



MAR 2 - 2001

Mr. Phil Laughlin
Regional Sales Manager
Dolco Packaging
Midwest Division
2110 Patterson Street
Post Office Box 469
Decatur, Indiana 46733-0469

Dear Mr. Laughlin:

This is in response to your letters of January 2 and January 12, 2001, in which you requested the Food and Drug Administration (FDA) to provide some flexibility for the placement of the newly required safe handling statement on egg cartons. We hope that the following clarifies our position.

You asked that FDA allow the safe handling statement to appear on the top, side, or inside of the egg carton. You maintained that under customary conditions of use, most individuals open egg cartons to check eggs before they purchase them. Thus, you stated that the information on the inside becomes conspicuous and likely to be read. In fact, you asserted that some consumers consider the "inlid print area" on eggs to be the information panel. You stated that most of your annual production of over a billion egg cartons have printing only on the carton top and inside the lid.

You further stated that complying with the placement requirements of the regulation would result in a financial hardship for your company. You contended that over half of your print lines do not have the capability to print on the front or back of the cartons and, thus, to comply with the regulation you would either need to buy more equipment or change all of the current artwork. The cost for this added printing would be over \$600,000 plus installation, labor and manufacturing interruption. You also stated that to change all existing artwork would cost approximately \$2 million in new printing plates.

You pointed out that sidelid printing is offered to customers as an optional feature at an added cost. You stated that most customers do not choose this option, resulting in less than 15 % of your cartons containing sidelid print. You stated that customers who do not want their artwork altered would either be forced to pay for sidelid printing, or will choose to buy from your pulp packaging competitors, which would negatively impact your business.

With your letter you provided samples of cartons illustrating the labeling on 6 egg, 8 egg and 1 dozen egg cartons. You noted that in some of the samples, allowance of space for the artwork does not accommodate nutrition labeling, USDA shields, and other required

information. You stated that you needed the ability to move information on the label to comply with federal and State requirements while still meeting the artwork needs of your customers.

First, we would like to thank you for the information that you provided regarding the practices of your company and the needs of your customers. As you are aware, the regulation requiring the safe handling statement requires that the statement appear either on the principal display panel (PDP) or the information panel. We recognize that many consumers open cartons of eggs before they purchase them. Although we do allow nutrition labeling on the inside of egg cartons, that fact does not establish an expanded definition of the information panel. The information panel is defined in Title 21 of the Code of Federal Regulations (CFR), section 101.2, as the panel to the right of the PDP or, in the case that the top of the panel is the PDP, any panel adjacent to the PDP.

With regard to your inability to print on the sides, we would like to point out that there appears to be sufficient space on the tops of many egg cartons such that printing on the sides of the cartons is not warranted. Thus, when there is sufficient space, the label safe handling statement may appear on the PDP instead of on the information panel.

With regard to your request for flexibility in placement of the safe handling statement so that you may still meet the artwork needs of your customers, we would like to point out that FDA's regulation in 21 CFR 101.15 requires that any information required on the label of foods under the authority of the Federal Food, Drug, and Cosmetic Act (the act) must appear prominently and conspicuously. The regulation further states that insufficiency of label space for the prominent placing of such required information may result from the use of label space for any word, statement, or design not required to appear on the label. In other words, artwork must not be considered in determining sufficiency of label space. FDA concluded that the requirement for prominence and conspicuousness for the safe handling statement is met if the statement appears on the PDP or information panel. Therefore, where there is sufficient space, notwithstanding artwork and other nonmandatory information, the safe handling statement must appear on the PDP or information panel, which are on the outside of the egg carton.

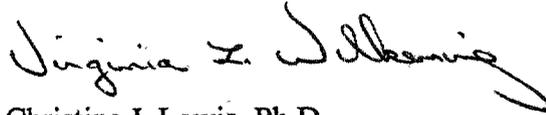
However, we do recognize that there are many requirements by States and other federal agencies such as USDA's Food Safety and Inspection Service and Agricultural Marketing Service for egg labeling that may limit the space on the PDP or information panel of some egg

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cartons. Thus, we will not object to the placement of the required safe handling statement inside the lid of egg cartons only in the instances where there is insufficient space on the PDP or information panel for all information required by State or federal laws.

If you need further information, please let us know.

Sincerely yours,



for Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition