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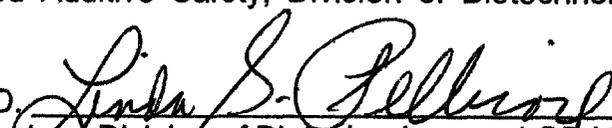
DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA/CFSAN/OFAS/DBGNR

Memorandum

Date: May 17, 2002

From: Timothy P. Twaroski, Ph. D.
Food and Drug Administration, Center for Food Safety and Applied
Nutrition, Office of Food Additive Safety, Division of Biotechnology and
GRAS Notice Review.

Through: Linda S. Pellicore, Ph. D. 
Toxicology Group Supervisor, Division of Biotechnology and GRAS Notice
Review.

Subject: FAP 9A4652 -- Submitted by Procter and Gamble Co.

To: Mary Ditto, Ph. D.
Consumer Safety Officer, Division of Biotechnology and GRAS Notice
Review

Toxicology Memorandum

Re: FAP 9A4652; Procter and Gamble Co., Use of Olestra in Place of Fats and Oils in
Prepackaged Ready-to-Heat Popcorn. Submitted February 25, 1999.

Procter and Gamble Co. (P&G) is petitioning for the expanded use of Olestra in Ready-to-Heat (microwave) popcorn, in addition to its current use in Ready-to-Eat savory snacks which include chips, pretzels and popcorn. Chemical and toxicological study data as well as environmental impact statements regarding the safety of Olestra were submitted previously in FAP 7A3997. This data was assessed prior to the regulation of Olestra (21 CFR 172.867).

The current petition focuses on the use of Olestra in microwave popcorn. The new data presented in this petition includes temperature measurements that occur in the heating process as well as measurements of thermal degradation of the included fat-soluble vitamins (A, D, E & K). Temperature maximum was determined to be 175°C (Section 3.2.2, Figure 1, p. 23). Fat-soluble vitamin loss was determined for vitamins A, D and K to be 44.0%, 4.3% and 24.4%, respectively. P&G conducted these measurements through Covance laboratories, a contract laboratory. Measurements of vitamin E degradation at high temperatures were not conducted since the vitamin E degradation issue was previously addressed in FAP 7A3997, with degradation levels observed to be approximately 4%. P&G also included a discussion on the issue of thermal degradation of fat-soluble vitamins.

In reviewing the submitted petition, chemistry and environmental review found no cause for concern with the safe use of this product in the proposed format.

During the safety review of the temperature measurements shown in Figure 1 (p. 23), we noted that temperatures were above 150 degrees for about 90 seconds whereas the petitioner notes these temperatures are reached for only 30 to 60 seconds. But, as was stated in the results section (3.2.2), it is not uncommon to fry foods for 2 to 5 minutes at similar temperatures. Thus, microwave heating for 90 seconds at 150 degrees is not likely a concern in terms of thermal degradation of vitamins.

In regards to thermal degradation of fat-soluble vitamins, we conducted a thorough examination of the published literature (Medline, Toxline, and a Dialog One search performed by the CFSAN library which included Biosis Previews(R)(1969-2000), Food Sci. & Tech. Abs. (1969-2000), and Medline (1966-2000)). This literature review pointed out several publications with scientific data that exhibited similar levels of vitamin A loss, compared to the studies provided by the notifier. The corroborating data was observed by Dutra-de-Oliveira, et al. (International Journal of Food Sciences and Nutrition 49:205-210, 1998), where they observed a vitamin A decrease of 35% at 170 degrees. One additional supportive study was mentioned by Burger & Walters (Proc. Nutr. Soc. 32:1-8, 1973), in which 40% of vitamin A was lost after 5 minutes at 200 degrees.

Regarding fat-soluble vitamins D and E, we see no reason to have the levels of the vitamins increased to compensate for any degradation during the microwave cooking process. This is because the levels that are degraded, amount to such a small quantity, approximately 4%, that the systemic levels of fat-soluble vitamins D and E would not be affected and thus not be considered biologically significant.

Given "that olestra from microwave popcorn would not likely be consumed concurrently with dietary sources of fat-soluble vitamins, and the vast majority of meals would not be consumed in the presence of olestra from ready-to-heat popcorn containing heating-related reduced amounts of added vitamins A and K" (M. Dinovi, Chemistry Memo, 5/3/02), we can rationalize that the person's daily intake of fat-soluble vitamins would be unaffected by the consumption of microwave popcorn which contains Olestra. Thus, the degraded fat-soluble vitamins A and K would not need to be replaced in the microwave popcorn utilizing olestra.

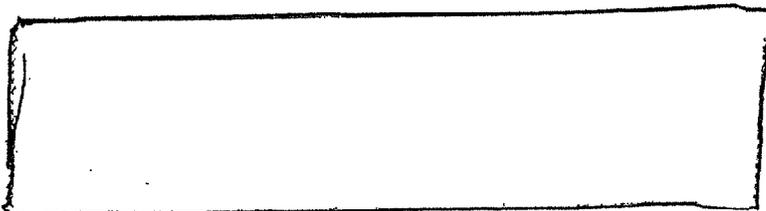
Regarding fat-soluble vitamins in general, since 99.6% of all meals are not eaten with popcorn, and popcorn is only eaten twice every 14 days by the average consumer or 4 times every 14 days by the high-intake consumer (M. Dinovi, Chemistry Memo, 5/3/02); we can say that intake of microwave popcorn utilizing Olestra will have no detrimental effects on the levels of fat-soluble vitamins in consumers. In addition, the loss of vitamins added to the Olestra, to offset fat-soluble vitamin loss with the concurrent consumption of Olestra products with other dietary sources of fat-soluble vitamins, from degradation will also not have a negative effect because popcorn eating occasions occur with a meal only 9% of the time (M. Dinovi, Chemistry Memo, 5/3/02).

One final concern that was discussed during the course of the safety review was the possible formation of retinoic acid metabolites, known to have teratogenic and embryotoxic effects in humans at minimal levels. Through the previously mentioned literature searches, we have not uncovered any problems that have been associated or linked to the thermal degradation of fat-soluble vitamins, especially regarding the formation of toxic metabolites.

Given the present knowledge and scientific data available we have no additional questions regarding the safety of olestra for human consumption in prepackaged Ready-to-Heat popcorn at this time.



Timothy P. Twaroski, Ph. D.



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