

U.S Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling and Dietary Supplements
Office of Plant and Dairy Foods and Beverages
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Guidance for Industry

FOOD LABELING: SAFE HANDLING STATEMENTS, LABELING OF SHELL EGGS; REFRIGERATION OF SHELL EGGS HELD FOR RETAIL DISTRIBUTION

SMALL ENTITY COMPLIANCE GUIDE

The Food and Drug Administration has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Fairness Act (P.L. 104-121). This guidance document restates in plain language the legal requirements set forth in the current regulations for the safe handling statement on labels of shell eggs and the refrigeration of shell eggs held at retail establishments. This is a Level 2 guidance document published for immediate implementation in accordance with FDA's good guidance practices (21 CFR 10.115). The regulations are binding and have the force and effect of law. However, this guidance document represents the agency's current thinking on this subject and does not, itself, create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

SUMMARY

The Food and Drug Administration (FDA) published a final rule in the **Federal Register** of December 5, 2000 (65 FR 76092) entitled, "Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution." The final rule applies to shell eggs that have not been specifically processed to destroy all live *Salmonellae* before distribution to the consumer. For these shell eggs, retail establishments must include the following safe handling statement on the label of the shell eggs:

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SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

The regulation also requires retail establishments to refrigerate shell eggs promptly when they are received and to store the eggs at 45° F (7.2° C) or cooler.

FDA is requiring these actions to reduce the risk of illness and death caused by *Salmonella* Enteritidis (SE), a pathogenic bacterium, which is associated with the consumption of shell eggs that have not been treated to destroy *Salmonella*.

QUESTIONS AND ANSWERS

GENERAL INFORMATION

- Question:** What products are subject to the requirements of this regulation?
- Answer:** All shell eggs that have not been treated specifically to kill all live *Salmonellae* before distribution to the consumer are subject to the requirements of this regulation.
- Question:** Are eggs sold in intrastate commerce (i.e., eggs sold only in the state where they were produced) subject to this regulation?
- Answer:** Yes. Eggs sold in both intrastate and interstate commerce (i.e., sold across state or international lines) are required to comply with this regulation.
- Question:** Are egg products (i.e., liquid, dried, and frozen whole eggs, egg whites, and egg yolks, with or without added ingredients) subject to this regulation?
- Answer:** No. FDA already has a separate regulation for egg products as

stated in the standards of identity for egg products (21 CFR part 160), which requires those products to be pasteurized or otherwise treated to destroy all live *Salmonella*. Therefore, egg products are not subject to this regulation. However, FDA recommends that those products be kept refrigerated or frozen to ensure quality. Dried egg products may be stored at room temperature.

Question: Are in-shell pasteurized eggs subject to this regulation?

Answer: No. Eggs that have been pasteurized while in the shell have been treated specifically to kill all live *Salmonella* and, therefore, are not subject to this regulation. However, FDA recommends that in-shell pasteurized eggs be refrigerated to retain shelf life.

Question: Are shell eggs produced under Quality Assurance Programs (QAP's) subject to this regulation?

Answer: Yes. Shell eggs produced under a QAP are subject to this regulation.

SAFE HANDLING STATEMENT AND LABELING REQUIREMENT

Question: What safe handling statement must be included in the label of shell eggs that have not been treated specifically to kill all live *Salmonella* before the shell eggs may be distributed to the consumer?

Answer: The safe handling statement is: "**SAFE HANDLING INSTRUCTIONS:** To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."

Question: How must the safe handling statement appear on the label?

Answer: The statement must appear on the label prominently, conspicuously, and in a type size no smaller than one-sixteenth of one inch. The statement must appear in a hairline box and the words "safe handling instructions" must appear in bold capital letters. For example:

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

Question: For shell eggs that are sold to consumers, where must the safe handling statement appear on the label?

Answer: The statement must appear on either: (1) the principal display panel (PDP) (i.e., that part of the label most likely to be seen by the consumer at the time of purchase); or (2) the information panel (i.e., the panel immediately to the right of the PDP or, in the instance where the top of the package is the PDP, any panel adjacent to the PDP).

Question: Must the safe handling statement appear on the package of shell eggs that are not for direct sale to consumers but rather are to be repackaged, relabeled or further processed (e.g., cases of shell eggs sold to food service establishments)?

Answer: No. Under such circumstances, there are no placement requirements for the safe handling statement. You may choose to place the safe handling instructions on the package label. Alternatively, you may choose to place the safe handling statement in the labeling (i.e., invoices and bills of lading), according to trade practices. However, if you choose not to place FDA's required statement on the label, you must comply with USDA's labeling requirements, specifically USDA's "Keep Refrigerated" labeling requirement, which can be found at 9 CFR § 590.50.

Question: By what date must the safe handling statement appear on the label?

Answer: The safe handling statement must appear on the label of shell eggs by September 4, 2001. However, FDA encourages you to begin voluntarily labeling your products now.

Question: Can eggs, currently labeled with a safe handling statement that is different from the one FDA is requiring, continue to bear that existing statement?

Answer: Eggs that currently have a different safe handling statement on

their labels may continue to do so until the supply of labels is used up, only if the statement includes a refrigeration instruction and a cooking instruction. Once the supply of labels is used up, you must comply with FDA's prescribed statement.

REFRIGERATION REQUIREMENT

- Question:** Which retail establishments are subject to the refrigeration provisions of this regulation?
- Answer:** Any retail establishment that is an operation that stores, prepares, packages, serves, sells, or otherwise provides food for human consumption directly to consumers is subject to the refrigeration provisions of this regulation. This includes, but is not limited to, supermarkets, restaurants, delicatessens, caterers, vending operations, hospitals, nursing homes, and schools.
- Question:** What are retail establishments required to do about refrigerating shell eggs that have not been specifically treated to kill all live *Salmonellae*?
- Answer:** Upon receipt, retail establishments promptly must store and display the eggs at an ambient (air) temperature of 45°F (7.2°C) or cooler.
- Question:** How soon after receiving eggs must a retail establishment refrigerate them?
- Answer:** Retail establishments must refrigerate the eggs promptly upon receipt, except when short delays are unavoidable. In these situations, the eggs must be refrigerated as soon as reasonably possible.
- Question:** By what date must retail establishments comply with the refrigeration requirements for shell eggs?
- Answer:** Retail establishments already must be complying with the refrigeration provisions of this regulation since they were effective on June 4, 2001.