Foodservice & Packaging Institute, Inc.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Ref: Docket Nos. 98N-1230, 96P-0418, and 97P-0197

Dear Sir or Madam:

The Foodservice & Packaging Institute, Inc. (FPI) is pleased to submit comments regarding the Food and Drug Administration's (FDA) proposed rule, "Food Labeling: Safe Handling Statements: Labeling of Shell Eggs." These comments *do not* address sections of the proposed rule concerning "Refrigeration of Shell Eggs Held for Retail Distribution."

FPI is submitting these comments on behalf of its Egg Packaging Division, a group of member companies that manufacture packaging for fresh shell eggs, a subject of this rulemaking. FPI is the national trade association of manufacturers of foodservice disposable packaging for use in quick-service and full-service restaurants, cafeterias, delis, medical facilities and other commercial and institutional establishments, and in the home. FPI also represents companies that supply materials to foodservice disposables manufacturers, distributors of those products, and machinery and equipment manufacturers who serve the industry. The Institute was established in 1933 to represent the industry before government, among other purposes.

Food safety is the most important public policy concern of this industry and a primary reason for the invention and development of foodservice disposable products. For that reason, FPI and its Egg Packaging Division members share FDA's concern about the incidence of illnesses caused by fresh shell eggs contaminated with Salmonella Enteritidis (SE). We acknowledge that the contamination may be caused by the mishandling or improper processing, storage or cooking of fresh eggs. However, we would submit that the contamination occurs most frequently in foodservice operations when food is being prepared, rather than at home.

As stated in our prior comments submitted on August 14, 1998 in response to the advance notice of proposed rulemaking on this matter, we understand and appreciate FDA's interest in requiring warning labels on shell egg packaging as a means of protecting the public from the effects of SE-contaminated eggs. After reviewing the proposed rule, however, we submit the proposed rule will be unnecessarily cumbersome and costly to implement and will not produce the hoped-for protections for the public from SE-contaminated eggs. Although the proposed rule allows egg packagers some leeway in designing and placing the warning label on the package (it does not designate a type size or font for the message nor does it specify a particular location for the label) which will ease its implementation, substantial difficulties remain. These are explained in the following comments.

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C601

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1. **The length of this warning message will be very difficult to accommodate because the printable surfaces of egg packaging are already consumed by labels, warnings, and product information required by federal and state government and customers.** As noted and emphasized in FPI's prior comments, egg packaging is subject to several sets of federal and state labeling requirements, such as the label required by the Nutritional Labeling and Education Act (NLEA), the U.S. Department of Agriculture's grade and quality standard logos, the product code, "sell-by" date, and the count and weight of the package contents, to name a few. Much of this information must be printed to specific type size, font, and placement requirements. Complying with this new Safe Handling requirement could compromise packagers' compliance with existing rules. Failure to comply with those existing rules may also place packagers in legal jeopardy with the administering government agency.

   On a related point, the length and size of this message presents special concerns for the open-view carton, a type of package that allows eggs to cool more quickly to the required 45 degrees Fahrenheit required by federal regulations. This particular type of package has even less space than its solid-lid counterparts, making accommodation for this message that much more difficult. Complying with the label requirements of this proposed rule will require the manufacturers of this type of package to make drastic changes in the product at enormous costs for a barely marginal benefit to the consumer.

2. **The proposed warning label is unnecessarily complex.** A major concern about this proposed rule is the length and complexity of the proposed warning message. Consumers could mistakenly perceive this message as applying to only the targeted groups, rather than the whole population, as intended. Therefore, we strongly recommend a simple, clear warning message aimed at all consumers, such as the label proposed by the United Egg Producers: DO NOT EAT RAW OR UNDERCOOKED EGGS.

   Inasmuch as available evidence indicates that most incidents of SE-contamination in eggs occurs in foodservice operations, we would support placing the proposed warning label on shipping containers and other foodservice packages that are handled by foodservice operators.

3. **FDA's proposed rule failed to acknowledge and accommodate the fact that hundreds of millions of egg cartons are already carrying "safe handling" labels and warning statements.** FDA justifies this labeling requirement as necessary to inform a largely uninformed consuming public – particularly children, the elderly and those with compromised immune systems – about the health risks associated with eating improperly stored or undercooked eggs. We question the validity of FDA's reasoning, however, because, for many years, our industry has produced substantially more than ½ billion retail egg cartons printed with prominent warning labels and/or preparation and storage instructions required by their customers.

   Egg producers and retailers stepped up their outreach efforts in recent years – in response to news reports about the incidence of salmonella contamination from raw eggs – through participation in a campaign sponsored by the American Egg Board, ***Fight BAC.*** A key component of that campaign was a warning label specifically designed to instruct consumers about proper storage, handling and cooking procedures for eggs. Many of our members and their customers participate in this campaign out of concern that consumers will be properly warned and instructed about how to prevent SE-contamination of eggs. Our prior comments suggested that if existing labels meet or exceed the content requirements of the new federal label, those existing labels should be

allowed to stand. Affected companies and their customers would save the costs of redesigning the cartons to accommodate the new label, yet the consumer would still have access to this important information. Although FDA did not address this suggestion in its proposed rule, we hope the final rule will be revised accordingly.

4. **The implementation time for this proposed rule is insufficient.** The proposed rule stipulates that the new warning label must appear on all egg cartons within 180 days after final publication of the rule. That time frame will impose substantial pressures and costs on package manufacturers and their customers. Given the logistics involved with changing carton designs, replacing inventory, making necessary adjustments to distribution channels, and accommodating seasonal product demand fluctuations, the industry respectfully requests a full year, or 360 days, to implement this rule.

5. **Small egg packages (6 to 8 count) do not have the surface area to carry the proposed label.** In our prior comments, we explained the industry's concerns about the printing limitations of small egg cartons. These packages are becoming more popular as consumer tastes and demands for eggs change. Once again, therefore, we suggest that FDA allow a modified label for small egg cartons because their printable space is too limited to accommodate such a lengthy, complex message. Alternatively, we suggest allowing the safe handling information to be communicated through an 800 number printed on the package (i.e., FOR SAFE HANDLING INSTRUCTIONS, PLEASE CALL 1(800) _ _ _-_ _ _ _.)

6. **The safe handling label should not be printed on invoices and other administrative materials.** In response to FDA's request for comments on its consideration of requiring the warning label on printed shipping documents and other administrative materials, we submit that such a requirement would be excessive and yield no advantage in achieving the proposed rule's intent. If the intent of this proposed rule is to inform those who handle eggs and prepare them for consumption about the health risks associated with undercooked or improperly stored fresh eggs, then it makes no sense to expose administrative personnel to the warning. They have no direct contact with the eggs and have no interest in taking precautions with their preparation. Such a requirement would only impose unnecessary costs on egg producers and distributors.

FPI and its Egg Packaging Division members appreciate the opportunity to comment on the proposed rule. We are very concerned about the implications of the proposed rule to our members and their operations and, therefore, stand ready to offer any assistance as you continue developing the proposed rule. Should you have questions about the content of these comments, please contact me at (703) 527-7505.

Sincerely,

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