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Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

Re: **Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504; Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; 69 FR 56824 (September 22, 2004)**

Dear Sir or Madam:

John R. Cady  
President and  
Chief Executive Officer

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, egg products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

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NFPA appreciates the opportunity to comment on this important rulemaking initiative.

General support

FDA is proposing to require environmental testing for *Salmonella* Enteritidis (SE) when the flock in the poultry house is 40 to 45 weeks of age and 20 weeks after the end of any induced molting. If SE is detected, egg testing or diversion to treatment (to achieve a 5-log reduction of SE) would begin. In general, NFPA supports the requirement to test for SE in the environment and to require SE testing of eggs if the environmental test results are positive for SE. We believe this is a reasonable approach. Nevertheless, we understand that there are a number of state egg quality assurance programs that already incorporate certain strategies similar to those being proposed. To the extent that these programs are documented as achieving significant food safety successes, it would be helpful if the FDA rule would recognize those programs as one way to meet, or at least partially meet, the proposed requirements.

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Preventing SE at restaurants and food service facilities

Since not all states have adopted the Food Code, and some may have adopted only parts of it, FDA should consider incorporation of the provision of the Food Code listed in 3-801.11 (B) into this rulemaking. This provision requires that food establishments serving highly susceptible populations use pasteurized eggs in recipes where eggs are raw or undercooked (e.g., Caesar salad, hollandaise sauce, eggnog); and if eggs are combined, unless eggs are cooked to order and immediately served, if eggs are used immediately before baking and thoroughly cooked, or a HACCP plan controls *Salmonella* Enteritidis. Other than these exceptions, restaurants and food service facilities serving highly susceptible populations should only be using liquid pasteurized eggs or eggs that have been pasteurized in the shell. Highly susceptible populations should not be served raw or undercooked eggs or foods containing raw or undercooked eggs.

Refrigeration of shell eggs

We question the need for the provision found at §118.4(e) requiring eggs to be refrigerated at 45°F within 36 hours of laying. This is neither a reasonable nor a scientifically justified requirement, especially for eggs that are destined for breaking or for hard cooked egg processors. Eggs that are broken are quickly chilled to less than 40°F within minutes after breaking. Studies have shown that *Salmonella* numbers may increase rapidly in artificially inoculated eggs. However, research has determined that naturally contaminated eggs contain  $\leq 10$  SE per egg, even when stored at room temperature up to 7 days, (Humphrey et al. Epidemiol. Infect. 103: 415-523, 1989). In fact, Humphrey et al. (Epidemiol. Infect. 106: 489-496, 1991) showed that SE-contaminated eggs had levels  $<20$  per egg when stored at room temperature up to 21 days; higher levels were only found after this time. Given the low numbers of SE that may be present in freshly laid eggs and the length of time between laying and treatment, it is unlikely that numbers of SE would increase to levels that would render the treatments ineffective. This is supported by the fact that no documented cases of SE have ever been associated with pasteurized eggs.

While it may be appropriate to refrigerate retail shell eggs at 45°F, in the absence of a scientific justification to do otherwise, there should be no need to require eggs to be refrigerated within 36 hours. We believe that the requirement to refrigerate shell eggs within 36 hrs could actually be counter-productive in regard to the safety of eggs destined for use in the table market. This is due to the fact that more checks and cracks will occur when previously refrigerated eggs are washed due to the greater change in temperature. There was increased penetration of cooled eggs by SE over that of control (not cooled) eggs when eggs were dipped in buffered peptone water containing approximately 5 CFU of SE per ml (Fajardo et al. J. Food Protection 58:473-477. 1995), presumably due to the fact that cracks were more numerous and larger in shells of eggs that had been cooled.

We recommend that FDA not set a prescriptive time requirement for refrigeration of table eggs at 45°F unless further research justifies the need. If the agency believes that a time requirement is absolutely necessary at this time, it should be more practical, e.g., 72 hours.

We also question the need for the provision found at §118.1(b) that requires that eggs that receive a treatment as defined in §118.3 (5- log destruction of SE for shell eggs, or processing in accord with the Egg Products Inspection Act) must also comply with the refrigeration provision delineated in §118.4(e). Particularly if these eggs are intended for use in further manufacturing, such a requirement will create a burden, but will in no way contribute to enhanced food safety. We believe that no specific storage temperature should be mandated for shell eggs that will receive a treatment to achieve a 5-log reduction of SE. At a minimum, the refrigeration requirement should not apply to eggs destined for breaking unless they are to be held more than 72 hours (which would address eggs that remain in a hen house over a long weekend).

We suggest the language be amended as follows.

Sec. 118.4 *Salmonella* Enteritidis (SE) prevention measures.

(e) "Refrigeration. You must store eggs at or below 45°F ambient temperature if you hold them for more than 72 hours after laying."

Furthermore, certain unintended adverse product quality consequences that would arise from such an across-the-board temperature storage requirement are not justified on a food safety basis. For example, eggs must exceed pH 8.8 to achieve the needed peeling qualities for hard cooked eggs. The pH of shell eggs increases much faster when eggs are stored at a temperature warmer than 45°F. Since hard cooked eggs are cooked to above 170°F, there is no food safety-related need to store these eggs below 45°F prior to cooking; such a storage temperature requirement significantly lengthens the amount of storage time required before hard cooked eggs will have the desired peeling qualities. In fact, the longer storage time could render this process economically unfeasible.

We support the 5-log SE reduction standard for shell eggs as a "safe harbor" but we believe the Agency should provide for regulated entities to utilize alternative approaches that can be documented to achieve an equivalent level of food safety.

Other SE prevention measures

The regulation would require the development of procedures for disinfecting a poultry house for use when the environment or an egg tests positive for SE. We are concerned that the requirement for wet cleaning may exacerbate a *Salmonella* problem. Wet cleaning could create an environment for growth of microorganisms in the poultry house and should not be mandated

when other corrective actions could be more effective. This should be one option, but not a requirement.

#### SE sampling and testing

Regarding SE sampling and testing methodology, we believe there is no need for prescriptive requirements about how to achieve the standard specified in the regulations.

NFPA agrees that the testing component would not apply to eggs that are destined for pasteurization. This exemption should be expanded to include farms that are dedicated suppliers to food service establishments that cook all eggs per the FDA Model Food Code and do not offer minimally cooked eggs on their menu. Requiring an SE monitoring program on these farms would not improve public health and would only add unnecessary cost.

#### Best practice guidance

We believe that best practice information is always useful but it may be necessary to take steps to assure that providing such information does not in any way hinder or restrict processors from pursuing new ideas and new techniques that may be more effective than those practices currently in use.

#### Encouragement for voluntary vaccination programs

In the preamble to the rule, FDA noted that vaccines show promise in reducing the prevalence of SE in laying hens. We concur that there is probably inadequate justification to mandate vaccination at this time. However, we would support additional means for recognizing and encouraging voluntary vaccination programs, such as by allowing producers that can demonstrate the effectiveness of their vaccination programs to follow an alternative protocol for environmental testing before depopulation.

#### Recordkeeping

FDA has proposed significant recordkeeping requirements and has cited Section 361 of the Public Health Service Act ("PHS Act") as support for its authority to inspect and copy records. NFPA does not believe that there is any need for FDA to expand its record keeping requirements beyond those proposed nor to require firms to have a written SE plan. However, if the Agency were to mandate that firms have an SE program, it should cover only the basics without dictating the details of such a plan. Maximum flexibility should be allowed for a firm to develop a plan that is most appropriate for its particular situation. This will not be possible with a prescriptive rule that specifies detailed requirements.

The Proposed Rule for the Prevention of *Salmonella* Enteritidis (SE) in Shell Eggs during Production would impose recordkeeping requirements for the SE prevention measures, and would require egg producers to make records available to FDA for inspection and copying. FDA asserts that records access is "essential to confirm compliance and achieve the full benefits of the rule," and cites Section 361 of the PHS Act to support its authority to inspect and copy records. As detailed below, NFPA believes that FDA's reliance upon Section 361 of the PHS Act is misplaced and cannot be used to impose records inspection on food establishments where such inspection is specifically not allowed under Section 704(a) of the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA").

Section 361 of the PHS Act, enacted in 1944, in relevant part authorizes FDA "to make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases," and provides that "[f]or purposes of carrying out and enforcing such regulations, [FDA] may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [its] judgment may be necessary." While this extremely broad grant of authority would seem to give FDA wide latitude in selecting remedial measures to control communicable diseases, this provision cannot be read alone, but rather must be considered in conjunction with other statutory provisions that specifically address, and limit, the agency's authority in this arena.

For the reasons and evidence cited in NFPA's earlier submission to FDA (**Docket No. 2004N-0230; Food; Current Good Manufacturing Practice Regulations 69 Federal Register 40312; July 2, 2004**) relating to the Agency's purported authority to inspect food records in conjunction with its potential revision of the food good manufacturing practice ("GMP") regulations, FDA's authority under the FDCA to inspect food records is strictly limited. Section 704(a) provides a sharp distinction between the agency's lack of authority to inspect records of food establishments and its authority to do so with respect to other regulated entities. Under the FDCA, FDA may only inspect the records of food establishments: (1) that document the interstate shipment of food (Section 703); (2) where FDA has "a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death" (Section 414(a)); (3) relating to "imports for export" (Section 801(d)(3)(A)(iv)); and (4) relating to acidified and low-acid canned foods (21 C.F.R. §§ 108.25(g) & 108.35(h), promulgated under FDA's emergency permit control authority set forth in Section 404 of the FDCA).

The FDCA addresses with specificity records inspection for food establishments, whereas the PHS Act merely provides in a general fashion for any inspection deemed necessary to control communicable disease. "It is a basic principle of statutory construction that a statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum. 'Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.'"

*Radzanower v. Touche Ross & Co., et al.*, 426 U.S. 148, 153 (1976), quoting *Morton v. Mancari*, 417 U.S. 535, 550-51 (1974). The Supreme Court in *Radzanower* explained the rationale behind this principle:

‘The reason and philosophy of the rule is, that when the mind of the legislator has been turned to the details of a subject, and he has acted upon it, a subsequent statute in general terms, or treating the subject in a general manner, and not expressly contradicting the original act, shall not be considered as intended to affect the more particular or positive previous provisions, unless it is absolutely necessary to give the latter act such a construction, in order that its words shall have any meaning at all.’

*Id.*, quoting T. Sedgwick, *The Interpretation and Construction of Statutory and Constitutional Law*, 98 (2d ed. 1874).

As detailed in NFPA’s earlier submission, the legislative history of the enactment of the FDCA in 1938 indicates that Congress did not intend to include certain records within the scope of required inspections, and Congress has been made aware of FDA’s lack of food records inspection authority on numerous occasions but has not availed itself of the opportunity to expand the agency’s authority in this arena. Accordingly, the general language of the 1942 provision of the PHS cannot be read to broaden FDA’s authority beyond that specifically, and repeatedly, circumscribed in the FDCA.

In *Nutritional Health Alliance v. FDA*, 318 F.3d 92, 102 (2d Cir. 2003), wherein the court held that FDA did not have authority under the FDCA to promulgate a dosage-unit packaging rule, the court analyzed a Supreme Court case in which an agency sought to expand its authority limited in one specific statute by relying upon a broader grant of authority in another general statute. The court explained that in *United States v. Estate of Romani*, the Supreme Court emphasized that “a later-enacted, more specific, comprehensive statute that targets the specific subject matter at issue in the case controls the construction of a more general statute where there is a potential conflict or discrepancy between the burdens imposed upon affected entities.” *Id.*, citing 523 U.S. 517, 530-32, 534 (1998). From this principle, the Supreme Court concluded that the IRS could not circumvent limitations imposed upon it by the Tax Lien Act in a case involving a federal tax claim by relying on a broadly applicable federal priority statute. *Id.*

Similarly, FDA cannot rely upon Section 361 of the PHS Act to do what the specific provisions of the FDCA relating to inspection of food establishments deny the agency authority to do. As FDA may not expand its authority by regulation beyond that provided by legislation, the records access provisions of the *Salmonella* in shell eggs proposed rule cannot stand.

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Conclusions

NFPA commends FDA for developing a regulation that will enhance the safety of shell eggs with respect to SE. Environmental testing followed by egg testing or diversion for treatment to inactivate SE, along with the specific SE prevention measures described in the rule should have a positive impact on public health. FDA should reconsider the requirement for shell egg producers to refrigerate eggs within 36 hours, as this is likely to impose a burden on producers without significantly enhancing public health.

Sincerely,

A handwritten signature in black ink, appearing to read 'Susan A. Ferenc', with a long horizontal line extending to the left.

Susan A. Ferenc, DVM, Ph.D.  
Executive Vice President & Chief Science Officer  
Scientific & Regulatory Affairs