

Letter to the Editor

Risks associated with foods having advisory milk labeling

To the Editor:

Milk avoidance diets can be quite effective in preventing reactions among subjects with milk allergy, but small amounts of milk contaminating other foods have provoked allergic reactions.¹⁻³ For dietary avoidance strategies to be effective, ingredient statements must be clear and accurate.⁴ Under the US Food Allergen Labeling and Consumer Protection Act, all packaged food products should contain clear labeling for the presence of commonly allergenic foods or any ingredients derived therefrom.⁴ However, the use of voluntary advisory labeling has become a common practice in the food industry.⁵ The 3 most popular forms of statements used are “may contain [allergen],” “manufactured on shared equipment with [allergen],” and “manufactured in the same facility with [allergen].”⁵ Because such labeling is voluntary and no regulations currently dictate criteria for which situations necessitate which labeling form, there is likely little congruity between statement form and situations of use.⁶ Consumers are also known to overlook or disregard such statements, creating a potentially hazardous situation.⁵

Thus we wished to determine the potential likelihood of milk exposure in subjects with milk allergy consuming products bearing advisory milk labels. Products with different forms of milk advisory labeling were examined to determine whether any differences occurred with respect to the presence, concentration, and dose per serving of milk. Comparisons were made between company sizes and food categories to determine whether any differences occurred among these classifications. Food products (100 total) bearing advisory statements regarding milk, including 81 with milk advisory labeling, 15 with milk listed as a minor ingredient (one of the last 3 ingredients on statement), and 4 with milk fat listed as a minor ingredient were purchased in Lincoln, Nebraska, in 2008 from 7 local grocery retail stores. Of the 81 products with advisory statements on the label, 28 (50 samples) were labeled “may contain,” 30 products (57 samples) were labeled “shared equipment,” 21 products (40 samples) were labeled “shared facility,” and 2 products (3 samples) had other unique forms of advisory labeling. Two different lot numbers of each product were obtained and analyzed for 85 products. Products were categorized as baked goods/mixes, dark chocolate candy, other candy/confectionery, cereals, frozen desserts, instant meals, nutritional/granola bars, snack foods, and miscellaneous. Products were also classified based on the size or type of manufacturer as coming from a large company (>500 employees), small company (<500 employees), or supermarket brand (uncertain size of manufacturer). A representative sample from each package was homogenized and analyzed for the presence of milk by using a commercial ELISA (Total Milk Veratox; Neogen Corp, Lansing, Mich; lot no. 12061). Dilutions were carried out when samples tested outside the standard curve provided with the kit (2.5–25 parts per million [ppm] or µg/g). The concentration results obtained were averaged, and the mean was recorded for use in further calculations. Concentrations for each sample and suggested serving sizes for each product were then used to determine dose amounts per serving in milligrams of milk as nonfat dry milk. Statistical comparisons of the percentage

of products with each type of advisory labeling having detectable milk residues was performed with the χ^2 test for equality of distributions.

Milk was detected in at least 1 lot in 34 of 81 products bearing milk advisory statements (Table I). Of products bearing milk advisory statements, detectable milk residues were found in 60.7% (17/28) of products with “may contain” labels compared with 33.3% (10/30) of products with “shared equipment” labels ($P < .10$) and 28.6% (6/21) of products with “shared facility” labels ($P < .10$) and in 50% (1/2) of other uniquely labeled products (not tested for significance). Detectable milk residues were found in products in 7 of the 9 product categories (Table I). Dark chocolate candy was an especially noteworthy category, with 14 of 18 products having detectable milk residues in 1 or both lots. Although not statistically significant, products with milk advisory labels and detectable levels of milk residues were more likely to be manufactured by small companies as opposed to large companies, with 48.9% (23/47) of products manufactured by small companies and 31.6% (6/19) of products manufactured by large companies testing positive for milk. Products with milk advisory labels that were considered supermarket brand products, which might have been manufactured by either small or large companies, had detectable milk in 33.3% (5/15) of products analyzed.

Of products with milk listed as a minor ingredient, detectable milk residues were found in at least 1 lot in 60% (9/15) of such products and from 5 of 7 categories in which that type of labeling was encountered (Table I). All products with milk fat listed as a minor ingredient had detectable milk present (4/4), and all were in the candy–dark chocolate category.

As shown in Table I, a very wide range of concentrations of milk was found in these products. For products bearing advisory labels, the milk concentrations ranged from 3.4 up to 15,000 ppm milk. No relationship was evident between the form of the advisory statement and the level of detectable milk. Levels of milk ranged from 3.5 to 4,800 ppm in products with “may contain” labels, from 22 to 4,700 ppm in products with “shared equipment” labels, and from 3.4 to 2,300 ppm in products with “shared facility” labels. The single product with the unique form of advisory labeling had a level of 15,000 ppm milk. The levels of milk in products with milk listed as a minor ingredient were similarly variable, ranging from 4.0 to 1,400 ppm. Dark chocolate samples had rather high but variable levels of residual milk, ranging from 3.7 to 15,000 ppm. Only a few of the products from other categories had residual milk levels of greater than 1,000 ppm.

The possible exposure doses for milk from these products were estimated based on the detectable level of milk and the suggested serving sizes for each product (Table I). Estimated doses for products with advisory labels and detectable milk ranged from 0.027 to 620 mg of milk. Surprisingly, the estimated doses for minor milk ingredient products were lower (0.11–36 mg). Estimated doses for products with milk fat as a listed ingredient ranged from 0.31 to 550 mg of milk. However, a consumer might eat more or less than the suggested serving size of product on any occasion. Therefore the dose amounts in Table I are estimates of true consumer exposure and offered for comparative purposes only.

Advisory labeling is voluntary, and different manufacturers likely use different criteria to determine which statement to use or whether to use an advisory statement at all. The prevalence of

TABLE I. Concentration and serving-size doses of milk in foods with allergy advisory statements for milk or indicating the presence of milk as a minor ingredient

Product category	“May contain” labeling			“Shared equipment” labeling			“Shared facility” labeling		
	No.*	Conc†	Dose‡	No.	Conc	Dose	No.	Conc	Dose
Baked goods/mixes	7 (2)	69; 4.7 6.1; 4.0	2.3; 0.15 0.20; 0.13	9 (5)	320; BLQ 22; BLQ 75; 43 37; BLQ 190; BLQ	4.5; <0.04 1.1; <0.13 2.5; 1.4 2.1; <0.14 6.8; <0.09	3 (1)	50; 33	2.4; 0.83
Candy (dark chocolate)	9 (7)	4,800 1,400 740 200 130; 68 19; 13 3.7	240 60 30 7.6 5.2 2.7 0.67, 0.46 0.1	4 (4)	4,700 610 110 1,200; 1,000	160 26 4.7 3.4; 2.8	3 (2)	680 2,300; 990	26 92; 40
Candy (other)	2 (1)	190; 27	9.9; 1.4	2 (0)			2 (0)		
Cereals	0 (0)			1 (0)			0 (0)		
Frozen desserts	3 (3)	35; BLQ 18; BLQ 3.5; BLQ	1.9; <0.13 1.4; <0.19 0.2; <0.14	0 (0)			0 (0)		
Instant/quick meals	1 (1)	18; BLQ	1.1; <0.16	4 (1)	310; 110	7.8; 4.3	4 (2)	5.6; 3.4 4.8; BLQ	0.045; 0.027 0.27; <0.14
Nutritional/granola bars	3 (2)	52; 7.1 3.5; BLQ	3.5; 0.48 0.17; <0.12	0 (0)			0 (0)		
Snack foods	1 (1)	3,800	110	9 (0)			7 (1)	22; BLQ	0.66; <0.075
Miscellaneous	2 (0)			1 (0)			2 (0)		
Totals	28 (17)			30 (10)			21 (6)		

BLQ, Below the lower limit of quantitation: 2.5 ppm.

*Number of samples tested (number of samples with detectable milk).

†Concentration in parts per million (micrograms per gram).

‡Dose in milligrams per suggested serving.

detectable milk in advisory labeled products varied among various statement forms, food categories, and manufacturer sizes. Detectable milk levels were found in 1 or both lots of 42% of products with advisory labels (28.6% to 60.7%, depending on form of labeling), 60% of products with milk listed as a minor ingredient, and 100% of products with milk fat listed as a minor ingredient. In contrast, detectable peanut was found at much lower frequency in products with either advisory labels (7.3%) or minor ingredient labeling (33%).⁶ The reasons for this disparity are unclear, although it might reflect greater caution on the part of the food industry with respect to peanut allergy. However, the results of this analytic survey are clearly skewed by the dark chocolate category, in which detectable milk residues were found in 82.6% of dark chocolate products. The sharing of chocolate-processing equipment between milk and dark chocolate and the known difficulty in cleaning of chocolate-processing equipment lead to this situation. However, even if the dark chocolate category is ignored, 36.4% of products in all other categories contained detectable levels of milk.

This was not an exhaustive survey, and therefore it should not be concluded that some categories of food products never contain detectable milk. Also, the purchasing of only 2 different lots, where possible, and only 1 sample per lot does not exclude the possibility of detecting milk in other lots of the same products or in other samples from the same lot because milk residues might not always be uniformly distributed within a lot.

Surveys indicate that consumers with food allergy are more likely to buy products with “shared facility” labeling than

“shared equipment” labeling and are more likely to buy products with “shared equipment” labeling than “may contain” labeling.⁶ However, attempts by consumers with food allergy to comparatively assess risks associated with different labeling forms are potentially faulty. Detectable milk residues were found in samples with all forms of advisory labeling, although the highest prevalence was found in products with “may contain” labeling. Furthermore, products within nearly all food categories contained detectable milk. Milk advisory labeling should be viewed as indicating some level of risk to consumers with milk allergy.

Surprisingly, many products (40%) with milk listed as a minor ingredient contained no detectable milk, although the purchase of only 2 lots of each product does not indicate that these products would never contain detectable milk. The absence of detectable milk in food listing milk as a minor ingredient might lead some consumers with milk allergy to mistakenly assume that their milk allergy is resolving. Products with milk fat listed as a minor ingredient are also potentially worrisome for consumers with milk allergy. The purchasing behaviors of consumers with milk allergy have not been studied, but these persons might not view milk fat as an ingredient that carries the same degree of risk as protein-based ingredients, such as casein and whey. However, dark chocolate products with milk fat listed as a minor ingredient contained among the highest levels of detectable milk in this survey. This form of labeling was only noted in the dark chocolate category.

Should consumers with milk allergy avoid ingestion of products with milk advisory labels or with milk or milk fat listed as a minor ingredient? On a per-serving basis, the doses of milk found in these

TABLE I. (Continued)

Unique advisory labeling			Milk fat as listed ingredient			Minor ingredient labeling			Totals
No.	Conc	Dose	No.	Conc	Dose	No.	Conc	Dose	
0 (0)			0 (0)			6 (3)	150; 88 690; 9.4 1,400; 340	4.4; 2.1 24; 0.32 36; 8.8	25 (11)
2 (1)	15000	620	4 (4)	13,000; 7700 91; 8.5 10,000 4,600	550; 320 3.0; 0.31 430 200	1 (1)	9.6	0.11	23 (19)
0 (0)			0 (0)			1 (1)	860; 670	13; 10	7 (2)
0 (0)			0 (0)			1 (0)			2 (0)
0 (0)			0 (0)			0 (0)			3 (3)
0 (0)			0 (0)			2 (2)	560; 210 4.0; BLQ	24; 9.0 1.1; <0.71	11 (6)
0 (0)			0 (0)			1 (0)			4 (2)
0 (0)			0 (0)			3 (2)	42; 20 14; 10	1.3; 0.60 0.20; 0.14	20 (4)
0 (0)			0 (0)			0 (0)			5 (0)
2 (1)			4 (4)			15 (9)			100 (47)

samples were quite low in some, but not all, cases. Although consensus does not exist on the minimal eliciting doses for milk, evidence suggests that amounts in the low milligram range are sufficient to cause mild allergic reactions in patients undergoing low-dose diagnostic oral challenges.⁷ Of the 68 samples with detectable milk, 49 contained less than 10 mg of milk per serving and likely pose a risk only to the most sensitive subjects with milk allergy. But much higher risk samples were also identified, including 8 samples that would provide more than 100 mg per serving; all but 1 of these were from the dark chocolate category, including 4 samples with milk fat listed as a minor ingredient. Dark chocolate products with advisory labeling and products with milk or milk fat listed as a minor ingredient pose a risk to a higher percentage of consumers with milk allergy. The level of risk posed to individual subjects with milk allergy from consumption on products with milk advisory labeling or with milk or milk fat listed as a minor ingredient will depend on their individual threshold dose. However, because some subjects with cow's milk allergy are known to be highly sensitive, physicians should advise such patients in particular to refrain from eating products with milk advisory labeling or milk listed as a minor ingredient. All patients with cow's milk allergy should likely avoid consumption of dark chocolate.

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Supported by the Food Allergy Research and Resource Program and the Undergraduate Creative Activities and Research Experiences Program of the University of Nebraska. This research was conducted with a contribution of the University of Nebraska Agricultural Research Division supported in part by funds provided by the United States Department of Agriculture. Additional support was provided by the Food Allergy Research and Resource Program and the Undergraduate Creative Activities and Research Experiences Program of the University of Nebraska.

Disclosure of potential conflict of interest: S. L. Taylor has licensed the milk ELISA used in this research to Neogen Corporation and has received research support from a consortium of food companies. M. P. Crotty has declared that he has no conflict of interest.

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doi:10.1016/j.jaci.2009.12.003