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Food and Drug Administration (FDA)

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[Docket Nos. 98N-1230, 96P-0418, and 97P-0197]

RIN 0910-AB30

Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution

Part III

65 FR 76092

DATE: Tuesday, December 5, 2000

ACTION: Final rule.

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SUMMARY: The Food and Drug Administration (FDA) is revising its food labeling regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms. The agency also is requiring that, when held at retail establishments, shell eggs be stored and displayed under refrigeration at a temperature of 7.2 [degrees] C (45 [degrees] F) or less. FDA is taking these actions because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis (SE) that are associated with the consumption of shell eggs. These actions also respond, in part, to petitions from Rose Acres Farm, Inc., and the Center for Science in the Public Interest (CSPI). Safe handling statements will help consumers take measures to protect themselves from illness or deaths associated with consumption of shell eggs that have not been treated to destroy *Salmonella* (all serotypes). Refrigeration of shell eggs that have not been treated to destroy *Salmonella* will help prevent the growth of SE in shell eggs.

DATES: This rule is effective September 4, 2001, except § 115.50, which is effective June 4, 2001.

FOR FURTHER INFORMATION CONTACT: For the labeling provisions: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561. For refrigeration provisions: Nancy S. Bufano, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-401-2022.

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I. Background

FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) share Federal authority to regulate eggs. The two agencies published in the **Federal Register** of May 19, 1998 (63 FR 27502), an advanced notice of proposed rulemaking seeking information on how to identify farm-to-table actions that would decrease food safety risks associated with shell eggs. On July 1, 1999, FDA and FSIS, in testimony before the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia of the Senate Committee on Governmental Affairs, committed to developing by November 1, 1999, an action plan to address the presence of SE in shell eggs using a farm-to-table approach. On August 26, 1999, FDA and FSIS jointly held a public meeting to gather stakeholders' input and to discuss the development of the action plan. On December 10, 1999, FDA and FSIS presented the Egg Safety Action Plan (Ref. 1) to the President. The plan identifies the systems and practices from production to consumption that must be implemented to reduce and, ultimately, eliminate eggs as a source of human SE illnesses. This plan includes requirements for refrigeration at retail and requirements for the safe handling statement being issued in this rulemaking. FDA, along with FSIS, intends to use information gathered by both agencies to develop and implement a comprehensive program to address the safety of shell eggs from farm to table.

In the **Federal Register** of July 6, 1999 (64 FR 36492), FDA published a proposed rule (hereinafter referred to as "the proposal") to require safe handling label statements on shell eggs that have not been treated to destroy *Salmonella* microorganisms and refrigeration of these shell eggs while held by retail establishments. In a separate document in the same issue of the **Federal Register** (64 FR 36516), FDA published a Preliminary Regulatory Impact Analysis (PRIA) and Initial Regulatory Flexibility Analysis of the proposal. FDA proposed these regulations because of the number of outbreaks and deaths associated with the consumption of shell eggs that have not been treated to destroy *Salmonella*. Interested parties were given until September 20, 1999, to comment on the proposal.

FDA received approximately 790 responses, each containing one or more comments, to the proposal. These responses were received from the egg industry, egg packaging companies, trade associations, consumers, consumer interest groups, animal interest groups, academia, State Government agencies, members of Congress, and a foreign Government agency. More than 700 of these comments addressed forced molting, which is directed at the production of shell eggs, and, therefore, outside of the scope of this rulemaking, and will not be addressed in this document. Other comments also addressed issues that are outside the scope of this rule and will not be addressed in this document (e.g., implementation of national standards for quality assurance (QA) programs, implementation of Hazard Analysis and Critical Control Points (HACCP) programs, use of sanitary standard operating procedures, Good Agricultural Practices/Good Manufacturing Practices, and other intervention procedures such as manipulation of feeds and competitive exclusion to control SE, sell-by dates, uniform coding, repacking of shell eggs, refrigeration of nest run [*76093] shell eggs, and creation of a single food safety agency responsible for eggs). These comments were considered by the agency in its action plan to address the presence of SE in shell eggs and will be considered in the development of subsequent proposed measures aimed at improving egg safety.

Some of the remaining comments supported the proposal. Others opposed the proposal or suggested modifications to the proposal. The relevant comments and the agency's responses to the comments are discussed below.