

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

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Certifier N. Hawkins

[Docket No. 2004N-0382]

RIN 0910-ZA23

**Food Labeling: Safe Handling Statements: Labeling of Shell Eggs**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending its food labeling regulations to permit the egg industry to place the safe handling statement for shell eggs on the inside lid of egg cartons if the statement “Keep Refrigerated” appears on the principal display panel (PDP) or information panel. This final rule will provide the industry greater flexibility in the placement of safe handling instructions on egg cartons, while continuing to provide consumers with this important information. This action is in response to numerous requests from the egg industry.

**DATES:** This final rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

**SUPPLEMENTARY INFORMATION:**

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## I. Background

On December 5, 2000 (65 FR 76092), FDA (we) published a final rule (hereinafter referred to as the shell egg refrigeration and labeling final rule) to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms ( § 101.17(h) (21 CFR 101.17(h))). The regulation also requires retail establishments to store and display shell eggs under refrigeration (21 CFR 115.50). FDA issued the shell egg refrigeration and labeling final rule because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis that are associated with the consumption of shell eggs. After the publication of the shell egg refrigeration and labeling final rule, the egg industry asked FDA to allow safe handling statements to be placed on the inside lid of egg cartons because of: (1) The lack of equipment to print on the side panels of egg cartons (i.e., the information panel), (2) the high cost to purchase equipment to print on the sides of egg cartons, and (3) the high cost to change the graphic design of the PDP for each brand that manufacturers produce for each customer.

In the **Federal Register** of May 5, 2005 (70 FR 23813), FDA published a proposed rule (the 2005 proposed rule) to allow the egg industry to place the required safe handling statement on the inside lid of egg cartons, if the statement “Keep Refrigerated” appears on the PDP or information panel. We tentatively concluded in the proposed rule that the inside lid would serve as an acceptable panel for the safe handling instructions without diminishing the effectiveness of the message. We further tentatively concluded that providing flexibility to allow the placement of the safe handling statement for shell eggs on the inside lid of egg cartons if the statement “Keep Refrigerated” appears

on the PDP or information panel may result in cost savings for the egg industry, and, thus, for consumers.

## **II. Comments and Agency's Responses**

FDA received a total of eight responses, each containing one or more comments, to the proposal. The comments were from consumer groups, a State government agency, a consumer, a consulting firm, and a trade association. Some of these comments were about issues that are outside the scope of this rulemaking and will not be addressed in this document. The majority of the remaining comments supported the proposal. One comment directly opposed the proposal, whereas two comments supported the proposal based on suggested modifications to the proposal.

(Comment 1) The comment that opposed the proposal asserted that there is no "lack of equipment" for printing the safe handling statement on the side panel of egg cartons. The comment contended that all the egg industry has to do is order new packages.

(Response) As we stated in the 2005 proposed rule, the egg industry sent letters to FDA stating that placing the statement on the top or sides of the carton would result in a financial hardship for their companies because of, among other things, the lack of equipment to print on the side panels of egg cartons (i.e., the information panel) and the high cost to purchase equipment to print on the sides of egg cartons. One of these letters provided specific information on the high costs to purchase new equipment required for printing on the information panel and on the high costs to redesign the egg carton. The comment that opposed the proposal did not provide data or other information that shows that the industry has the necessary equipment. Consequently, we are not persuaded by this comment, and we maintain our

view that allowing the safe handling instructions on the inside of the lid could result in cost savings for the industry and ultimately the consumer, while continuing to provide mandatory safe handling instructions to consumers.

(Comment 2) Several comments requested that FDA make format changes for the safe handling statement. Two comments stated that FDA should replace the current standard of “conspicuous” with specific formatting requirements for the safe handling statement, e.g., use of dark color, such as black, blue, dark blue, or brown on a light background. In addition, several comments stated that the type size of the safe handling statement should be increased and two of these comments suggested specific sizes, e.g., 12-point or larger and “10-inch type”<sup>1</sup> or larger. In addition, one of these comments stated that a survey of egg cartons found that the safe handling statement is printed in type as small as 7-point and, sometimes, the statement is printed directly on a gray cardboard carton, which makes the statement difficult to read. Therefore, according to this comment, a significant number of consumers may not notice or may have difficulty reading this information.

(Response) We do not agree that specific formatting requirements for the safe handling statement are needed. Provisions in section 403(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(f)) and FDA implementing regulations in §§ 101.2 and 101.15 (21 CFR 101.2 and 101.15) address the prominence and conspicuousness of mandatory information on food labels. Specifically, § 101.2(c) provides that mandatory labeling information must appear prominently and conspicuously and should be at least one-sixteenth inch in height. In addition, § 101.15(a)(6) provides that labeling information may lack the necessary prominence and conspicuousness if it is crowded with

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<sup>1</sup>We believe that the comment did not actually mean “10-inch” type but meant another type size, such as a 10-point font.

other written or graphic matter or has insufficient background contrast. The comments did not provide data that show that the existing requirements in §§ 101.2 and 101.15 are not adequate when followed. In addition, the type size required in § 101.2 is a minimum type size and does not restrict manufacturers from using a larger type size to print information on food labels if they choose. Also, while the comments stated that the safe handling statement may be difficult to read, the comments did not provide any data that demonstrate that consumers are unable to read the statement. Therefore, we are not persuaded that specific formatting requirements are needed in this regulation in addition to the requirements already in place in §§ 101.2 and 101.15 to ensure that the safe handling statement is noticeable and legible.

We remind manufacturers that they must comply with FDA's regulations on the prominence and conspicuousness of mandatory information on food labels in §§ 101.2 and 101.15. In addition, we encourage manufacturers to print the safe handling statement in fonts larger than the minimum required if space is available on the carton.

(Comment 3) One comment stated that a referral statement should accompany the "Keep Refrigerated" statement. The comment argued that a referral statement is necessary so that consumers would know to look on the inside of the lid for safe handling instructions. However, the comment did not provide any supporting data.

(Response) We are not persuaded by the comment that a referral statement should accompany the "Keep Refrigerated" statement. In the proposal we did not propose to require a referral statement because we assumed that the number of consumers who would read the safe handling statement on the inside lid under this rule to be about the same as the number who read it

on the outside of the carton. We base this assumption on the following reasons:

(1) All consumers open egg cartons before consumption; and (2) the greater potential for larger font sizes and lower text density on the inside lid, which may equate to a larger number of consumers reading the safe handling statement.

However, in the proposed rule we asked for comment on whether it is necessary to require a referral statement on the outside lid when the safe handling instructions are placed on the inside lid. The comment did not provide any supporting data or other information that demonstrates that when consumers open egg cartons before consumption, they will not see the safe handling instructions. Therefore, we are not persuaded that there is a need for a referral statement to accompany the “Keep Refrigerated” statement.

### **III. Analysis of Economic Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has determined that this final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule provides additional options for placing the safe handling statement on egg cartons. No small business would be forced to use this option,

and so the final rule imposes no costs on small businesses. For those small businesses choosing the option, the final rule reduces labeling costs. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

#### *A. Need for This Regulation*

The need for this regulation is to provide the shell egg industry, which includes egg producers, carton manufacturers, egg distributors, and retailers, additional flexibility in complying with FDA requirements for the placement of safe handling instructions on egg cartons, without reducing the prominence or conspicuousness of the information and without undermining the effectiveness of the shell egg refrigeration and labeling final rule. Allowing the inside lid to be used for the safe handling instructions may create cost savings for firms that were concerned that complying with the labeling requirement of the shell egg refrigeration and labeling final rule would be a financial hardship. This final rule allows for the safe handling instructions to be placed on the inside lid of egg cartons if the words “Keep Refrigerated” are placed on the PDP or information panel.

## *B. Comments*

In response to the proposed rule, FDA received several comments. None of the comments provided information that would alter the conclusions of the economic impact analysis of the proposed rule.

## *C. Cost-Benefit Analysis*

In the proposed rule, FDA evaluated three regulatory options to allow the safe handling statement to be printed on the inside lid of egg cartons. The options considered were the following: (1) No new regulatory action, (2) allow the safe handling statement to be placed on the inside lid with a referral statement on the outside of the carton if the words “Keep Refrigerated” are placed on the PDP or information panel, and (3) allow the safe handling statement to be placed on the inside lid with no referral statement required if the words “Keep Refrigerated” are placed on the PDP or information panel.

### **1. Costs: Potential Reduction in the Numbers of Consumers Reached**

FDA estimated that the costs of this rule are likely to be zero. The only costs that could arise are from changes in the number of consumers who read the safe handling statement. The number of consumers who would read the safe handling statement on the inside lid under this rule is assumed to be about the same as the number who read it under the existing regulation. The reasons for this assumption are: (1) The consumer practice of looking inside the egg carton either at the time of purchase or at a time before consumption, and (2) the potential for more space on the inside lid of egg cartons because of its relatively larger surface area.

At least one study has shown that labels that are larger and have less text density attract more attention (Ref. 1). Another study has shown that larger font sizes enhance label legibility (Ref. 2). Because the inside lid may allow

less text density and more space for printing the safe handling statement in larger font sizes, such placement may result in a larger number of consumers reading the safe handling statement than under the existing regulation. Because all consumers look inside the egg carton at some time before consumption, FDA concludes that there are no costs of this final rule.

## 2. Benefits: Cost Savings Realized by Egg Carton Manufacturers

The benefits from this rule are the costs savings to firms from avoiding placing the safe handling statement on the PDP or information panel. The estimates of the total cost savings for this rule are based on previous estimates of costs savings of option two in the proposed rule. Under option two, the costs savings for a firm from additional flexibility equal the difference between the sum of the costs of printing the safe handling statement on the inside lid and printing a referral statement and the costs of printing the safe handling statement on either the PDP or information panel. The agency estimated the cost savings associated with option two by computing the costs of full label redesign and of adding a safe handling statement using the FDA Labeling Cost Model, Final Report (Ref. 3). The range of cost savings from option two is estimated to be between \$5 and \$19 million, with a mean of \$11 million, assuming a 12-month compliance period.

## 3. Comparing the Benefits of Option Two With Those of Option Three, the Chosen Option

A comparison of the estimates of the total costs savings reported for option two with those reported for option three, the chosen option, indicates the potential for substantial cost savings with option three. The larger cost savings from option three compared with option two reflects the lower cost from not requiring a referral statement on an outside panel in option three as well as

the cost savings from a larger share of the industry choosing the inside lid statement under option three. The cost savings from option two and this final rule are reported in table 1 of this document.

TABLE 1.—COST SAVINGS OF OPTION TWO AND OF OPTION THREE, THE CHOSEN OPTION

Estimates of Cost Savings	Cost Savings of Option Two (12-Month Compliance)	Cost Savings of Option Three, the Chosen Option (12-Month Compliance)
Mean estimate	\$11,032,000	\$14,843,000
Low estimate (5th percentile)	\$5,125,000	\$8,039,000
High estimate (95th percentile)	\$19,022,000	\$24,645,000

#### 4. Summary of Costs and Benefits of this Final Rule

FDA estimated the costs and benefits for three regulatory options for flexibility in the placement of the safe handling statement on egg cartons. The analysis concludes that the costs, measured as the public health effects of a decrease in the number of consumers that would read the safe handling statement, are zero for option three, the chosen option. We conclude that because all consumers open egg cartons before consumption, and given the potential for larger font sizes and lower text density on the inside lid, it is likely that most consumers will notice the safe handling statement on the inside lid if it is located there. The benefits from the options considered are measured as the cost savings from allowing firms additional flexibility of printing the safe handling statement on the inside lid. The estimated cost savings from option three, the chosen option in this final rule, range from \$8 to \$25 million, with a mean of \$15 million, assuming a 12-month compliance period.

#### IV. Analysis of Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **V. Paperwork Reduction Act of 1995**

FDA concludes that this final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### **VI. Federalism**

FDA has analyzed this rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule would have a preemptive effect on State law. Section 4(a) of the Executive Order requires agencies to “construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”

The shell egg refrigeration and labeling final rule set minimum national standards to ensure the safety of eggs for all consumers in this country. Because State and local public health officials are the primary enforcement officials in retail establishments, FDA has recognized that it must rely on these officials to provide the bulk of the enforcement of this regulation. If less stringent State or local refrigeration and labeling requirements are not preempted, enforcement of those less stringent requirements will interfere with the cooperative enforcement of the Federal egg refrigeration and labeling requirements. FDA believes that such cooperative enforcement is critical to effective implementation of this important food safety requirement.

Thus, although Congress did not expressly preempt State law in this area, FDA found in the shell egg refrigeration and labeling final rule that preemption

is needed because State and local laws that are less stringent than the Federal requirements will significantly interfere with the important public health goals of this regulation (65 FR 76092 at 76109–76110). This final rule amends the shell egg refrigeration and labeling final rule to permit the egg industry to place the safe handling statement for shell eggs on the inside lid of egg cartons if the statement “Keep Refrigerated” appears on the PDP or information panel. FDA believes that preemption of State and local labeling requirements that are the same as or more stringent than the requirements of this regulation would not be necessary, as enforcement of such State and local requirements would not interfere with the food safety goals of this regulation. Further, it is likely that any states that enacted similar labeling requirements to those in this final rule would change those requirements to be consistent with any changes made by FDA as a result of this rulemaking. Accordingly, the preemptive effect of this rule would be limited to State or local requirements that are not as stringent as the requirements of this regulation. Requirements that are the same as or more stringent than FDA’s requirement would remain in effect.

Further, section 4(e) of the Executive Order provides that “when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the 2005 proposed rule. FDA received two comments from a State Department of Agriculture, which agreed with the proposal.

In addition, on March 12, 2007, FDA’s Division of Federal and State Relations provided notice by fax and e-mail transmission to State health

commissioners, State agriculture commissioners, and food program directors of FDA's intended amendment to its food labeling regulations to permit the egg industry to place the safe handling statement for shell eggs on the inside lid of egg cartons if the statement "Keep Refrigerated" appears on the PDP or information panel (§ 101.17(h)). The notice provided the States with further opportunity for input on this rulemaking. It advised the States of the intended publication of the final rule and encouraged State and local governments to review the notice and to provide any comments to the docket (Docket Number 2004N-0382), opened May 5, 2005, when the 2005 proposed rule was published in the **Federal Register**, by a date 30 days from the date of the notice (i.e., by April 11, 2007). FDA received no comments in response to this notice. The notice has been filed in the previously referenced docket.

For the reasons set forth previously in this document, the agency believes that it has complied with all of the applicable requirements under the Executive order. In conclusion, FDA has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

## VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Tuominen, R., "Why Do Some Yellow Page Advertisements Capture Attention Better Than Others?," *Acta Odontologica Scandinavica*, 59: 79-82, 2001.

2. Dietrich, D.A., "Enhancing Label Readability for Over-the-Counter Pharmaceuticals by Elderly Consumers," *Journal of Safety Research*, 27: 132, 1996.

3. RTI International, "FDA Labeling Cost Model, Final Report," prepared by Mary Muth, Erica Gledhill, and Shawn Karns, RTI, prepared for Amber Jessup, FDA, Center for Food Safety and Applied Nutrition, April 2002.

**List of Subjects in 21 CFR Part 101**

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

**PART 101—FOOD LABELING**

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.17 is amended by revising paragraph (h)(2) to read as follows:

**§ 101.17 Food labeling warning, notice, and safe handling statements.**

\* \* \* \* \*

(h) \* \* \*

(2) The label statement required by paragraph (h)(1) of this section shall appear prominently and conspicuously, with the words “SAFE HANDLING INSTRUCTIONS” in bold type, on the principal display panel, the information panel, or on the inside of the lid of egg cartons. If this statement appears on the inside of the lid, the words “Keep Refrigerated” must appear on the principal display panel or information panel.

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Dated: 5/25/07  
May 25, 2007.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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COPY OF THE ORIGINAL**

Dawn P. Hopkins