large quote. Subtracting this normal discount from the 37.7-cent difference between table eggs and breaking stock leaves 22.7 cents per dozen, close to the 20-cent discount estimated by participants in the cost survey, but 77% greater than FDA's estimate, which appears to be based on data several years old.

Whatever the normal discount between table eggs and breaking stock is estimated to be, it is clear that most observers would expect an *additional* discount if eggs sold to a breaker are known to come from an SE-positive flock. FDA estimates this added discount at up to \$0.08 per dozen, taking the estimate from a survey of producers involved in tracebacks that was conducted in 1996. As discussed below, however, developments in the egg industry since that time would tend to suggest a wider additional discount. The egg industry cost survey found that responding egg producers expected an additional discount of \$0.097, on average. However, some estimates were as high as \$0.21 (Bell, 2004).

The more important question, however, is whether eggs from an SE-positive flock will find a market at any price. Fully 41.3% of respondents to the egg industry cost survey believe processors will refuse to accept these eggs. (A majority, 54.3%, believe processors will accept the eggs, but at an additional discount.) If processors will not purchase the eggs – perhaps because their own customers, newly aware of the SE rule, have told them not to – then the egg producer has few if any options. In such a situation, the producer might well choose to send the flock to slaughter or rendering ahead of schedule. In addition to the formidable logistic obstacles this course of action would present, the producer would then face a substantial period of downtime before the depopulated house could come into production again, since chicks are supplied by hatcheries on predetermined schedules, often arranged two years or more in advance.

FDA should be aware of certain trends that have materially changed the egg industry in recent years – even in the period since FDA unveiled the Egg Safety Action Plan in 1999. These trends make diversion substantially more problematic than was the case four or five years ago.

- Egg production has increasingly moved to the Midwest, with Iowa recently emerging as the number-one producing state. Despite some periods of tight supply (e.g., 2003), the more frequent pattern has unfortunately been overproduction, and that is the case today.

- Many egg processors have invested in production facilities, established supply-chain relationships or otherwise arranged for dedicated production. This means that the processor has a constant supply of eggs for its own breaking needs. It is a highly significant change from the older pattern where processors bought shell eggs on the open market.
- As a result of the structural change in the processing industry, processors' demand for shell eggs in the open market is less. Therefore the producer who wishes to sell to a processor is in a weaker bargaining position than just a few years ago.

It follows that eggs from SE-positive flocks will have a harder time finding a home than just a few years ago. Processors can afford to be more selective because an increasing number control their own dedicated flocks. As a result of the same phenomenon, the competition among producers to sell surplus eggs into processing is also fiercer than a few years ago because there are fewer ready sales outlets.

Physical proximity to breaking plants is also an issue. The egg industry survey found that only 59.5% of producers were within 100 miles of a breaking plant, while 28.6% were between 100 and 250 miles of a plant. Thus, transportation costs must be added onto normal and additional discounts to determine the true cost of diverting eggs. It is not clear, however, that FDA has done so in arriving at its "total cost of diverting eggs" in Table 23 of the PRIA (FR p. 56876).

A recent UEP economic analysis of the overall egg industry outlook, though not addressing SE-positive flocks directly, provides a cogent summary of the economics:

**"The trend in egg breaking/egg products is in-line production, growth in upper Midwest states, and dedicated supply.**

"Companies dedicated to egg breaking are becoming more self-sufficient. The trend is that breakers will not be a buyer of shell eggs but instead will likely be a surplus seller of eggs into the shell egg market. A drastic change from the days when shell egg producers could move their surplus into the breaker market.

"It was estimated [at an industry conference] that 20 egg breaking companies now have in-line production/breaking and the trend is to follow the shell egg industry by building more in-line systems.

"The number of layers needed for breaking has increased by 5 million since 2000 while the number of layers in Iowa, most of which are dedicated to breaking, has increased by 16 million and another 5 million will be added during 2005." (UEP, 2004, emphasis in original.)

The analysis was focused on the problems created by excessive industry expansion. However, it is also highly relevant to the economics of diverting eggs. Simply put, diversion's economic consequences are likely to be far more severe than FDA or anyone else thought in 2000 when the present outlines of the proposed rule were first developed.

**Issue 8: Are FDA's estimates of the economic impact due to diversion accurate, and if not, how should the agency revise its estimates?**

*Discussion: It is admittedly impossible to know in advance the reaction of the egg processing industry to producers' efforts to market eggs from SE-positive flocks. FDA has estimated that cumulatively, producers will bear a cost of \$5,133,000 per year because of diversion provisions (FR p. 56885). This estimate is based on a total cost of diverting eggs of \$0.13-\$0.21. However, producer costs would be much greater per dozen if processors refuse the eggs: Instead of the difference between the table egg price and the discounted breaking price, the cost would be the difference between the table egg price and no revenue at all. A simple average of the producer shell egg prices used by FDA in Table 23 (FR p. 56876) is \$0.448. (In reality, producers' costs could exceed this amount, because they could incur disposal costs for the eggs.)*

*It is not completely clear from the Federal Register document whether FDA has calculated diversion costs on the basis of \$0.13, \$0.21 or an average of these numbers. The simple average would be \$0.17, which would imply a view by FDA that \$5.133 million in diversion costs would result from an average total cost of diversion of \$0.17. If the relationship between per-dozen costs and total costs is more or less linear, then a total diversion cost of \$0.448 would mean total industry diversion costs of \$13.527 million if no eggs from SE-positive flocks could be sold. If we assume, however, that in some cases sales would indeed occur, then total costs would be somewhere between \$5.133 million and \$13.527 million.*

*To our knowledge, FDA has not surveyed processors to determine their intentions with respect to eggs from SE-positive flocks. Legal considerations would make it difficult for UEP or its counterpart trade association, United Egg Association, to conduct such a survey. However, FDA would certainly have the authority to do so. It would seem that FDA would at least want to reassure itself that its proposed remedy for positive egg tests is a feasible one, rather than instituting a final rule without any way to be sure that the resulting system will work.*

**UEP Comment:** *Elsewhere in these comments, UEP has suggested that the initial year after publication of a final rule be devoted to a variety of tasks that will clarify the rule's scope, such as a survey of laboratory capacity and the development of a "recognition regime" for existing egg quality assurance programs (EQAPs). UEP believes FDA should, during the same period, conduct a survey of the egg processing industry to determine processors' readiness to accept eggs from SE-positive flocks, and on what terms. FDA should then analyze the responses and, if necessary, make appropriate modifications before the final rule takes effect (UEP has suggested that the final rule should be phased in over a two-year period following publication).*

**On-Farm Egg Refrigeration**

Current regulations enforced by the U.S. Department of Agriculture require that shell eggs packed for the ultimate consumer be stored and transported at an ambient temperature of 45° F.

These regulations enforce a 1991 amendment to the Egg Products Inspection Act, supported by the egg industry, which recognized that poor handling of shell eggs, frequently by marginal packers and egg purchasers, could be the cause of human illnesses associated with eggs. Egg refrigeration was seen as an effective way to improve egg safety. While other actions have contributed to the reduction of SE in shell eggs since the early 1990s, refrigeration of shell eggs after processing throughout the food chain has likely reduced egg related human illnesses.

As noted above, the 1991 egg refrigeration amendment to the EPIA required storage at an ambient temperature of 45° F. Similarly, FDA's Food Code requires raw shell eggs to be received in refrigerated equipment maintained at an ambient air temperature of 45°F or less. Both the 1991 amendments and the Food Code are science-based, recognizing research that demonstrated shell eggs' natural resistance to microbial growth. Eggs only experienced significant microbial growth after a few weeks of non-refrigerated storage, and subsequent breakdown of the yolk membrane.

Although FDA has proposed that eggs must be refrigerated on the farm after 36 hours, classic scientific studies do not support this view. A study by Humphrey and Whitehead states: "In the majority of eggs, held at 20 degrees C [68 degrees F], the bacterium was unable to grow rapidly until eggs had been stored for approximately 3 weeks" (Humphrey, 1994). Another paper by Humphrey and others notes that in contrast to experimentally contaminated eggs, naturally contaminated eggs "had sometimes been stored at ambient temperature (20° C) for 5 days before examination. Despite this, all were found to contain fewer than 10 salmonellas per egg" (Humphrey, 1989). Important studies demonstrate that naturally contaminated eggs contain very few cells of SE, and the SE does not grow until the yolk membrane breaks down, which even at room temperature does not occur for approximately three weeks. At lower ambient temperatures (e.g., the 55-65° F that is common in on-farm refrigeration), SE growth would be still slower.

Some producers now refrigerate eggs at the farm when those eggs will not be immediately processed, but will subsequently be transported to a packing facility or egg processing plant. This practice, which occurs in off-line operations where shell eggs could potentially be stored for several days or longer, has been employed since at least the 1940s. Producers that process eggs in-line, when eggs are mechanically conveyed directly to the grading or processing operation, do not refrigerate shell eggs at the farm since these eggs are usually processed within a few hours after production.

**Issue 9: Is refrigeration of unprocessed eggs at 45°F on the farm an effective way to ensure food safety of shell eggs?**

*Discussion: Scientists and the food processing industry know that refrigeration of food, particularly raw, unprocessed food, is an effective step to assure food safety and maintain desired quality. However, a rule of reason must determine when and how products are refrigerated. The FDA proposed rule recognizes the impracticality of refrigerating eggs before processing in certain cases and also the natural antimicrobial characteristics of eggs. Based on*

*these considerations, the rule tentatively requires that only those eggs held longer than 36 hours after being laid be refrigerated at an ambient temperature of 45°F.*

*Those egg producers, packers, and processors that refrigerate eggs held for processing generally refrigerate at temperatures of 55°-65°F. These storage temperatures are effective in assuring product quality and inhibiting rapid microbial growth for several weeks. In fact, storage of raw shell eggs at temperatures lower than this has several disadvantages.*

*When eggs are subjected to greater temperature differentials, the frequency of checked eggs (those with a hairline crack in the shell but an intact shell membrane) increases. Checked eggs are required to be processed and pasteurized because of the increased risk that bacteria could enter the shell and contaminate the egg contents. Requiring a refrigeration temperature of 45 F would likely result in increased checks in shell eggs, because the eggs will undergo a greater-than-normal temperature increase when they are subsequently washed. It is this temperature differential which creates checks.*

*Washing is undoubtedly an important step in promoting safe, high-quality eggs. U.S. consumers expect to buy clean eggs, but washing serves a critical sanitizing function, removing bacteria from the shell. Procedures used during the washing process are tightly controlled to assure effective cleaning and avoid contamination of eggs during washing. This includes use of appropriate and safe washing compounds, maintenance of the proper pH in wash water and sanitizing and removing excess moisture from washed eggs before packaging.*

*One of the most critical requisites of egg washing is proper temperature of the wash water. Water that is too cold is obviously not as effective in cleaning as hot water, while water that is too hot can denature protein in the egg white. It is desirable to use the hottest water possible that will not result in any protein denaturing. Also, the wash water must be hotter than the internal egg temperature or there is the risk that the egg white and yolk will cool, thereby contracting and drawing in wash or sanitizer water through the porous egg shell. However, there is a limit to the differential between egg temperature and wash water temperature. A temperature difference that is too great will create thermal checks, an undesirable result from both an economic and more importantly, a food safety standpoint. So not only is refrigeration of eggs at 45°F before processing ineffective, it can negatively affect food safety*

***UEP Comment:*** *We believe that refrigeration of shell eggs held for processing is sometimes appropriate, but should follow a rule of reason. We suggest that refrigeration at an ambient temperature of 55-65° F of eggs held longer than 72 hours after they are laid is practical and an effective food safety measure for the reasons stated above. When eggs are held longer than 7 days after lay, the ambient temperature should be lowered to 45°F or less.*

**Issue 10: What is the total economic impact of on-farm refrigeration of shell eggs?**

***Discussion:*** *We question if FDA has considered the total economic impact of on-farm refrigeration at 45°F. Even those producers that now refrigerate before processing use storage*

*temperatures of 55-65°F. Current refrigeration equipment is largely incapable of providing an ambient temperature of 45°F. Therefore, even those producers, grading plants, and processors that currently refrigerate eggs held for processing would need to make major expenditures for new refrigeration equipment.*

*In egg products processing it is desirable to obtain a high yield of liquid egg from shell eggs that are broken for the production of egg products. When eggs are cold the egg white is thicker and hangs up in the shell which reduces overall yields. Similarly, it is more difficult to separate egg white from egg yolks in cold eggs. This not only reduces overall yields, but can also make it difficult for processors to comply with FDA's standard of identity for liquid egg yolks. To comply with the standards requirement for minimum egg solids content of 43 percent, the processor must effectively separate low-solids egg white from the egg yolk. In very cold eggs, the egg white clings to the yolk, requiring that the processor first temper the shell eggs at room temperature before breaking and separation.*

***UEP Comment:*** *We believe that FDA should give additional consideration to capital investment costs and operating costs associated with the proposed requirement to refrigerate eggs at 45°F prior to processing.*

### **Laboratory Capacity and Related Issues**

A reliable, technically proficient and robust laboratory system is critical to the success of FDA's proposed rule. Environmental testing and, where necessary, egg testing are the basic means of assessing the effectiveness of each producer's SE control program. Laboratories will need to –

- Test samples and report results in a timely manner;
- Carry out tests consistently according to accepted procedures;
- Operate with a high degree of reliability – false positives can be economically ruinous for the producer, while false negatives could jeopardize human health; and
- Provide services at a cost that is competitive and affordable.

In response to questions at a public meeting held in Maryland on October 28, FDA officials stated that they would not establish a fixed list of acceptable laboratories, and appeared to suggest that the agency would put the most stress on whether tests were conducted accurately, rather than on which laboratories are permitted to carry out the tests.

However, UEP believes FDA needs to provide some further clarity on this subject. UEP has identified the following issues in the proposed rule:

**Issue 11:** **Are public, private and in-house laboratories all equally acceptable to FDA for purposes of carrying out required environmental and egg tests?**

**Discussion:** *As discussed further elsewhere in this section, the proposed rule will create a substantial new workload for the nation's analytical laboratories. This workload will occur at*

*the same time that laboratories (sometimes the same ones) may be called on to conduct an enhanced level of testing for low pathogenic avian influenza. In light of these potential demands, it seems prudent to utilize all available laboratory capacity, but require that testing be carried out in accordance with scientifically accepted methods.*

**UEP Comment:** *We believe that both public and private (including in-house) laboratories should be able to carry out the tests required under the proposed rule.*

**Issue 12:** **Is current laboratory capacity adequate to handle an increased SE test level?**

*Discussion: There is no doubt that the proposed rule will require a substantial increase in the number of environmental and egg tests for SE. In its Preliminary Regulatory Impact Analysis (FR p. 56874), FDA estimates that 275,520 additional swabs will need to be tested, based on its assumptions about the amount of testing already being carried out. (In particular, FDA asserts that producers with more than 3,000 layers have 8,610 houses not presently in compliance and that on average, each of these houses would need to test 32 swabs.) FDA does not provide an explicit estimate of the number of new egg tests that will be required, but the agency asserts that the cost for testing 1,000 eggs will be \$1,859 (FR p. 58674) and also estimates the first-year cost of egg testing to be \$5,487,000 (FR p. 56885). Arithmetic suggests, therefore, that the agency expects just over 2,950 new egg tests initially.*

*These new tests will be required at approximately the same time that the federal government and private industry introduce a nationwide surveillance, control and indemnification program for low pathogenic avian influenza (LPAI). This program, which will be administered by the National Poultry Improvement Plan for commercial poultry, will require frequent and regular serological testing. Although these tests may not be carried out by the same personnel or departments in all states, experts have advised UEP (see discussion below) that an outbreak of LPAI (or, a fortiori, its highly pathogenic variant) could place a significant strain on laboratories as resources were diverted into LPAI testing.*

*During an October 7, 2004, conference call with scientific experts from academia and industry, UEP asked for advice on questions of laboratory adequacy. The experts were unanimous in believing that FDA should clarify lab eligibility. (FDA did subsequently provide some clarifications at the Maryland public meeting, which UEP appreciates.) Several experts, but not all, expressed the view that the current laboratory system was adequate, at least in some states. Among the experts' comments were that –*

- *Resource adequacy varies from state to state; not all states routinely do SE testing.*
- *The volume of egg testing that will be required is difficult to predict, since it depends on the prevalence and persistence of environmentally positive houses, which is also not known with certainty on a nationwide basis. Hence, if egg testing is required more often than expected, lab resources could be strained.*

- *Laboratory resources would be diverted in the event of a low pathogenic avian influenza (LPAI) outbreak, and this could also strain the system – e.g., delaying producers' receipt of test results.*

*Elsewhere in these comments, UEP is suggesting that FDA phase in the requirements of this rule over two years for all operations, rather than only for those with between 3,000 and 50,000 layers. A fundamental reason for this suggestion is FDA's need to develop, test, disseminate and evaluate training programs for the industry during the first of these two years following adoption of a final rule.*

*In light of UEP's belief that this phase-in period is appropriate, the organization also believes that FDA should devote resources – during the first year following adoption of a final rule, and before the effective date of that rule – to an assessment of laboratory capacity throughout the United States, in order to identify any gaps in the system and ascertain whether it is necessary to develop fallback procedures to assure continuity of testing during an unexpected event such as a LPAI outbreak.*

*UEP suggests that this assessment should be conducted in cooperation with state public health, veterinary and agricultural officials, who will be most knowledgeable of the public system in each state, as well as with the private sector. Should FDA determine that the current system would be unduly strained by the new testing requirements, FDA would retain the option of modifying the requirements or altering the phase-in period.*

**UEP Comment:** *FDA should carry out an assessment of laboratory capacity throughout the United States, in order to identify any gaps in the system and ascertain whether it is necessary to develop fallback procedures to assure continuity of testing during an unexpected event such as a LPAI outbreak.*

### **Cleaning and Disinfection**

FDA would require all producers to develop a cleaning and disinfection plan. In the event of a positive environmental test, the house would have to be both wet- and dry-cleaned after depopulation of the flock.

Cleaning and disinfection are important elements in most if not all EQAPs. However, the plans vary in their specific requirements. The Pennsylvania EQAP, for instance, requires wet and dry cleaning of a house with a positive flock. Cleaning and disinfection are not, however, required in negative houses. By contrast, the California EQAP requires cleaning and disinfection of all houses before placement of new flocks, but does not specifically require wet cleaning.

**Issue 13:** **Should the final rule require wet cleaning in all cases if a flock is found to be positive by an environmental test?**

*Discussion:* FDA acknowledges that the scientific evidence on the efficacy of wet cleaning is not conclusive. The agency states: “We are aware of studies that indicate that wet cleaning may have a detrimental effect on the SE status of a poultry house.” UEP found a similar divergence of views among the scientific experts we consulted. Several experts participating in recent conference calls felt there were serious questions about whether wet cleaning was necessary or even effective. However, at least one respected scientist believed that on balance, wet cleaning should be required and would be effective as long as manure was completely removed.

*Several objections have been raised to a wet-cleaning requirement:*

- *That it is impractical during the coldest months in some states;*
- *That it can actually be counterproductive by encouraging a “bloom” of SE;*
- *That existing equipment and cages were not designed to be wet-cleaned, and some mechanical and electrical parts should not be wet-cleaned; and*
- *That belts and feed delivery systems and the joints in cages may hold excess water and become rusted.*

*Since there is not a scientific consensus in favor of wet cleaning,, it seems unwise for FDA to mandate this practice in all circumstances. An alternative would be simply to require dry cleaning and disinfection after depopulation of an environmentally positive house. A second alternative would be to provide flexibility, allowing producers to either wet clean or carry out a cleaning of equivalent effect, taking into account weather conditions and other circumstances. This approach would be consistent with FDA’s approach elsewhere in the proposed rule: In several instances, the agency has listed a preferred means of achieving a particular goal, but has clearly permitted alternative means (cf. §118.4(b)(3) and (c)(1)-(2) in the proposed rule [FR p. 56894]).*

*A third option would create a positive incentive for the use of SE vaccines, as discussed more fully elsewhere in these comments. Under this alternative, wet cleaning would be optional for producers with an acceptable vaccination program.*

*FDA should recall that producers have every incentive to perform a thorough cleaning and disinfection in a positive house, whether wet or dry cleaning methods are used. The incentive is very simple: If the house environment remains positive, the next flock will have a greater likelihood of experiencing a positive environmental test and the subsequent cost of egg testing and, potentially, diversion. So a rational producer will not willingly neglect cleaning and disinfection. The issue with wet cleaning is not that producers do not wish to do it – the issue is that wet cleaning may be impractical in some climates during certain months, and that there is a danger it will actually make things worse and perpetuate or enhance the growth of SE.*

*Therefore, a fourth alternative would be to require wet cleaning if it appears dry cleaning is ineffective. Thus, if a house tested positive for the first time, only dry cleaning would be*

*required. But if a house tested positive a second time within a reasonable period, wet cleaning would be required unless there were overriding practical considerations that rendered it infeasible at that time.*

***UEP Comment:*** *UEP suggests that FDA modify its proposed language on cleaning and disinfection to (1) permit an exception to any wet cleaning requirements if cold weather makes it impractical, (2) permit dry cleaning alone (with wet cleaning optional) if a house tests positive for the first time in a multi-year period, and (3) permit dry cleaning alone (with wet cleaning optional) if a producer has implemented an approved SE vaccine program.*

**Issue 14:** **Is the requirement to “remove all visible manure” practical?**

*Discussion:* *FDA received several comments at its November 9 public meeting in Chicago on the practicality of the requirement to “remove all visible manure.” Egg producers are used to dealing with regulations governing shell eggs in which even minuscule specks of manure can affect the marketability of their product. In the context of a large building in which chickens are kept, the mandate to remove all visible manure raises real questions of practicality, the more so because no apparent flexibility is provided in the requirement.*

*Presumably, “all” means “all.” Thus, a producer could be in violation of FDA regulations if a single speck of manure could be located anywhere in a building which, only a short time before, held 125,000 chickens.*

*There is no question about the desirability of removing manure to the maximum extent that is practical. As noted above, producers have every incentive to do a good job of removal, because if they do not, they raise their odds of getting another environmental positive test. No producer will knowingly increase his odds of such a result.*

*The problem lies in the attempt to apply a “zero tolerance” approach to what is, at the end of the day, a farm – not an antiseptic food processing plant, but a farm on which animals live, eat and defecate. It is not realistic to suppose that every last trace of manure will be removed from this environment.*

*That does not mean that manure removal should go unmentioned in the final rule, however. Experts consulted by UEP generally concur that the less manure or other organic matter in the house, the less chance for a wet cleaning to trigger an SE “bloom” and defeat its purpose. Similarly, FDA notes that manure “is a reservoir of SE that has been shed by laying hens” (FR p. 56836).*

*What is needed is not the deletion of the requirement, but simply a common-sense recognition that these regulations are being applied on farms, not in food manufacturing plants or restaurants.*

*In addition to dealing with the apparently rigid standard of “all visible manure,” FDA also needs to recognize other operational needs. In particular, houses with manure pits store manure*

*for up to a year and, practically speaking, can only remove that manure at times when it can be applied to nearby farmland. In its final rule, FDA should clarify how it will treat these situations.*

**UEP Comment: UEP believes FDA should amend the manure-removal requirement to read: "Remove manure to the extent practical."**

### **Testing Methods**

In the proposed rule, the FDA specified in §118.8(a) that the method "Detection of Salmonella in Environmental Samples from Poultry Houses," January 19,2001, be used for environmental testing of poultry houses. In §188.8(b) it is specified that the method for egg testing is as outlined in the paper "Preenrichment versus direct selective agar plating for the detection of *Salmonella* Enteritidis in shell eggs," in the *Journal of Food Protection*, Vol. 66(9) 2003, Pages 1670-1674. The proposed rule allows for substitution of "equivalent" methods for both environmental and egg sampling. The requirements or procedures for demonstrating that methods are equivalent is not specified in the proposed rule.

**Issue 15: The proposed methods contain extra steps that may not be justified scientifically. The environmental testing method and the egg testing method contain extra media that have not been proven to be effective in isolating SE. The environmental test does not allow for pooling of the samples, which would reduce the number of samples the laboratory must run with no loss in sensitivity of the test.**

*Discussion: The methods currently in use vary and it would be helpful to have several, scientifically appropriate methods for the industry to use. The methods should be validated so that all laboratories are obtaining similar results. The method FDA proposed method differs from the National Poultry Improvement Plan (NPIP) method for SE testing (9 CFR 147 subpart B), as well as methods from other federal government agencies. The methods currently in use by the industry, state EQAPs, state laboratories, and private laboratories have proven to be effective for the purposes of the testing. FDA should work with scientists currently conducting SE testing of environmental and egg samples to identify appropriate laboratory methods recognizing that the goal is to accurately identify if SE is present in the environment and in the egg samples.*

*The bismuth sulfate (BS) agar should be eliminated from both the environmental testing and the egg testing methods. BS agar is the medium of choice for isolating *S. Typhi* from clinical samples. BS is not effective for environmental samples of SE, and therefore is an unnecessary step that should be eliminated from the method.*

*Two selective agar plates should be inoculated (BGN and XLT-4) instead of five as specified in the methods for egg testing. Brilliant green with novobiocin (BGN) and xylose lysine agar Tergitol 4 (XLT4) are the selective media that should be used for both environmental and egg*

*testing. If the proposed FDA method is followed and three plates are used for the streaking from both primary enrichments, we will start with a total of six plates. For a six-row house, this totals 72 plates if both sides of the manure pile are sampled. If five suspicious colonies are picked from each plate and inoculated into lysine iron agar (LIA) and triple sugar iron agar (TSI), this is 360 tubes of each medium for a total of 720 tubes of media. If BS is eliminated, the sample will be 48 plates, 240 tubes of each medium for a total of 480 tubes instead of 720. This change would result in a reduction of laboratory cost and time, while the result of the test would not be affected.*

**UEP comment: UEP recommends that FDA –**

- ◆ *Reduce the unnecessary steps in both the environmental testing and the egg testing. Both methods include additional steps and time and are not scientifically necessary for the purpose of this testing regime. The purpose of each test is to determine if SE is present in the environment (layer house) or in the eggs using a 1000 egg sample.*
- ◆ *Change the method to streak the enrichments onto two selective agar, BGN and XLT4 and not BS, unless the FDA has a strong scientific reason for doing so.*
- ◆ *Clarify the steps in the method for egg testing in the proposed method. For example, it is not clear if the 4 day incubation is required for the preenrichment method as it is in the APHIS method.*
- ◆ *Provide guidance on what the agency considers a "scientifically valid sampling procedure" (FR p. 56895) for environmental sampling. Clarify the sampling procedures for environmental samples including allowing the samples collected to be pooled. Pooling environmental samples would reduce the number of tests and cost, and would not change the final outcome of the test results.*
- ◆ *Consult with state EQAPs, laboratories, and industry to determine the appropriate methods for the purpose of the environmental and egg testing.*

**Issue 16: The methods proposed by FDA are specific, detailed and differ from methods the industry is currently using. The methods currently being used are accurately identifying SE in environmental and egg tests.**

*Discussion: The proposed methods do not allow for flexibility in the approval and adoption of new methods as improvements are made, or novel methods become commercially available. Since the regulation specifies two methods one for environmental and one for egg testing, there is little room to adopt new methods especially over time*

**UEP comment: UEP recommends that FDA –**

- *Allow for improvements in the methodology for Salmonella testing to be easily and quickly adopted by the industry upon validation of the new method.*
- *Work with other federal agencies with approved testing methods to facilitate approval of methods and to reduce the need for one facility to use several different methods for Salmonella testing. APHIS, NPIP, FSIS and scientific organizations all have approved methods for detecting Salmonella and SE. Methods need to provide*

*consistent results, yet be flexible enough to allow the industry to adapt quickly when improvements are made. For example, rapid testing methods are available and approved by some federal agencies (FSIS). The current proposed rule would not allow a producer to use a rapid method for testing of environmental or egg samples.*

- *Conduct a literature review and if necessary, additional research to determine what methods are appropriate to detect SE in the environment and egg samples. The goal should be to identify methods that are appropriate for the purpose of the testing and would be less costly (in both time and money) to the industry.*

### Biosecurity

Biosecurity is a critical tool for egg producers to protect their laying hens from infectious diseases. UEP agrees that all egg producers should have biosecurity plans implemented.

In the proposed rule, the FDA has outlined specific requirements for biosecurity (FR p 56894). These requirements include

1. Limiting visitors to farm and poultry houses
2. Shared equipment should be clean and not a source of SE contamination
3. Ensure hygiene of persons moving between houses with protective equipment and sanitizing stations
4. Prevent stray poultry, birds and other animals from entering the grounds and facilities
5. Not allowing employees to keep poultry at home

In several cases, FDA has proposed specific and prescriptive biosecurity measures to prevent SE contamination. Not all of the measures proposed are practical in every egg operation. FDA needs to administer biosecurity requirements with some degree of flexibility.

The agency has put provisions for flexibility in some of the biosecurity requirements, but not in others. For example, one requirement reads as follows: “(3) Ensure the proper hygiene of persons that move between poultry houses through use of protective clothing and sanitizing stations, or other appropriate means that will protect against cross contamination.” UEP feels strongly that FDA should permit the use of “other appropriate means,” as the proposed rule plainly says. In another case, however, the proposed rule appears to have no such flexibility: “(4) Prevent stray poultry, wild birds, and other animals from entering grounds and facilities.” FDA needs to consult with administrators of USDA’s National Organic Program on this requirement, because the regulations for organic egg production require access to the outdoors for organically raised hens, making it virtually impossible to prevent contact with wild birds and perhaps other animals. UEP has repeatedly expressed its view that this particular requirement is unnecessary and could contribute to the spread of avian influenza or other diseases, but our concerns have been ignored and the regulation remains in place. Several UEP members are organic or free-range producers. We assume FDA does not intend its proposed rule as a means of compelling these individuals to abandon organic or free-range production, but it is difficult to see how they will reconcile their normal practices with FDA’s proposed rule.

Beyond the issue of organic production, however, it is unclear how a producer could possibly prevent wild birds from entering the operation's "grounds and facilities" since these would include not only *inside* the henhouses but also the outside of buildings and the perimeter of buildings. There is no way that producers can prevent wild birds from flying over farming operations that typically cover several acres. It seems clear that the priority should be to keep wild birds out of the *interior* of houses, and to prohibit employee ownership of backyard flocks.

**Issue 17: Should FDA clarify the flexibility embodied in its biosecurity requirements?**

*Discussion: In order for the biosecurity plan to be effective it must be followed. If the plan contains measures that are not practical, then the risk is that the entire plan will not be put into effect. In that case, the biosecurity plans will not have any impact. Biosecurity plans are important for SE prevention as well as animal health protection. It would be more practical for producers to have one comprehensive biosecurity plan that incorporates their entire program. To require protective equipment between houses on a farm in every instance would be overly prescriptive and burdensome for producers.*

*In addition, little if any scientific evidence exists to determine whether personal protective equipment and sanitizing solutions between houses on one farm are either effective or necessary for SE control. FDA may be relying on anecdotal reports and opinion rather than science in this case. UEP strongly encourages its members to develop biosecurity plans and implement them. But the lack of scientific finality on the efficacy of biosecurity measures against SE lends support to a flexible application of biosecurity requirements.*

**UEP Comment: FDA should modify the on-farm biosecurity requirements in the proposed rule so that, for each component, other appropriate means of attaining biosecurity may be used instead of the means listed.**

**Administration, Enforcement and Related Issues**

Under the proposed rule, one individual at each farm must be responsible for administration of SE control measures. This individual is subject to training requirements, which may be waived because of equivalent work experience.

For in-line operations, the requirement is not overly onerous in itself. Each such operation would be likely to designate such an individual in the normal course of business. However, the situation of off-line operations served by (in most cases) individual contract producers is quite different. These producers tend to own operations of modest size and are likely to be diversified farms, with few if any full-time employees beyond the family that owns the farm.

These farms will find the designation and training requirements much more burdensome. Devoting two to three days to a training seminar may simply not be compatible with the

responsibilities of operating a diversified poultry and crop operation with minimal hired help. Although FDA states that work experience could substitute for the training requirement, it is unclear on what basis FDA would decide in individual cases if the training could be waived.

**Issue 18: Should the requirement to identify an individual responsible for SE control measures apply to each farm that supplies an off-line packing facility?**

*Discussion: The preponderance of newer egg facilities are in-line operations, but off-line operations remains a significant part of the industry. Contract producers may also produce other crops or livestock, and some may exit the egg industry if administrative and regulatory burdens become excessive. Presumably the federal government would not wish to encourage the exit of smaller firms from an already-consolidating industry; indeed, FDA has evinced a concern for small producers by exempting flocks of less than 3,000 from its proposed rule.*

*The requirement to designate an individual at each farm seems inconsistent with this desire to minimize burdens on smaller operations. Of course, someone does need to be in charge. But since all contract farms supply eggs to a central packing facility, and produce eggs to the specifications of that facility, it seems reasonable for the packing facility to designate an individual who could be responsible for multiple farms.*

*Such an arrangement would not obviate the need to provide information and training to individual contract producers, but would reduce the burden on them substantially. At the same time, it would maintain and clearly define accountability and responsibility.*

**UEP Comment: UEP suggests that FDA provide the option, for off-line operations, of designating one individual at each packing facility who could be responsible for SE control measures at all the farms supplying that facility.**

**Issue 19: What penalties apply to which violations of the regulations?**

*Discussion: FDA's discussion of enforcement and penalties (FR p. 56842) has prompted questions from some producers that the agency should clarify in a final rule. Several scenarios could be constructed, but the issue really involves the distinction between (1) violations of the on-farm provisions in the proposed rule (e.g., a rodent control program subsequently deemed inadequate by FDA), vs. (2) a violation of an order to destroy or divert eggs because of a regulatory violation. Do the criminal penalties cited under Sec. 361 of the PHS Act apply to any violation, even inadvertent, of the various regulations for on-farm control measures? Or do the criminal penalties apply where a producer actually violates a destruction or diversion order, with lesser penalties applying to other violations?*

**UEP Comment: UEP requests that FDA clarify the types of violations to which various levels of penalty would apply, and urges that criminal penalties apply only where a destruction or diversion order has been violated.**

**Issue 20: To ensure that its regulations are carried out in a realistic manner, should FDA establish a producer advisory committee?**

*Discussion:* FDA has proposed a rule with detailed requirements for the way egg farming operations are conducted. UEP understands the rationale for each requirement that has been proposed. However, UEP believes that –

- FDA wishes to write and enforce its regulations with a high degree of understanding of the industry affected, both to make those regulations more workable for the industry and also because the regulations are likely to be more effective in promoting good human health outcomes if they are realistic and practical; and
- Both FDA and UEP have benefited from dialogue and information exchange on a regular basis in recent years, as undoubtedly has been the case with respect to other private groups with which FDA has contact.

*If these beliefs are justified, it seems logical that FDA would want to establish a mechanism to obtain regular, expert advice on how emerging science, economic and structural trends within the egg industry, and technological advances may affect the agency's implementation of its regulations, and may suggest changes to those regulations as time goes on.*

*An advisory committee comprising egg producers and processors; scientific experts; state egg regulatory officials; and other interested parties would offer numerous benefits to FDA as it takes on the substantial responsibility of administering SE regulations. Such a committee would be a valuable sounding board for the agency, could advise FDA of relevant developments as they occur, and would bring a useful perspective to administration of the rules.*

**UEP Comment: FDA should establish a producer advisory committee on SE control, a body whose membership should comprise egg processors, scientific experts and state and federal egg regulatory officials in addition to egg producers. The advisory committee should be patterned after the successful public-private partnership that is the National Poultry Improvement Plan. The committee should be empowered to suggest changes to the SE regulations, with FDA having discretion whether to formally propose the suggested changes.**

### **Vaccination**

Vaccines to protect hens from Salmonella infection are being used in the United States by many egg producers. In recent years, producers have increased their use of vaccines as a cost-effective and efficacious means of preventing Salmonella infection. Vaccination against Salmonella infection is required or strongly encouraged by some countries such as the United Kingdom, Germany and Japan.

Two types of Salmonella vaccines are commercially available and are commonly referred to as "killed" and "live". Killed vaccines contain inactivated SE and must be injected into each hen. Killed vaccines are approved for administration at any point in the lifespan of the hens. Only one administration of the killed virus is required for the desired level of protection.

Live vaccines for Salmonella contain a live attenuated strain of *Salmonella* Typhimurium and may be administered in water or in aerosol form. Live vaccines are only approved for administration to young hens, usually prior to 16 weeks of age. Since the live vaccines can be administered in water or aerosol, the cost of administration is very low; however, two to three administrations are required for the desired level of protection. Killed and live vaccines are both used on their own and are effective. It is generally accepted in the industry that the maximum protection possible to protect hens from Salmonella is two doses of the live vaccine and one dose of killed vaccine. This regimen is frequently used on hens if they are placed in houses that have had a history of environmental positive Salmonella tests.

**Issue 21: Should FDA encourage vaccination and provide incentives for its use?**

*Discussion:* The FDA mentioned vaccines in the Supplementary Information section of the proposed rule (FR p. 56869), yet did not address vaccines in the proposed rule itself. UEP believes that vaccines are an effective control measure to prevent Salmonella infection and should be recognized by the FDA in the proposed rule since they significantly reduce the chances that SE would contaminate eggs. The cost of vaccines is not insignificant. Producers who vaccinate could be given an incentive to do so by modifying other requirements proposed in the rule.

*Vaccines have been an effective Salmonella prevention measure for producers in the United States. An egg industry survey (Bell, 2004) recently found that more than half (54.2%) of the respondents already vaccinate for SE, while 45.8% do not. The average vaccination cost per bird among these producers was 7.2 cents, and birds were vaccinated an average of 2.4 times. The survey results are interesting both because they show that a large segment of the egg industry already vaccinates, and also because they illustrate a considerable potential to reduce SE through more widespread adoption of vaccination by those producers who have not yet done so.*

*The Pennsylvania EQAP has been collecting data on the environmental status of layer houses and eggs laid by vaccinated hens since the pilot project in the early 1990s. Data from the pilot project showed that the prevalence of SE-positive eggs was nearly five times greater in unvaccinated flocks than in vaccinated flocks. Many producers nationwide have used vaccines effectively and have reduced or eliminated the incidence of Salmonella in the environment and in eggs.*

*The UK requires vaccination for its successful Lion Code program. The UK had a serious problem with SE in the late 1980s and early 1990s. The Lion Code program was adopted to improve the safety of eggs, and mandatory vaccination is a key component of that program.*

*Salmonella illness data from the UK have been improving significantly since 1998 when vaccination of laying hens became mandatory. British authorities believe that this reduction in illnesses from SE is largely due to the improved safety programs for eggs including vaccination.*

*According to a paper by Cogan and Humphrey (2003), citing data from the PHLS Salmonella Dataset, the number of SE cases in England and Wales dropped by more than half from 1998 to 2001. Vaccination of Lion Code eggs became mandatory in 1998.*

*A survey by the Food Standards Agency of the British government reports that Salmonella levels now are one-third their 1996 level. The survey found that the prevalence of Salmonella in retail boxes of eggs had fallen from 1 in 100 in 1995-96 to 1 in 290 (FSA, 2004).*

*The UK reports that salmonella is rarely found in laying hens and has not been found in over 150,000 egg tests. This information is quite significant, since eggs in the UK are not washed or refrigerated. Since washing and refrigeration of eggs is already required in the U.S., vaccination has the potential to further reduce the incidence of Salmonella contamination of eggs.*

*FDA has not placed major emphasis on vaccination in its SE control work, and may want to see additional evidence of its effectiveness. This is a reasonable expectation, and UEP recommends that FDA carefully review the substantial data that will be submitted during the comment period by vaccine makers and other experts in this area. UEP's recommendations will focus on how regulatory policy might recognize the value of vaccines and encourage their use, but do so in a manner that is based on evidence of effectiveness.*

*Such an approach could center around the proposition that if a producer can show favorable results through the use of vaccines, then his or her vaccination program may be regarded as an acceptable component of an overall SE control program. In turn, the addition of this component would provide a higher degree of confidence that the producer's flocks were extremely unlikely to be the source of an SE-related illness. Accordingly, certain provisions of FDA's proposed rule that will impose substantial costs on producers might be relaxed. For example, normally under the proposed rule, flock environments will be tested when the flock is 40-45 weeks of age and again about 20 weeks after the end of any molting period. This testing regimen may be regarded as a reasonable baseline. However, if FDA agrees that vaccination is effective in avoiding environmental positives among the flocks on a farm, the agency may wish to consider an alternative testing regimen that serves as a fail-safe check on the overall system's effectiveness – e.g., a requirement to test the environment two weeks or more prior to depopulation. (In this scenario, egg testing and diversion requirements would remain the same in the event of a positive environmental test, and a positive test would also require a return to the normal testing at 40-45 weeks, as well as subsequent post-molt testing if applicable.)*

***UEP Comment:*** *UEP does not believe that vaccination should be mandatory. FDA was correct in not requiring vaccination in the proposed rule. However, vaccines should receive recognition as an effective SE prevention measure. Vaccination has become significantly more common among producers in the several years since discussion of the proposed rule began, and its demonstrated effectiveness justifies some modifications in the basic regulatory structure contemplated by FDA for those producers who vaccinate, in order to encourage the practice and recognize the additional, voluntary producers costs entailed in vaccination.*

***In order to encourage vaccination of laying hens, UEP recommends that the FDA provide one or more of the following incentives for producers who follow an approved vaccination program:***

- ***Producers with an approved vaccination program would be exempt from wet cleaning requirements, but would be subject to dry cleaning and disinfection provisions; and***
- ***If producers implemented an effective vaccination program, then only one environmental test would be required two weeks prior to depopulation to verify that the environment is negative. The sampling and testing costs involved in this modification would be significantly lower than in the base requirement of testing at 40-45 weeks plus an additional test 20 weeks post-molt, which FDA estimates to cost nearly \$9 million if random sampling techniques are employed (FR p. 56883). Under this modification, egg testing and, if necessary, diversion would still be required in the event of an environmental positive. An environmental positive would also require the producer to return to the normal environmental testing at 40-45 weeks and 20 weeks after the end of any molt period.***

### **Indemnities**

The regulation of agricultural production, with the attendant costs that this oversight imposes on U.S. farms and ranches, is something that Congress and federal agencies have traditionally regarded as a serious matter. Regulations have generally been imposed on production agriculture only upon a clear showing that they were required by the public interest. Thus, for example, the public interest in preventing the spread of animal diseases such as avian influenza has been used to justify emergency measures such as quarantines and the destruction of large numbers of animals.

In such situations, producers have frequently been compensated for all or some of the costs associated with the regulation. In the case of animal diseases, the U.S. Department of Agriculture has normally calculated the value of an animal required to be destroyed and paid all or a portion of that value to the producer who owned the animal.

The rationale for paying such indemnities has been articulated in different ways, but the following reasons may be cited:

- Quarantine and destruction impose concentrated costs on an individual farm, but provide benefits that are diffused throughout society. Thus, there is a rational basis for compensating the individual in recognition of the benefit his act confers on society.
- Depending on the circumstances, a “takings” claim under the U.S. Constitution might lie against the government’s action were it completely uncompensated.
- Unlike many other types of businesses, agricultural producers have virtually no ability to set their own selling price and pass on higher costs to their customers, since they sell

fungible, undifferentiated commodities in an environment of near-textbook “perfect competition” on the selling side, with much more concentration and market power on the buying side. These economic considerations provide a further rationale for indemnities, since otherwise all costs would be concentrated on the producer, who in some cases might well go out of business without compensation.

- An indemnity compensates the producer for an event that was not his or her fault. Animal disease outbreaks occur despite the best efforts of producers to prevent them (though normally indemnities are *not* paid if a producer has been uncooperative or a “bad actor”).
- Indemnities or other compensation provide incentives for producers to cooperate with regulatory programs, and in the total absence of compensation, a moral hazard may exist where producers have a motivation not to disclose unfavorable results, e.g., positive test results.

Each of these rationales applies equally to SE control, although they have been most frequently cited in justifying indemnities for animal-health-related losses. Indeed, the argument for compensation is if anything stronger where human health, and not just animal health, is implicated. The need to ensure cooperation; the motivation to avoid penalizing producers who have implemented required precautions conscientiously; the imperative to avoid any potential legal challenges – all these seem stronger rather than weaker when the objective is preventing human illness.

In any case, it needs to be understood that the economic stakes for egg producers are high. The FDA estimates the annual total cost to the egg industry of diverting eggs from SE-positive flocks will be only \$5 million. However, this estimate assumes that all such eggs will be salable at a discount. As explained in more detail elsewhere in these comments, this assumption is subject to argument. In a survey conducted for UEP by the University of California’s poultry specialist emeritus, more than 40% of producers expected that egg processors will refuse to take eggs from SE-positive flocks at *any* price. If that turns out to be true – i.e., if 40% of egg producers turn out to be better predictors of egg-processor behavior than the federal officials who wrote the FDA’s proposed rule – then any egg operation with a positive egg test potentially faces economic devastation.

In such a case, the survivors will be the largest operations – those with more than one site or multiple laying houses, such that the loss of production in a single house would be a survivable event. For smaller producers, a positive egg test might *not* be a survivable event. The result would be the smaller producer’s forced liquidation or acquisition by a larger operator. The consolidation that has occurred throughout much of production agriculture in recent years – including in the egg industry – would then be accelerated because of federal regulations. This is not a result that FDA should simply accept without giving some thought to the alternatives.

**Issue 22: Should FDA design and implement indemnities to cover some or all costs attendant on positive SE results, especially where diversion to breaking is required?**

*Discussion:* UEP is aware that FDA states it does not have legal authority to pay indemnities. However, FDA also defends its authority to issue prescriptive, detailed regulations to govern egg production methods. Such authority is also not specifically mentioned in any statute, but FDA argues it possesses the authority nonetheless: “The P[ublic] H[ealth] S[ervice] Act authorizes the Secretary to make and enforce such regulations as ‘are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States \* \* \* or from one State \* \* \* into any other State’ (section 361(a) of the PHS Act).” (FR p. 56842)

*If the PHS Act grants the authority to impose regulation on privately-owned farms, and also grants the authority to expend federal resources (salaries, travel budgets, etc.) in pursuit of the development and enforcement of such regulations, might the Act not also grant the authority to expend federal resources in pursuit of fair treatment of, and cooperation from, producers?*

*Some additional legal analysis by FDA of this question seems advisable. Even if the agency concludes it does not presently possess the legal authority to pay indemnities, it should consider whether to request such authority from Congress.*

*An indemnity program would not, presumably, offset normal costs of implementing an SE control program. Thus, costs involved in rodent control, biosecurity and the like will be substantial, but likely would not be indemnified. Instead, indemnities would most logically be paid on the loss in value in egg production from a flock where a positive egg test required diversion to breaking. This loss in value, notionally, would be based on the difference in price actually received for eggs during the period of diversion, compared to the price received for other eggs sold into the table market during the same period by the producer (or other producers), as documented through bills or sale or other appropriate means.*

**UEP Comment: FDA should re-examine its present legal authorities to determine whether an indemnity program for losses related to SE-positive flocks could be developed. In the event FDA determines it has no such legal authority, the agency should request specific authority from Congress.**

### **Issues Raised by FDA**

In this section of our comments, UEP provides brief responses to all issues raised for comment by FDA. In several cases, we simply refer to other sections of this document where we have discussed the same or a similar issue in substantially more detail. As is the case throughout these comments, listed page numbers are those in the document published in the *Federal Register* of September 22, 2004.

Recordkeeping

Pages 56825 and 56841

“We also are soliciting comment on whether we should include additional requirements in the final rule, particularly in two areas. First, should we expand the recordkeeping requirements to include a written SE prevention plan and records for compliance with the SE prevention measures?”

***UEP Comment:*** *A written SE prevention plan will undoubtedly be an important management tool for most egg producers, and indeed many operations undoubtedly have such a plan. However, we do not believe it is necessary for FDA to mandate such a document. It would be a mistake for FDA to place undue emphasis on paperwork and documents, as opposed to actual results. What really matters, after all, is whether an operation does or does not have a problem with SE. Instead of mandating a written plan, UEP suggests that FDA work with us and other interested parties to develop a model SE prevention plan that could be provided to producers for their use.*

Food code guidelines mandated

Page 56825

“Second, should the safe egg handling and preparation practices in FDA's 2001 Model Food Code (as outlined in section IV.D of this document) be federally mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers)? These issues are discussed in more detail in the following relevant sections of this document.”

***UEP Comment:*** *Earlier in these comments, UEP has stated our support for codification of certain safe handling and preparation practices.*

Exemption for less than 3,000 birds

Page 56832

“We are soliciting comment on the exemption for producers with fewer than 3,000 laying hens and producers who sell all of their eggs directly to consumers. Specifically, should these producers be covered by some or all of the SE prevention measures?”

***UEP Comment:*** *The strongest argument for exempting flocks of less than 3,000 birds is administrative convenience – inspecting these sites would greatly expand the number of annual inspections and therefore the demand on federal and state personnel. However, UEP is concerned that FDA appears to have made a decision to exempt small flocks without much supporting evidence. Many UEP members believe that small flocks are –*

- *Less likely to have refrigeration capacity;*
- *Less likely to have an effective rodent control or biosecurity program;*
- *More likely to be exposed to manure on building floors and exposed to the outdoors, both conditions which risk more exposure to Salmonella; and*

- *Possibly more at risk for transporting eggs improperly or holding them for longer periods without refrigeration.*

*We do not state these views as facts, only as impressions conveyed by our membership – and that is really the point, since we are not sure FDA is presently in a position to support or refute these concerns. We are unaware of research that would specifically demonstrate that the smallest operations are either more or less likely to have an SE problem than larger, commercial operations. And yet since these small operations frequently sell directly to the ultimate consumer, we would think it would be of some concern to FDA. Therefore, until FDA can demonstrate the safety of a small-flock exemption, UEP cannot support such an exemption.*

*Sec. 118.1, which provides for an exemption for flocks of fewer than 3,000 laying hens, also raises another issue of intent with respect to coverage of the proposed rule. Under Sec. 118.1, the basic coverage tests apply to "a particular farm," in language that implies that one "producer" might operate more than one "particular farm" and thus be subject to the proposed rule on some farms, but not on others. FDA may wish to consider whether this construct creates any perverse incentives.*

*For example, if an operation is so configured that only one house out of a large number of houses, perhaps at several sites, is intended to sell surplus eggs into the table egg market, then it could be argued on the basis of Sec. 118.1 that all the other houses owned by that operation would be exempt from most provisions of the proposed rule. Since eggs are fungible, there would seem to be a significant likelihood that eggs from unregulated houses would be sold into the table egg market instead of eggs from the regulated house. This might occur for a variety of reasons, including when flocks were placed into, and depopulated from, the respective houses.*

*From an economic standpoint, the owner of these facilities might be indifferent as to which house supplied the eggs sold into the table market. From a food safety standpoint, however, FDA might well feel that it made a substantial difference -- since the eggs from the unregulated house, ostensibly intended for further processing and pasteurization, would not have been produced under the same stringent regulations as eggs from the regulated house. Where a single ownership structure is permitted to accommodate both regulated and unregulated houses, it is difficult to see how such substitution can be prevented, in a practical sense.*

*FDA may therefore wish to consider striking the phrase 'at a particular farm' from the first sentence of Sec. 118.1, and similarly striking the phrase 'at the particular farm' in the two places where it occurs in Secs. 118.1(a) and 118.1(b), respectively.*

5 log reduction appropriate?

“We are soliciting comment on whether a 5-log reduction or an alternative approach to achieve an equivalent level of protection is still appropriate to ensure the safety of shell eggs. We intend to work with USDA to ensure that shell eggs and egg products are given adequate treatments to destroy SE.”

***UEP Comment:*** *UEP, in conjunction with the further processor division of United Egg Association and the American Egg Board, arranged for a survey of egg processors to determine their current pasteurization practices. After looking at the results of this survey, we conclude that from a regulatory standpoint, a 5-log reduction remains the appropriate requirement. Many processors achieve a substantially greater kill than the mandated level. Specifically, 50% of respondents indicated that they achieve a 5-log reduction, while the other 50% reported a 7-log or greater reduction.*

*The current 5-log reduction requirement appears to provide an extra margin of safety, since specified temperatures and holding times do not take into account the additional kill achieved in the product while it is heating up to, and cooling down from, the pasteurization temperature. We do not see a need to change the 5-log standard at this time.*

*UEA and UEP worked with the American Egg Board to develop an International Egg Pasteurization Manual, a project carried out by a team of distinguished researchers at three universities, led by Dr. Glenn W. Froning of the University of Nebraska. This manual reflects a multi-year effort to update pasteurization times and temperatures for a range of products at various pH levels. Given the impressive results documented in the pasteurization manual, we believe the 5-log requirement should be regarded as entirely sufficient at this time. We note that the pasteurization manual won praise from food safety leaders at USDA, including then-Administrator William Hudnall of the Food Safety and Inspection Service, who wrote that “FSIS believes the data from the University of Nebraska study provide a reliable source of information for use in developing models for predicting the lethality of Salmonella spp. for pasteurization treatments and thus can be considered in developing guidelines.”*

Certify that pullets come from SE monitored facility?

page 56835

“We specifically request comment on whether we should include in any final rule based on this proposal, a requirement that producers certify that pullets they procure have come from a facility that has an SE-monitoring program. If so, what requirements should producers certify that a pullet-raising facility has met in order to ensure that the pullet raising facility has an adequate SE-monitoring program?”

***UEP Comment:*** *UEP feels that the proposed rule’s requirement -- to acquire chicks and pullets that came as chicks from SE-monitored breeder flocks meeting NPIP standards – should be a sufficient safeguard at this time.*

Comment and data on wet cleaning  
Page 56836

“Because there is some evidence, though inconclusive, suggesting that wet cleaning may result in an SE-positive poultry house environment, we specifically request comment and data on this subject.

***UEP Comment:*** *UEP commented extensively on this subject earlier in this document. In summary, our own consultations with scientific experts lead us to conclude that no scientific consensus exists on whether wet cleaning is generally beneficial, or can risk generating an SE “bloom.” Because of this lack of consensus, and the practical difficulties that a wet cleaning requirement would create during colder months, UEP has suggested a flexible approach that would permit weather-based exceptions, generally make wet cleaning optional where an approved vaccination program is in place, and also make wet cleaning optional where a house tests positive for the first time in a multi-year period.*

Refrigeration and sweating  
Page 56837

“We seek comment and data on the impact of refrigeration on eggs after they leave the farm, such as the possibility that the eggs may ‘sweat’ when removed from refrigeration.”

***UEP Comment:*** *UEP believes that “sweating” is a legitimate concern, and must be weighed against other considerations as FDA determines what refrigeration requirements to include in a final rule. When UEP convened a discussion among scientific experts on egg science and technology, one scientist stated that sweating would likely be a problem in eggs that are subsequently tempered before processing. Another scientist reported observing mold growth in only a few hours after eggs had “sweated.” UEP believes the modifications to the refrigeration requirement which we have suggested elsewhere in this document would mitigate concerns about sweating.*

36 hour refrigeration requirement  
Page 56837

“We are soliciting comment and data on the 36-hour threshold that eggs may be held unrefrigerated at a farm. Is this time frame practical for producers with daily egg pickup? Is it practical to refrigerate eggs held at farms for less than 36 hours?”

***UEP Comment:*** *UEP has commented extensively in this issue earlier in this document. In our judgment, a 36-hour time frame would be workable, in most cases, for producers with daily egg pickup. But that is not really the issue, because many producers in off-line operations do not have daily egg pickup. Practical considerations like the capacity of the central packing facility, and how many trucks and drivers are available, determine the frequency of egg pickup. Even on farms with daily pickup, the 36-hour requirement might not be feasible over weekends or holidays.*

*From our cost survey of producers, it appears that it is not practical to refrigerate eggs held at farms for less than 36 hours, given the extensive new equipment purchases which would be necessary for a significant portion of the egg industry. The cost survey is attached to these comments, and its implications are discussed earlier in the comments, in the section on refrigeration.*

*We have elsewhere suggested modifications to the 36-hour requirement which are consistent with available science and would accommodate the needs of small, off-line contract producers. The existing requirement, while feasible for in-line operations, is not feasible for off-line operations, and therefore discriminates against smaller producers: They are the operations which supply eggs to off-line packing facilities.*

*The 36-hour requirement is also impractical and unnecessary for egg processors who have dedicated production. Every one of the eggs so refrigerated will subsequently be pasteurized. This kill step makes refrigeration unnecessary as long as the eggs move regularly into the processing facility. Again, 36 hours is too short a time to be practical, since processing plants may be closed over weekends and holidays.*

#### Alternative regulatory schemes

Page 56830

“We are soliciting comment and data on alternative regulatory schemes that would achieve the same public health protection as the set of measures we are currently proposing. One possibility is a requirement for a specified frequency of environmental testing for all producers, followed, if necessary, by egg testing and diversion. As long as producers were maintaining poultry houses that tested negative for SE, the SE prevention measures would be recommended but not required. However, some or all of the measures may be required of producers whose houses were contaminated with SE. We solicit comment on a testing-based regulatory scheme and combinations of the prevention measures that might achieve the same public health goals as the current proposal.”

***UEP Comment:*** *Elsewhere in these comments, UEP has proposed a “recognition regime” that would accommodate existing state and industry EQAPs. Conceptually, a recognition regime is similar to the alternative regulatory scheme described here, in that producers would continue to comply with on-farm measures prescribed under the existing EQAPs, but would need to test and divert in accordance with FDA rules. UEP is also receptive to the concept laid out by FDA in its discussion of alternative regulatory schemes. We do believe that the increased flexibility implied by the alternative scheme needs to be balanced against the value of having all industry participants competing on equal terms and applying similar measures*

#### Methods for environmental sampling

Page 56839

“We are specifically soliciting comment on the appropriateness of different methods of drag swabbing, including manure belt and floor swabbing, and egg machinery swabbing. We would like comments on the distance an individual swab should be dragged and

whether or not it is necessary to drag every row of every house. We would also like comments on alternative methods of sampling (e.g., sampling of the air in a poultry house to detect SE) that could be utilized more uniformly in different styles of poultry houses. Based on comments received, we will consider what poultry house environmental sampling methods should be required in any final rule.”

***UEP Comment:*** *We believe FDA should permit but not require alternative methods of sampling, and continually evaluate the best sampling methods as more science becomes available. In a recent egg industry survey, responding producers reported most frequently sampling manure pits (44.9%) and egg belts (26.1%). Among responding producers, 81.3% already conduct some sampling. UEP encourages FDA to apply sampling requirements with some measure of flexibility, because*

- *Producers already have considerable experience in sampling, so substantial reliance should be placed on their ability to collect samples in an appropriate manner;*
- *Producers in many states are sampling in accord with the provisions of state EQAPS, which have been shown to be effective in reducing illness – a track record that should give FDA comfort in relying on existing sampling practices; and*
- *FDA should avoid unnecessarily increasing sampling costs, which are already substantial – on average, the survey respondents estimated the cost of one environmental sample at \$76.54 (Bell, 2004).*

#### Egg sampling intervals

Page 56839

“We are proposing that eggs be tested in 2-week intervals because infected flocks shed SE intermittently (Ref. 14). However, the false negative rate of the sampling scheme is sensitive to the assumption regarding the prevalence of SE-contaminated eggs (Ref. 61). We are soliciting comment on this assumption, as well as other scientifically valid egg sampling procedures.”

***UEP Comment:*** *FDA has spent several years developing the proposed rule, including the present scheme for egg testing. UEP believes the egg testing requirements in the proposed rule, based on the best available science, should not be changed until there is new scientific evidence justifying a change. Already, egg testing is one of the more costly components of the proposed rule, and some UEP members have expressed concern about this issue. With current testing methods, false negatives should not be a concern.*

#### Registration with FDA?

Page 56841-2

“We also are soliciting comment about whether we should consider requiring, in a final rule, that you register with FDA if you are a producer who must comply with all of the SE prevention measures, as described in proposed Sec. 118.1(a). We would use the producer registration information to create a database that we would use to efficiently conduct inspections and allocate inspection resources. When the provisions of this rule

are finalized, FDA intends to conduct annual inspections of egg farms. Oversight through annual inspection is necessary to ensure that shell eggs are being produced under controls that will prevent SE contamination and reduce the likelihood that SE-contaminated eggs will cause foodborne illness. Therefore, we solicit comment on the efficacy of requiring that producers register the location and size of their business with FDA.”

***UEP Comment: Every producer with packing facilities is registered with the FDA under the bioterrorism rule (21 CFR 1.225- 1.243) and should not be required to register a second time. All egg-producing farms that do not pack their own eggs will have a relationship, contractual or otherwise, with a packing facility. The latter facilities, already registered with FDA, would need to have information about individual farms from which they receive eggs. Regardless, producers that do not pack eggs, but sell eggs that will ultimately go into the table egg market, should be registered so that FDA can assure these firms are following the on-farm production and testing requirements of the SE rule.***

Induced molting

Page 56847

“We specifically request comment and data related to our discussion of induced molting. In view of the scientific data that suggest that molting by feed withdrawal may increase shedding of SE into the environment or eggs (Refs. 68, 70, and 71), we seek comment on the following potential prevention measures that we may consider for inclusion in any final rule: (1) The use of alternative diets to replace feed and water withdrawal to induce molting, (2) the use of competitive exclusion (defined in footnote 3 of this document) to reduce fecal shedding of SE during molting, (3) more frequent removal of manure during and immediately following molting, (4) alternative timing for environmental testing or additional environmental testing during or immediately following molting, and (5) a prohibition of molting in SE-positive houses. Depending upon the comments received, we will consider including provisions regarding molting in any final rule. These provisions may include, but are not limited to, the need for additional testing of molted flocks or restrictions on the manner in which a molt may be induced.”

***UEP Comments: UEP believes FDA was correct in its decision not to include molting components in the proposed rule. Much of the research on which claims about post-molt SE shed are based has been laboratory rather than field research, involving large challenge doses of SE that would not be duplicated in the field, as well as strains of chickens different from those common in commercial laying operations. We attach a letter from a distinguished federal government scientist, Dr. Jean Guard Bouldin, who has published extensively on SE. Her letter compares outcomes in the United States and the European Union and states: “The epidemiological outcome strongly suggests that molting does not impact food safety associated with the problem of egg contamination, because Europe still has a much worse problem than does the United States.” In discussing recent scientific work, she also states: “It is possible that molting is providing a type of vaccination, or a type of competition, that is suppressing***

***widespread emergence of the most dangerous [SE] subpopulations within the United States.” She concludes that “the United States should not abandon molting as a management practice.”***

***We have provided Dr. Bouldin’s letter, as well as a related peer-reviewed article, to illustrate that there is no scientific consensus that molting is a food safety issue. A number of UEP members have adopted alternative regimens, notably the use of wheat middlings or other feed substitutes, to induce a molt. However, producers have not adopted these regimens out of food safety concerns, because as we have already noted, there is no consensus that induced molting is problematic for food safety.***

***UEP does not believe science justifies any provisions on molting in the final rule, and would oppose such provisions.***

**Washing eggs in offline operations?**

Page 56848

“We request comment specifically on the prevalence of on-farm washing of eggs in offline operations. If comments indicate that prewashing of eggs on the farm is more prevalent than indicated in data the agency currently have, we may consider adding a provision for washing of eggs to the required SE-prevention measures.”

***UEP Comment: In general, eggs are not washed at off-line farms, but at packing facilities to which they are transported. UEP does not believe it would be practical to require on-farm prewashing of eggs. Such a requirement would impose significant costs on farmers, and to no apparent purpose: These eggs are all washed before they are packed anyway.***

**Refrigerated transport from farm to plant?**

Page 56849

“In order to close any gaps in the farm-to-table continuum, FDA is seeking comment on whether to require refrigerated transport of shell eggs not already required by regulation or within USDA's jurisdiction; for example, transport of shell eggs from a farm or a packer to a food manufacturing facility. We will consider putting into place requirements similar to those we finalized for refrigerated storage of shell eggs at retail (i.e., transport of shell eggs at or below 45 [deg]F ambient temperature).”

***UEP Comment: UEP is not aware of significant gaps in coverage of the refrigeration requirements. Eggs being transported to a “food manufacturing facility,” for instance, would likely be processed egg products and therefore would already be refrigerated during transport. In other cases, such as off-line farms supplying eggs to a packing facility, the farms are almost always in relatively close proximity to the packing house, reducing any concerns about unrefrigerated transportation.***

**Food code – high risk population**

Page 56850

“If you contend that the desired public health outcome for high-risk populations can only be achieved through mandatory Federal standards, we specifically request comment on which, if any, of the following measures should be mandated for retail establishments that serve highly susceptible populations:

- Using raw eggs that are clean, sound, and meet the restricted egg tolerances for U.S. Consumer Grade B, which minimizes the entry of surface bacteria to the inside of eggs;
- Using raw eggs that have been transported under refrigeration, because refrigeration lengthens the effectiveness of the eggs' natural defenses against SE and slows the growth rate of SE;
- Using only egg products that have been pasteurized in accordance with USDA's requirements under 9 CFR 590.570, which are designed to kill or inactivate SE and other bacteria;
- Cooking raw eggs and raw egg-containing foods thoroughly, which kills viable SE that may be present;
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods, e.g., soft-boiled, poached, or sunny-side-up eggs, meringue, Caesar salad, hollandaise or Bearnaise sauce, homemade mayonnaise, eggnog, homemade ice cream, that will be served undercooked, which minimizes the risk of egg-associated SE illnesses in consumers of those foods; and
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods where eggs are combined, since combining raw eggs to prepare a large volume of food that is subsequently temperature-abused or inadequately cooked can cause illness in large numbers of people if any of the eggs were initially contaminated with SE.

If FDA were to require any of these measures, we would rely on section 361 of the PHS Act, just as we are relying on it for the requirements we are proposing in this document. (See section III.L of this document.)”

***UEP Comment: UEP supports codifying the Food Code provisions listed above with respect to institutions serving vulnerable populations, as we have discussed in detail earlier in these comments. The listed provisions are, in our judgment, the only Food Code provisions which should be codified at this time.***

#### Program Management Cost

Page 56886

“In table 34 of this document, we include a cost for program management, because we assume that some management will be necessary to plan and carry out the provisions of the proposed rule. We assume that program management costs will be roughly equal to the cost of the potential plan design with eight provisions. We ask for comment on this assumption.”

***UEP Comment: This assumption is described in a somewhat confusing manner, but UEP questions whether the assumed \$2,672,000 industry-wide cost is realistic. In many operations,***

*additional amounts of time by management and technical employees will need to be devoted to SE control measures. Elsewhere in these comments, we have suggested that some of FDA's cost estimates (e.g., the total cost of diversion) are likely too low. We recommend that FDA study closely the producer cost survey which is attached to these comments, for additional perspective on what producers believe their costs will be. For example, nearly 20% of the respondents do not presently carry out environmental testing, so the value of new management and technical time devoted to this activity is likely to be substantial, above and beyond the testing costs themselves.*

Burden of record keeping for testing and diversion

Page 56886

“We ask for comment regarding the actual burden of keeping records associated with the testing and diversion provisions of the proposed rule.”

***UEP Comment:*** *The integrity of an SE control program requires adequate record keeping. Keeping appropriate records is also in producers' interest. Records should be concise, complete and easily accessed. In general, UEP believes the proposed rule requires an appropriate level of record-keeping. UEP also strongly commends FDA's statement (FR p. 56841) that “we intend to consider records that come into our possession under this rule as generally meeting the definition of a trade secret or commercial confidential materials.” However, UEP is not certain whether this intention is entirely consistent with actual agency practice or informal statements, and anticipates that some special interest groups might challenge FDA's interpretation. Therefore, UEP urges FDA to provide a more complete, definitive discussion in the final rule that will explain to producers exactly what information is to be considered commercial confidential or a trade secret, and under what legal authority FDA will defend this designation against any legal challenges.*

Comments related to paperwork reduction act

Page 56890

“FDA invites comments on these topics:

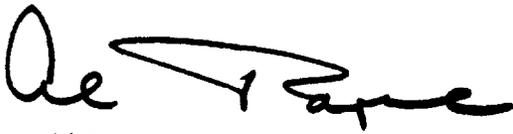
- (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;
- (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, or other forms of information technology.”

**UEP Comment:** See our response to the previous item.

**Conclusion**

On behalf of the nation's egg producers, UEP appreciates this opportunity to file detailed comments on a regulation that will profoundly affect our industry. We share common goals with FDA, as responsible food producers who want to deliver safe eggs to our customers. We have tried to make constructive suggestions for improving the proposed rule so that it will be workable for the industry, faithful to its goals, and defensible on sound scientific grounds. Thank you for your attention to our comments.

Sincerely,



Al Pope  
President



Roger Deffner  
Chairman of the Board

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Personal Communication via telephone conference convened by United Egg Producers, Oct. 7, 2004, with individual follow-up calls on subsequent days. Participants included Howard Magwire, Randy Green, Gene Gregory (all UEP), Hilary Shallo Thesmar, PhD., RD, Marcia Greenblum, MS, RD (Egg Nutrition Center), Rich Dutton DVM (Michael Foods), Dave Halvorson, DVM, (University of Minnesota), Joe Madden, PhD (Neogen Corporation), Doug Waltman, PhD (Georgia Poultry Laboratory), Gary Waters, DVM (Moark LLC/Land-O-Lakes), Debbie Murdock (Pacific Poultry and Egg Producers Association) and several other scientists and professionals from academia and industry.

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[http://www.fsis.usda.gov/OPPDE/rdad/Acts/epia\\_toc.htm](http://www.fsis.usda.gov/OPPDE/rdad/Acts/epia_toc.htm)

United Egg Producers, UEP "5 Star" Total Quality Assurance Program: A HACCP type *food* safety program with validation. (document attached)

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