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SENT VIA ELECTRONIC AND U.S. MAIL

DIVISION OF DOCKET MANAGEMENT
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2000N-0504

**Re: Prevention of *Salmonella* Enteritidis in Shell Eggs;
Comments on Proposed Rules Regarding Safe Eggs Handling and
Preparation Practices in FDA's 2001 Model Food Code**

To Whom It May Concern:

This letter is written in response to the request made by the U.S. Food and Drug Administration (FDA) for comment on certain proposed rules regarding the prevention of *Salmonella enteritidis* in shell eggs during production. See 69 Fed. Reg. 56,825 (Sept. 22, 2004) ("Proposed Rule"). Specifically, we comment on whether the FDA should include in the final rule an additional requirement that:

The safe egg handling and preparation practices in FDA's 2001 Model Food Code...be federally mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers).

Id. at 56,825. We support such a mandate, despite the fact that our law firm might suffer a decrease in business as a result. We further recommend and support an extension of the mandate to all retail establishments, there being no logic in protecting highly susceptible populations in institutional settings while failing to do so anywhere else.

INTRODUCTION

I am one of four principals in Marler Clark, a law firm that has a practice devoted to the representation of persons injured in foodborne illness outbreaks. It is probably safe

to say that, of those victims of outbreak-related foodborne illnesses over the last ten or so years, Marler Clark has represented the majority of them, at least those who had sought to obtain financial compensation for their illness. Among clients with salmonella infections, the firm has represented persons injured in the following outbreaks:

- Sheetz Salmonella Outbreak (contaminated tomatoes)
- Paramount Farms Almond Salmonella Outbreak
- Golden Corral Restaurant Salmonella Outbreak
- Seasons at the Pond Restaurant Salmonella Outbreak
- Chili's Grill and Bar Salmonella Outbreak
- St. Louis Children's Hospital Salmonella Outbreak
- Sunset House Restaurant Salmonella Outbreak (mushrooms)
- Harmony Farms Salmonella Outbreak (sprouts)
- Clarkston Quality Inn Salmonella Outbreak
- Velotta v. KFC Salmonella Outbreak
- Brook-Lea Country Club Salmonella Outbreak
- Kunick Salmonella Outbreak (cantaloupes)
- Western Sizzlin' Restaurant Salmonella Outbreak
- Shipley Sales Salmonella Outbreak (cantaloupes)
- Black Forrest Bakery Salmonella Outbreak (cross-contamination from raw eggs)
- Malt-O-Meal Toasty-O's cereal Salmonella Outbreak
- Sun Orchard Unpasteurized Orange juice Salmonella Outbreak
- San Antonio Taco Salmonella Outbreak
- Linh's Bakery Salmonella Outbreak
- Country Kitchen Salmonella Outbreak (undercooked eggs)
- Si Redd's Casino Salmonella Outbreak (unpasteurized raw eggs used in hollandaise sauce)

In addition to these outbreaks, we have represented persons killed or seriously injured in cases involving the consumption of contaminated food at nursing homes. Therefore, from a legal perspective, there is no law firm in the United States with the breadth and depth of experience as that which Marler Clark and its attorney possess.

FDA FINDINGS RELEVANT TO THIS COMMENT

The FDA, in its proposed rules regarding *Salmonella* enteritidis in shell eggs, set forth a number of findings that, in and of themselves, support a federal mandate requiring the “safe egg handling and preparation practices in FDA’s 2001 Model Food Code...be federally mandated for retail establishments that specifically serve a highly susceptible population.” Proposed Rule at 56,825. These findings include:

- Reported cases [of salmonellosis] are likely to represent only a small portion of the actual number of illnesses that occurred. *Id.* at 56, 826.
- CDC used updated information and data from a FoodNet population

study to estimate that there are 38 cases of salmonellosis for every one that is reported. Proposed Rule at 56,826.

- Shell eggs are now the predominant source of SE-related cases of salmonellosis in the United States. Id.
- Between 1990 and 2001, an average of 78 percent of vehicle-confirmed SE outbreaks were egg associated. Id.
- [T]here is evidence that the infectious dose...for SE can be very low. Id. at 56,827.
- The FDA Food Code...represents the best advice...to ensure that food at the retail level is safe, properly protected, and properly represented. Id. at 56,828.
- The Food Code provides advice on how to prevent foodborne illness based on information obtained from CDC investigations. Id.
- [T]he scientific evidence on the growth of SE in eggs shows that control of storage temperature of shell eggs can effectively prevent the multiplication of any SE present. Id. at 56,837.
- SE outbreak investigations show that outbreaks commonly occur when foods not prepared with raw shell eggs are not properly handled by food preparers. Id. at 56,849.
- Common inappropriate practices for foods containing SE-contaminated shell eggs include temperature abuse. Id.
- Temperature abuse gives SE the opportunity to multiply, thereby increasing the number of viable microorganisms ingested. Id.
- CDC reported that 54 of 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes. Id.
- [T]he likelihood of dying from a foodborne illness contracted in a nursing home was 13 times higher than outbreaks in other settings. Id.

Based on the foregoing findings, the FDA issued its Proposed Rule, along with a request for comment on “whether the public health outcome for high risk populations can only be achieved through mandatory federal standards and, if so, how those standards would best be implemented.” Proposed Rule at 56,850.

OUR COMMENTS

Notably absent among the FDA’s findings is a decrease in the number of cases of salmonellosis among high-risk populations since issuance of the 2001 Model Food Code. This, coupled with the fact that twenty four states do not require food service operators to use pasteurized eggs for food items that usually contain raw eggs, shows the inadequacy of the current FDA Food Code system’s reliance on State adoption and implementation.

Performing a simple risk-utility analysis shows why a mandatory Federal standard requiring food service operators to use pasteurized egg products for high-risk populations is necessary. We already know that the risk of infection is severe if a member of a high-risk population is exposed to SE. We also know that the cost paid by the infected person is significant because death is significantly more likely to occur. This is in contrast to the

cost of complying with the mandate, which is relatively insignificant. See Lin C-T J., R. A. Morales, and K. Ralston, “Raw and Undercooked Eggs: A Danger of Salmonellosis,” *Food Review* 20:27-32, 1997 (noting at p. 32 that, at retail, pasteurized eggs cost from 39-59 cents more, and the expected cost of production added only one-cent per egg). And because only the kind of eggs used will be changed, no new procedures will be required, and no retraining of personnel. Thus, the added cost of the egg, which would presumably come down as increased demand resulted in greater economies of scale in production, is the only cost to the food service operator.

Further incentives for a federal mandate can be found when the risks of litigation and product liability are added to the equation. As presently constituted, the legal system provides only weak and limited incentives for the production of safer food. See Buzby J. C., P. Frenzen, and B. Rasco, “Product Liability and Microbial Foodborne Illness, ERS AER 799, April 2001, Chap. 5, at 27. This is in large part due to the fact that most cases of outbreak-related injury claims or lawsuits are resolved through confidential settlement, and without the case being tried to verdict. As a result, and as pointed out by Buzby, “the legal system provides only limited feedback to firms about the need for greater food safety.” Id. This means, of course, in the absence of an effective administrative mandate, food service operators will continue to make product purchasing decisions based mostly on cost and more generalized quality considerations, rather than those safety-specific.

To appreciate the importance of the last point, two things must be well understood about the product liability system, and the food industry’s understanding of it. First, there is a widespread misconception that there is no liability for injuries caused by food unless there is proof of some sort of negligence. That is not the case.¹ Where a food product is defective as a result of it containing a pathogen, the manufacturer is *strictly* liable, which is to say, liable without regard to fault. Put another way, an injured person need not show negligence in order to recover for his or her damages.

The second thing that must be understood is that, regardless of the action the FDA decides to take, the portions of the 2001 Model Food Code regarding safe egg-handling and preparation practices already have the force of law, even if not yet adopted by the State. Because the Model Food Code represents the best available thinking on subjects of food safety and eggs, it defines the de facto standard of care one would expect from a reasonably prudent food service operator. Given the long and widespread availability of the Code, along with the food service fact sheets that the FDA has targeted to institutional preparers of food for children, the elderly, and immunocompromised individuals, there is no way that such preparers could deny knowledge of the serious safety risk posed by the use of raw shell eggs in food, and the ready availability of a relatively inexpensive and proven safe alternative. As a result, a food service operator who injures or kills a person in their case, such as in a nursing home, would likely face an award of punitive damages²

¹ For a comprehensive discussion of the history of food product liability, see D. Stearns, An Introduction to Product Liability Law, 2001, *available at* <http://www.marlerclark.com/WPMarlerClark.pdf>. See also Buzby, Product Liability as it Applies to Foodborne Illness, 2001, Appendix, at pp. 34-41.

² Punitive damages are awarded in addition to compensatory damages, and are intended to punish and deter conduct that is considered particularly egregious. The legal standard in the majority of States that

if the injury or death were linked to the use of unpasteurized eggs.

Finally, given that it is fairly clear that a federal mandate imposing the safe-egg handling and preparation practices in the 2001 Model Food Code for retail establishments that specifically serve a highly susceptible population is justified, the only other questions to be answered is why protect highly susceptible people only in an institutional setting? If such people deserve to be protected from injury and death in one setting, it makes no real sense to fail to protect them in all settings. Accordingly, in our view the federal mandate should apply to all retail food establishments, and not just those that specifically serve a highly susceptible population. And while the food industry may reflexively seek to oppose such a move, it should consider that, in doing so, it is not only choosing to not protect vulnerable customers, but also choosing to not protect itself—from lawsuits filed by us.

Very truly yours,

[Signed original to follow by mail.]

Denis W. Stearns

cc: File

allow an award of such damages is proof of conduct that constitutes a willful and conscious disregard of a known safety risk. See, e.g. California Civil Code, § 3294-3295. Using raw, unpasteurized shell eggs in a food product intended for consumption by a member of a high risk population easily meets this standard.