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Official U.S. Council Representative

July 19, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004N-0382, RIN 0910-ZA23

Dear Sir or Madam:

United Egg Producers (UEP) appreciate the opportunity to submit comments on the Food and Drug Administration's proposed rule of May 5, 2005, to permit 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. UEP is a cooperative whose members account for some 90% of shell egg production in the United States.

UEP strongly supports the proposed rule. Our industry has supported appropriate safety messages to consumers, and has also urged flexibility in the exact placement of these messages, including the ability to place the safe handling statement on the inside carton lid. We believe inside lid placement –

- Constitutes a display site of at least equal prominence to the principal display panel or the information panel, since as FDA notes, a survey showed 91.5% of consumers open the carton before purchasing eggs;
- Exposes consumers to the safety message at multiple decision points, i.e., at the time of purchase and at each subsequent removal of one or more eggs from the home-refrigerated carton;

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- Permits producers to utilize the outside lid for marketing, brand-building and related purposes, thus encouraging the development of differentiated, recognizable brands – a desirable outcome from a food safety standpoint, since brand identification increases the importance to the producer of assuring the safety and quality of every product associated with that brand; and
- Conforms to the needs of the marketplace, allowing compatibility with a variety of carton materials, label patterns and manufacturing practices.

Following are UEP's views on several specific issues raised in FDA's discussion of the proposed rule.

UEP agrees with FDA that among the reasons for accepting inside-lid labeling should be that "[c]onsumers must open egg cartons before removing the eggs and thus would be exposed to the instructions before cooking ... [and] many consumers open the lids of egg cartons to check for cracked eggs at the point of purchase" and so would again be exposed to the message.

In addition, UEP agrees with FDA that the inside lid may facilitate "print[ing] the safe handling instructions in a larger font because there is generally more space available inside the lid for such labeling." UEP would not support a binding requirement for a larger type size than the font presently required, however. Although FDA states that a consumer group has raised the issue whether the present warning is legible to some consumers, UEP notes FDA's statement that the group "did not provide data or other appropriate information to support this assertion." In the absence of any affirmative indication that typeface size constitutes a problem for consumers, UEP would oppose further requirements in this area, but again notes its agreement with FDA that the ability to place the statement inside the lid will probably facilitate use of a larger font in many cases.

UEP agrees with FDA's concern that cost of printing safe handling instructions on the PDP or information panel "may be prohibitively expensive for some firms." In addition, producers and carton manufacturers might be affected in a disparate manner by such a requirement, depending on the type of material used to manufacture the carton. Because the number of carton manufacturers is small, and each manufacturer is primarily identified with a single material, a strict requirement to print on the PDP or information panel could have an inequitable effect on some firms and producers.

UEP supports FDA's proposal to require the phrase "Keep Refrigerated" on the PDP or information panel in cases where the safe handling instructions appear on the inside lid. UEP notes that separate regulations of the U.S. Department of Agriculture's Food Safety and

Inspection Service (FSIS) presently require this statement, that nearly all if not all egg cartons already bear the statement on the outside lid, and that the requirement would serve the useful purpose of alerting the consumer at the point of purchase to refrigerate the product quickly.

Because it takes up little space, the phrase "Keep Refrigerated" does not raise the same issues regarding scarce lid space that are raised by the full safe handling instructions. Notably, the National Egg Regulatory Officials (NERO, the association comprising state government regulators of eggs) made this point in its comment of April 24, 2001. NERO supported in-lid labeling in part because "[m]ost states have labeling requirements in addition to those at the federal level ... As the federal government adds labeling requirements to those already required by both federal and state government, there is less space available on cartons." However, NERO also said that "there should continue to be a refrigeration statement prominently displayed on the principal display or information panel."

On a related matter, we strongly support FDA's proposed option, rather than its "Option Two." The difference between the two options is that in the case of Option Two, a referral statement would be required in all cases where safe handling instructions appear on the in-lid. FDA has stated that industry costs would likely be as much as $11.5 million higher with Option Two, compared to the proposed rule.

We believe Option Two would be quite onerous, because FDA has been responsive to "requests from individual companies for permission to place the safe handling statement on the inside lid of egg cartons," as the agency stated in the "Background" section for the proposed rule. Therefore, many existing labels have "Keep Refrigerated" on the PDP and the safe handling instructions on the in-lid. Under Option Two, the PDP would have to be redesigned to add a referral statement, and this would entail substantial costs for both carton manufacturers and producers. This requirement would also be counterproductive in that the required reference would consume some of the PDP labeling space gained by moving the safe handling statement to the inside lid of the carton.

Regardless of what packaging material they utilize, all carton manufacturers – and the egg producers who are their customers – wish to avoid unnecessary redesigns of labels, which are costly. We agree with FDA's statement that "[b]ecause all consumers open egg cartons before consumption, we assume the same number of consumers will notice the safe handling statement on the inside lid as would notice [the] statement on the outside of the carton, because of the greater potential for larger font sizes and lower text density on the inside lid. If this is true, *there would be no additional benefit from the required referral statement on an outside panel* under option two." (Emphasis added.) With no added benefit and as much as $11.5 million of extra cost under Option Two, we believe it is clear that the FDA's preferred option is the appropriate choice in the agency's final rule.

NERO's letter from April 24, 2001, supports this argument, although the association was not commenting on the specific options in the proposed rule because these had not yet been presented to the public. NERO wrote that a refrigeration statement on the outside lid should be required because "both retailers and consumers would be alerted to the need to refrigerate. *This is the only portion of the safe handling instruction that is applicable at the time of purchase. The remainder of the instruction addresses home use.*" (Emphasis added.)

UEP commends FDA both for the flexibility the agency has shown on a case-by-case basis until now, and for the proposed rule that will create a single, flexible standard for the entire industry. UEP urges FDA to adopt the proposed rule as final without change.

Sincerely,

Howard M. Magwire
Director of Government Relations

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