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Research Paper

A Limited Survey of Dark Chocolate Bars Obtained in the United States for Undeclared Milk and Peanut Allergens

BINAIFER BEDFORD,[1] YE YU,[2] XUE WANG,[2] ERIC A. E. GARBER,[3] AND LAUREN S. JACKSON[1]*

[1]U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Processing Science & Technology, 6502 South Archer Road, Bedford Park, Illinois 60501; [2]Institute for Food Safety and Health, Illinois Institute of Technology, 6502 South Archer Road, Bedford Park, Illinois 60501; and [3]U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Regulatory Science, Division of Bioanalytical Chemistry, 5001 Campus Drive, College Park, Maryland 20740, USA

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ABSTRACT

Undeclared allergens in chocolate products have been responsible for numerous allergen-related recalls in the United States. A survey was conducted to determine the prevalence of undeclared milk and peanut in 88 and 78 dark chocolate bars, respectively. Concentrations of milk (as nonfat dry milk) or peanut in three samples of each chocolate product were determined with two milk- or peanut-specific enzyme-linked immunosorbent assay kits. In 75% of the chocolate bar products with a milk advisory statement, milk concentrations were above the limit of quantitation (2.5 μg/g [ppm]), with the majority having concentrations >1,000 ppm. An additional 67% of chocolate bars with a "traces of milk" statement contained 3 to 6,700 ppm of milk. Fifteen percent of chocolates labeled dairy free or lactose free and 25% labeled vegan were positive for milk, all with concentrations >1,000 ppm. Even for chocolates with no reference to milk on the label, 33% of these products contained 60 to 3,400 ppm of milk. The survey of chocolate products for peanuts revealed that 8% of products with an advisory statement contained peanut, with the highest concentration of 550 ppm. All nine chocolates bearing the peanut-free or allergen-free statement were negative for peanut, but 17% of chocolates with no label statement for peanut were positive for peanut at concentrations of 9 to 170 ppm. Evaluation of multiple lots of four chocolate products revealed that milk was consistently present or absent for the products investigated, but mixed results were obtained when multiple lots were tested for peanut. This study indicates that a large proportion of dark chocolate bars contain undeclared milk. The type of advisory statement or the absence of a milk advisory statement on products did not predict the amount or absence of milk protein. In contrast, a lower proportion of chocolates containing undeclared peanut was found. Consumers with food allergies should be cautious when purchasing dark chocolate products, particularly those that have an advisory label statement.

Key words: Chocolate; Cross-contact; Labeling; Undeclared allergens

Food allergies are a health concern around the world. Recent reports estimate an increased prevalence of food allergies, which impact nearly 15 million people in the United States, including 2 to 4% of the adult population and 5 to 8% of children *(3, 4, 12, 19–21, 23)*. Milk allergy occurs in 3% of young children *(3, 23)* and is a frequent cause of self-reported food allergy in adults *(32)*. Peanut allergy accounts for nearly 2% of food allergies among children *(12),* and the prevalence in adults has been estimated at 0.6% *(23, 24)*. Although milk allergy is more prevalent than peanut allergy in children, peanuts have generally accounted for the majority of food allergen–related deaths. Milk allergy was associated with 13% of food allergen–related fatalities in 2001 to 2006 *(2, 6, 12)*. Strict avoidance of the offending food allergen is the only way to avoid allergic reactions. For this reason, food-allergic consumers depend on accurate food labels to disclose the presence of allergenic ingredients, such as milk and peanut.

* Author for correspondence. Tel: 708-924-0616; Fax: 708-924-0690; E-mail: lauren.jackson@fda.hhs.gov.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 *(28)* amended the Food, Drug and Cosmetic Act to require that manufacturers of all packaged food products sold in the United States list the presence of major food allergens (milk, egg, peanuts, tree nuts, wheat, soy, fish, and shellfish) in clear language on or near the ingredient statement when the allergen is an ingredient in the product. More recently, the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) *(30)* enhanced the FDA's authority to recall foods contaminated with allergens. FSMA also added requirements that the FDA issue regulations that would require food facilities to implement allergen controls where necessary. One example of a control is prevention of cross-contact, i.e., the unintended introduction of allergens into food. Cross-contact can occur through the transfer of allergens during processing or handling, such as when allergen-containing and non–allergen-containing foods or ingredients are produced in the same facility or on the same processing line and allergen controls are not properly implemented. Some causes for cross-contact during manufacturing include

improper use of product rework, incomplete cleaning of food contact surfaces, and contamination of nonallergenic foods with airborne dust and aerosols created during production of allergenic foods *(15)*. Failure to catch such errors and labeling mistakes have resulted in a high rate of food recalls, with nearly 60% of food allergen entries in the FDA Reportable Food Registry *(29)* attributed to products in the bakery, snacks, candy, dressing, and dairy market segments *(9, 10)*. From 2009 to 2014, approximately 12% of food allergen entries in this registry were undeclared allergens in chocolates and other confections *(29)*. The primary allergen in the majority of the Reportable Food Registry reports was undeclared milk, followed by peanuts. Before the implementation of FALCPA, Vierk et al. *(33)* reported that 37% of total recalls due to undeclared allergens were in the candy and chocolate category. Other published reports include case studies of adverse consumer reactions associated with ingestion of undeclared milk or peanut in a variety of products, including dark chocolate *(1, 11, 13, 14, 17, 34)*.

Complete, accurate, and truthful product labels are crucial for consumers with food allergies. Although FALCPA focuses on the declaration of allergens intentionally added to a product, a wide variety of advisory label statements currently appear on products that may have unintentional allergens present as a result of cross-contact during production. No U.S. regulations or policies address the use of advisory labeling or mandate the content of advisory statements, including statements describing the potential presence of unintentional allergens in food products resulting from the food manufacturing process. Such advisory labeling is voluntary; however, when statements are used they must be truthful, not misleading, and not used in lieu of good manufacturing and food allergen preventive practices. The term "vegan," which implies that a product does not contain milk, eggs, or any other animal-derived component, has not been defined in this context. The proliferation of advisory label statements, which are often open to interpretation, can make purchasing "safe" products, i.e., those without the allergen of concern, challenging for consumers *(22, 25)*.

Food manufacturers use labels and cross-contact controls to prevent allergen-related misbranding and adulteration of their products. The high number of recalls associated with milk, peanut, and other allergens in dark chocolate products suggests that either these controls are not being widely implemented or that inherent problems are associated with providing sufficient allergen control in this segment of the food industry. To evaluate the prevalence of milk and peanut in dark chocolate products that are not explicitly labeled as containing these allergens, in this study dark chocolate bars, primarily from manufacturers throughout the United States, were examined for the presence of undeclared milk and peanut. The products selected for the survey included a wide variety of dark chocolate bars with different label statements on the product packaging. To obtain a better understanding of allergen controls used by manufacturers and to evaluate consistency across lots, multiple lots of some chocolate bars were analyzed for the presence and concentrations of milk and peanut.

MATERIALS AND METHODS

Undeclared milk in chocolate: sample collection, label review, and sample preparation. One hundred chocolate samples primarily from domestic manufacturers located throughout the United States were purchased between September 2013 and September 2014. Of the 100 samples, 93 were dark chocolate bars (labeled as dark chocolate, bittersweet chocolate, or semisweet chocolate or having a high cocoa content, typically >50%) that did not have milk listed on the ingredient label or an allergen declaration indicating that the product "contains milk." The remaining seven chocolate bars (six dark chocolate and one milk chocolate) listing milk in the ingredient statement were used as positive control samples in this study. The chocolate bars evaluated in this survey differed in size and weight.

Multiple lots, as indicated by different expiration dates, were purchased for four dark chocolate products to evaluate the extent of milk in products obtained from different production runs. The five samples that were obtained from the additional lots were not counted as individual unique products (each having a unique stock keeping unit code) in this survey. Thus, the final sample size for the milk survey was 88 unique dark chocolate products after the 7 positive control samples and 5 multiple lot samples were excluded from the initial 100 chocolate samples. A minimum of 300 g of product with the same lot number or expiration date was required for the chocolate to be included in the evaluation study.

Product labels were reviewed, and the chocolates were organized into seven categories for the milk survey based on the label statements: (i) advisory statement for milk alone, (ii) advisory statement that specifically included "may contain traces" of milk, (iii) advisory plus vegan statement, (iv) advisory plus dairy-free or lactose-free statement, (v) dairy-free or lactose-free statement alone, (vi) vegan statement alone, and (vii) no statement regarding milk. Chocolate bars with the same lot number and/or expiration date were frozen (–20°C) overnight and homogenized using dedicated knives, cutting boards, and mini food processors (model DLC-2ABC, 3-cup Mini-Prep Plus Chopper/Grinder, Cuisinart, Stamford, CT). The ground chocolate was transferred to three plastic bags, each containing at least 100 g of sample. Milk content was measured in the chocolate samples with enzyme-linked immunosorbent assays (ELISAs).

Undeclared peanut in chocolate: sample collection, label review, and sample preparation. For the peanut study, 93 chocolate samples were purchased primarily from domestic manufacturers across the United States from September 2013 to April 2015. For this survey, all samples were dark chocolate bars of various weights and dimensions with the exception of one milk chocolate bar (product AP7, Supplemental Table 2) (all supplemental material is available at https://doi.org/10.4315/0362-028X.JFP-16-443.s1). One dark chocolate bar that had peanuts listed as an ingredient on the label served as a positive control sample. The remaining 92 chocolate bars did not explicitly state the presence of peanuts on the ingredient statement or have the phrase "contains peanuts" on the label.

To determine consistency across lots for peanut, multiple lots indicated by different lot numbers and/or expiration dates were obtained for 12 dark chocolate products. The 14 chocolate samples obtained from the additional lots were not counted in the survey; thus, the total number of unique dark chocolate products (unique stock keeping unit codes) surveyed for peanut was reduced to 78. At least 300 g of dark chocolate bars with the same lot number or expiration date were homogenized using a mini food processor.

The homogenized chocolate was transferred to three plastic bags, each containing at least 100 g of sample.

Label review of the statements on the chocolate packaging resulted in the following four categories: (i) advisory statement for peanut, (ii) "traces of peanut" or "residual peanut" subset of the advisory category, (iii) peanut-free or allergen-free statement, and (iv) no statement for peanut. Although some chocolate bar labels used the term "nuts," it was unclear whether this term was referring to peanuts or tree nuts. Thus, chocolates with the term "nuts" were considered to have no statement regarding the possible presence of peanuts for the purposes of this study and were classified in the "no statement for peanut" category.

Qualitative evaluation of milk and peanut in chocolate samples. Preliminary qualitative screening of chocolate samples for milk and peanut was accomplished using the Veratox for Total Milk ELISA kit (catalog no. 8470, Neogen, Lansing, MI) and the Veratox for Peanut ELISA kit (catalog no. 8430, Neogen). Each chocolate product was screened in triplicate following the protocol included with each kit. The only modification made to the milk analysis procedure was to screen 12 chocolate samples with each 48-well plate and use the 0-, 2.5-, and 5-ppm nonfat dry milk (NFDM) control standards provided in the test kit. Modifications to the peanut procedure included centrifuging the sample extracts at 2,325 × *g* at 23°C for 20 min, evaluating 12 chocolate samples with each 48-well plate, and using only the 0-, 2.5-, and 5-ppm peanut standards provided in the test kit. An ELX-808 plate reader (BioTek Instruments, Winooski, VT) with Gen 5 (version 2.04) software was used to measure sample absorbance at 650 nm. Chocolate samples with absorbance values at or above the 2.5-ppm milk or peanut standard were considered positive for the respective allergen. Chocolates testing positive for the allergen were evaluated further to quantify milk or peanut in these samples.

Quantitative evaluation of milk in chocolate samples. Chocolate samples testing positive for milk with the qualitative method were evaluated further for milk concentrations using the Veratox total milk ELISA and the Morinaga Milk Protein (casein) ELISA (catalog no. M2102, Morinaga Institute of Biological Science, Yokohama-Shi, Japan). As indicated by the manufacturers, the antibodies used in the Veratox total milk ELISA and the Morinaga milk protein ELISA specifically target total milk proteins (caseins plus whey) and casein, respectively. Pacari 100% raw cacao chocolate (Pacari Chocolates, Pichincha, Ecuador) was used as a milk- and peanut-free control material sample (CMS) for this study. Reference standards, which were used to estimate recovery with the ELISAs, were prepared by spiking the homogenized ground chocolate CMS with solutions of NFDM (catalog no. 1549, National Institute of Standards and Technology [NIST], Gaithersburg, MD) in phosphate-buffered saline (PBS; catalog no. P3813, Sigma-Aldrich, St. Louis, MO) through a series of steps. A primary stock solution of 100,000 ppm of NFDM in PBS was prepared, and aliquots were frozen at −20°C. Fresh substock solutions at 10,000, 1,000, and 100 ppm of NFDM were made, diluting the primary milk stock solution with PBS. The appropriate stock solution was used to spike the homogenized ground chocolate CMS to obtain reference standards of 0 (R0), 5 (R5), 25 (R25), and 50 (R50) ppm of NFDM.

Each Veratox milk test kit was used to analyze two chocolate samples for milk, each in triplicate, with all reference standards (R0, R5, R25, and R50). Samples and reference standards were extracted and analyzed using the procedures described by the manufacturer of the test kit with the following exceptions. After the extracts reached ambient temperature, a reagent blank (extraction buffer containing PBS plus Tween and extraction additive) was used to prepare serial dilutions of the sample extracts ("as is," 6-fold, 36-fold, 216-fold, and 1,296-fold) to ensure that the milk concentration in the sample was within the range of the standard curve. All of the provided standards (0, 2.5, 5, 10, and 25 ppm), freshly prepared reference samples, and sample extracts were analyzed in duplicate ELISA wells. The ELX-808 plate reader measured absorbance of wells at 650 nm. All raw data were transferred to an Excel spreadsheet (Microsoft, Redmond, WA), and the concentration of milk (NFDM) was calculated from the standard curve, which was constructed with a third-order polynomial trendline. R^2 values for standard curves were typically $\geq$0.98.

The Morinaga milk protein (casein) ELISA was used as a confirmatory test for samples with a positive response with the Veratox milk ELISA. All samples were extracted using the overnight extraction procedure and analyzed using the instructions included in the test kit with the following exceptions. After the sample extracts reached ambient temperature, a reagent blank sample was used to prepare serial dilutions of the sample extracts ("as is," 6-fold, 36-fold, 216-fold, and 1,296-fold) to measure a wide range of milk concentrations with each assay. Reference standards (R0, R5, R25, R50) of the CMS spiked with various concentrations of NFDM were prepared as described previously. Each of the sample extracts, reference standards, and the seven test kit standards were analyzed in duplicate ELISA wells. Absorbance of the ELISA wells was read with the ELX-808 plate reader at 450 nm and a reference wavelength of 650 nm. Raw data were transferred to an Excel spreadsheet, and the Morinaga milk protein concentrations (in parts per billion) were interpolated from the third-order polynomial standard curve. R^2 values for standard curves were typically $\geq$0.98. The concentrations of milk (in parts per million of NFDM) in chocolate samples were calculated using the following equation, which accounted for the two 20-fold dilutions (400-fold total) during sample extraction and preparation and a minimum protein concentration in NFDM of 34% *(27)*: ppm milk (NFDM) = (ppb milk protein × 400 × 2.94)/1,000.

Quantitative evaluation of peanut in chocolate samples. Chocolate samples testing positive for peanut with the qualitative method were evaluated further for peanut concentrations using the Veratox for peanut ELISA and the RIDASCREEN FAST Peanut (R6202, R-Biopharm, Darmstadt, Germany) ELISA. Antibodies used in the Veratox and RIDASCREEN kits specifically target total peanut proteins. Pacari 100% raw cacao chocolate was used as the CMS.

Reference standards, which were used to estimate recovery with the ELISAs, were prepared by spiking the CMS with stock solutions of peanut butter (SRM 2387, NIST) in PBS to achieve the R0, R5, R25, and R50 peanut reference standards. An assumption was made that the NIST peanut butter reference material contained 100% peanut even though the peanut content was 90 to 95% (w/w) because of the inclusion of other ingredients (sugar, partially hydrogenated oil, and salt) needed to formulate the material. Preparation of the peanut reference standards required several steps. First, a solution of 2% carboxymethylcellulose (CMC; C9481, Sigma-Aldrich) was prepared by mixing 2 g of CMC with 100 mL of water that was heated in a microwave for 2 min and adding 50 mg of thimerosal (T8784, Sigma-Aldrich) and 250 mg of bovine serum albumin (B4287, Sigma-Aldrich). The next step was to prepare a 10,000-ppm peanut suspension by dispersing 0.556 g of SRM 2387 peanut butter in 49.4 g of the 2% CMC

TABLE 1. *Overview of dark chocolate bar products testing positive for milk separated by label category and milk concentration detected with Veratox and Morinaga ELISAs*

Label category	Total no. (%) of products[a]	No. (%) of positive products	No. of products with Veratox total milk concn (ppm of NFDM[b]) of:				No. of products with Morinaga milk concn (ppm of NFDM) of:			
			2.5–100	101–1,000	1,001–5,000	>5,000	2.5–100	101–1,000	1,001–5,000	>5,000
Contains milk (positive control)[c]	6 (ND)[d]	6 (100)	0	1	1	4	ND	ND	ND	ND
Advisory statement alone	30 (34)	23 (77)	2[e]	7	10	3	3	7	10	3
Traces of milk	18 (20)	12 (67)	5	5	0	2	5	3	4	0
Advisory plus vegan	8 (9)	7 (88)	1	4	1	1	1	3	1	2
Advisory plus dairy or lactose free	3 (3)	2 (67)	0	1	1	0	0	1	1	0
Dairy- or lactose-free statement	13 (15)	2 (15)	0	0	2	0	0	1	1	0
Vegan statement alone	4 (5)	1 (25)	0	0	1	0	0	0	1	0
No milk statement	12 (14)	4 (33)	1	2	1	0	0	2	2	0

[a] Percentage of total products excluded the positive control samples.
[b] NFDM, nonfat dry milk.
[c] Results for only the six dark chocolate control products. Excluded from table is the milk chocolate positive control, which contained >37,000 ppm of NFDM based on the Veratox total milk ELISA.
[d] ND, not determined.
[e] One chocolate product that tested positive with the qualitative Veratox ELISA had negative results (<LOQ) with the Veratox quantitative ELISA and a positive result with the Morinaga ELISA. The NFDM concentration present in this sample probably was close to the LOQ of the Veratox test (2.5 ppm).

solution. The mixture was homogenized with a homogenizer (model PT 10/35, Polytron, Fisher Scientific, Waltham, MA) at 1,000 rpm for 5 min. Aliquots of the 10,000-ppm peanut suspension were frozen at −20°C for future use. The aliquots were thawed as needed, vortexed, and used for the preparation of fresh 1,000- and 100-ppm peanut stock solutions in PBS. The appropriate substock solution was used to spike the homogenized ground chocolate CMS to achieve the R0, R5, R25, and R50 peanut reference standards. The Veratox peanut ELISA was used to evaluate two chocolate samples, each in triplicate, with the reference standards (R0, R5, R25, and R50) using the procedure described previously for the milk analysis. All raw data were transferred to an Excel spreadsheet, and the concentrations of peanut were calculated from the standard curve, which was constructed with a third-order polynomial trendline. R^2 values for standard curves were typically ≥0.98.

The RIDASCREEN FAST peanut ELISA was used as a secondary confirmatory test for samples with a positive result with the Veratox peanut ELISA. All samples were extracted in a shaking water bath at 60°C for 10 min at 150 rpm and then centrifuged for 10 min at 2,325 × *g* and 4°C. Extraction buffer was used to prepare sixfold serial dilutions of the sample extracts, and reference standards (R0, R5, R25, R50) of the CMS spiked with various concentrations of peanut were prepared as described previously. Each of the sample extracts, reference standards, and the five test kit standards were analyzed in duplicate ELISA wells. Absorbances of the ELISA wells were read with a plate reader at 450 nm. Raw data were transferred to an Excel spreadsheet, and the peanut concentration (in parts per million) in the chocolate sample was interpolated from a third-order polynomial standard curve. R^2 values for standard curves were typically ≥0.98.

Statistical analysis. Raw data manipulations for calculation of means, standard deviations, coefficients of variation, and polynomial best fit standard curves were accomplished with Excel.

RESULTS

Survey of undeclared milk in dark chocolate products: chocolate label review and assignment. A detailed review of the product packaging and label statements on the dark chocolate bars (excluding the positive control samples) revealed a variety of statements regarding milk allergens. The samples were organized into categories based on label statement (Table 1). The highest percentage (34%) of dark chocolate bars had an advisory statement for milk alone, with phrases such as "may contain milk," "processed on shared equipment with milk," "made in a facility that handles products containing milk," and other similar statements. Another advisory statement category, "traces of milk," was found on nearly 20% of the chocolate products. An additional type of statement on 9% of the products included some type of an advisory statement combined with a vegan claim. Another 3% of the chocolate products had inconsistent or conflicting information on the packages, such as an advisory label for milk combined with specific references to dairy free or lactose free. Dairy-free or lactose-free statements alone were found on 15% of the surveyed chocolate samples. Vegan claims alone were found on 5% of the sample products, and 14% had no statement or reference to milk anywhere on the label.

Evaluation of milk in dark chocolate. All dark chocolate products were initially screened qualitatively using the Veratox total milk ELISA to identify samples containing ≥2.5 ppm of milk (NFDM), the test kit limit of quantitation (LOQ). Of the 88 chocolate products evaluated for milk, 51 (58%) were positive. Table 1 summarizes the

TABLE 2. *Milk concentrations measured in multiple lots of several dark chocolate products*

Chocolate ID[a]	Qualitative Veratox results[b]	Veratox total milk concn, ppm of NFDM (%CV)[c]	Morinaga milk concn, ppm of NFDM (%CV)	Label category
A7-lot A	Positive	580 (9.5)	900 (3.5)	Advisory alone
A7-lot B	Positive	2,100 (18)	2,100 (5.0)	Advisory alone
A12-lot A	Negative	<LOQ	<LOQ	Advisory alone
A12-lot B	Negative	<LOQ	<LOQ	Advisory alone
T13-lot A	Positive	160 (12)	400 (1.1)	Traces of milk
T13-lot B	Positive	150 (1.6)	460 (3.6)	Traces of milk
T13-lot C	Positive	440 (12)	320 (16)	Traces of milk
F5-lot A	Negative	<LOQ	ND[d]	Dairy free
F5-lot B	Negative	ND	ND	Dairy free

[a] Dark chocolate products with different lot numbers or expiration dates are denoted by capital letters A, B, or C.
[b] Positive results were obtained when milk concentrations were ≥LOQ (2.5 ppm) with the Veratox ELISA.
[c] NFDM, nonfat dry milk; %CV, % coefficient of variation.
[d] ND, not determined.

percentage of chocolate products testing positive for milk as a function of label statement.

Chocolate products testing positive for milk were analyzed further for milk concentrations using two milk-specific tests: the Veratox total milk ELISA and the Morinaga casein ELISA. The average milk recoveries for the CMS spiked with NFDM (R5 and R25) were 30% ± 19% and 65% ± 57% with the Veratox and Morinaga ELISAs, respectively. However, the concentrations of milk reported for chocolate samples were not corrected for recovery. Thus, on average, the milk concentrations present in the chocolate samples were likely higher than those reported. The Veratox total milk and Morinaga milk protein (casein) ELISAs are inherently different. In addition to the differences in extraction methods and antibody-conjugate detection systems, these assays are likely impacted differently by the presence of interfering compounds in the food matrix. The lower percentage of milk recovered with the Veratox ELISA might be due to the presence of high amounts of fat in dark chocolate that interfered with the ELISA *(16)*. The presence of reducing agents and strong detergents in the extraction buffer in the Morinaga kit may explain the higher recovery obtained with this ELISA.

Quantitative Veratox tests confirmed the presence of milk in the six dark chocolate samples bearing the "contains milk" declaration. Milk concentrations in these dark chocolate samples were 240 to >74,000 ppm (7.4%) (Supplemental Table 1). The positive control sample labeled "milk chocolate" contained >37,000 ppm (3.7%) of milk with the Veratox ELISA. The Morinaga ELISA was not used to further evaluate the positive control samples because both the ingredient labels and the qualitative and quantitative Veratox ELISAs confirmed the presence of milk in all chocolate bars in this category.

The umbrella term "advisory category" included four subcategories created for this study described as (i) advisory statement alone that excludes the term "traces of milk," (ii) "traces of milk" advisory statement specific to this phrase, (iii) advisory plus vegan statements, and (iv) advisory plus dairy-free or lactose-free statements. The range of milk concentrations based on label categories (Table 1) indicates that 23 (77%) of 30 dark chocolate bars bearing an advisory statement alone tested positive for milk. Milk was present at concentrations >100 ppm in the vast majority of products (20 of 23; >86%) with an advisory statement alone, and more than half of them had >1,000 ppm. Milk concentrations were 33 to >17,000 ppm with the Veratox ELISA and 16 to 14,000 ppm with the Morinaga ELISA (Supplemental Table 1). The differences in the concentrations reported are likely due to differences in extraction efficiencies and antibody specificities associated with the two kits. The chemical nature of the milk present in the samples (i.e., fluid whole milk, fluid nonfat milk, dry whole milk, NFDM, or whey powder) and the processing conditions involved in the preparation of the chocolate samples may also have been responsible for the differences in milk concentrations measured with the two kits *(16)*.

Multiple lot testing of two chocolate products in the "advisory statement alone" category resulted in consistently positive results for milk for product A7 (lots A and B) and consistently negative results for milk for product A12 (lots A and B) (Table 2).

Eighteen dark chocolate products with an advisory label statement "traces of milk" were categorized separately from products with other milk advisory statements. ELISA results indicated that 12 (67%) of 18 products in this category contained milk (Table 1) at concentrations of 3 to 6,700 ppm as measured with the Veratox ELISA and 3 to 2,600 ppm as measured with the Morinaga ELISA (Supplemental Table 1). Although a substantial number of positive samples (5 of 12; 42%) contained milk at <100 ppm, the majority of the products contained milk at >100 ppm (Table 1 and Supplemental Table 1). Three lots (with different expiration dates) for chocolate product T13 were tested (lots A, B, and C), and all samples were positive for milk at 150 to 460 ppm with both ELISAs (Table 2).

Among the dark chocolate bars bearing an advisory plus vegan statement on the packaging, 88% were positive for milk (Table 1). Milk concentrations in positive samples were 5 to 5,900 ppm with the Veratox ELISA and 20 to 7,000 ppm with the Morinaga ELISA, and all but one of the products contained >100 ppm (Table 1 and Supplemental

TABLE 3. *Overview of dark chocolate bar products testing positive for peanut separated by label category and peanut concentration detected with Veratox and RIDASCREEN ELISAs*

Label category	Total no. (%) of products	No. (%) of positive products	No. of products with Veratox peanut concn (ppm) of:				No. of products with RIDASCREEN peanut concn (ppm) of:			
			2.5–100	101–1,000	1,001–5,000	>5,000	2.5–100	101–1,000	1,001–5,000	>5,000
Contains peanut (positive control)	1[a]	1 (100)	0	0	0	1	0	0	1	0
Advisory statements (all)	51 (65)	4.3[b] (8)	2.5[b]	1.8[b]	0	0	2.5[b]	1.8[b]	0	0
"May contain traces or may have residual amounts of peanut" statements	15 (19)	0.5[b] (3)	0	0.5[b]	0	0	0	0.5[b]	0	0
Peanut-free or allergen-free statement	9 (12)	0 (0)	0	0	0	0	0	0	0	0
No statement for peanuts	18 (23)	3 (17)	2.5[b]	0.5[b]	0	0	2	1	0	0

[a] Positive control was not counted in the total number of products (78) evaluated in the survey.
[b] Multiple lots of one or more products in this category were analyzed for peanut. Fractional positive results were obtained when some but not all of the lots tested positive for peanut.

Table 1). Another category that may be confusing to consumers is the combination of an advisory statement plus a dairy-free or lactose-free claim. Two of three products with this combination label contained milk at 140 to >2,200 ppm as determined by both ELISAs (Table 1 and Supplemental Table 1).

Dark chocolate bars bearing the dairy-free or lactose-free statements and no milk advisory statement were predominantly negative for milk (11 of 13 products tested negative for milk; Table 1). Multiple lots of product F5 (lots A and B; Table 2) were also screened, and negative results for milk were obtained for both lots. However, two dark chocolate products in this category contained >1,000 ppm of milk based on the Veratox ELISA (Table 1 and Supplemental Table 1). The positive results were confirmed using the Morinaga ELISA with milk concentrations of 360 ppm for one chocolate bar labeled dairy free and 3,900 ppm for the other bar labeled lactose free (Supplemental Table 1). Neither of the two products that tested positive in this category had labels that indicated that they were produced in a dedicated facility or on dedicated processing lines.

Only four dark chocolate bars surveyed had a vegan statement alone with no other references to milk. Milk was detected in one of the four products tested at 1,100 to 3,200 ppm with the two ELISAs (Table 1 and Supplemental Table 1).

Evaluation of chocolate bars with no advisory statement or reference to milk in any form on the label resulted in detection of undeclared milk in 4 of the 12 products (Table 1). Milk concentrations were 60 to >1,600 ppm with the Veratox ELISA and 440 to 3,400 ppm with the Morinaga ELISA, and in virtually all products the milk concentrations exceeded 100 ppm (Table 1 and Supplemental Table 1).

Survey of undeclared peanut in dark chocolate: chocolate label review and assignment. A detailed review of the product packaging and label statements on the dark chocolate products indicated a variety of advisory statements existed regarding the possible presence of peanut allergen. Complicating the interpretation of some of the label statements was use of the term "nuts." To avoid confusion, this survey focused on only the specific term "peanuts." Table 3 lists the label statement distribution for samples included in the survey for peanut in chocolate. Of the 78 products collected, 51 (approximately 65%) had a label advisory statement using the word "peanut" within the advisory category (including "traces of peanut"). Fifteen (19%) of 78 products had a "traces of peanut" or "residual peanut" statement. Nearly 12% (9 of 78) of the chocolate products included a statement that the product was either peanut free or allergen free. Eighteen chocolate bars (23% of the survey samples) had no statement or no specific reference to the term "peanut."

Evaluation of peanut in dark chocolate. Chocolate products were initially screened for the presence of peanut using the Veratox peanut ELISA. With the exception of the positive and negative control samples, all samples that were positive in the qualitative screening were evaluated quantitatively using the Veratox peanut and the RIDASCREEN FAST peanut ELISAs. The average peanut recoveries obtained using the spiked reference materials (R5 and R25) with each method were 64% ± 10% and 96% ± 16%, respectively. The difference in the recovery associated with the two kits may be because of dissimilarities in the extract buffer compositions and the sensitivities of the antibodies used in each kit to detect peanut proteins present in the reference material *(16)*. Peanut concentrations reported in this survey were not corrected for recovery. The only positive control, a dark chocolate bar containing peanuts, contained 5,500 and 3,600 ppm of peanut as

TABLE 4. *Peanut concentrations in multiple lots of several dark chocolate products detected with Veratox and RIDASCREEN ELISAs*

Chocolate ID[a]	Qualitative Veratox results[b]	Veratox peanut concn, ppm (%CV)	RIDASCREEN peanut concn, ppm (%CV)	Label category
AP9-lot A	Negative	ND[c]	ND	Advisory: "may contain traces of peanut"
AP9-lot B	Negative	ND	ND	Advisory: "may contain traces of peanut"
AP9-lot C	Negative	ND	ND	Advisory: "may contain traces of peanut"
AP11-lot A	Positive	270 (1.4)	130 (11)	Advisory statement
AP11-lot B	Negative	<LOQ	<LOQ	Advisory statement
AP11-lot C	Negative	<LOQ	<LOQ	Advisory statement
AP18-lot A	Negative	ND	ND	Advisory statement
AP18-lot B	Negative	ND	ND	Advisory statement
AP30-lot A	Positive	280 (4.4)	440 (7.8)	Advisory: "may contain traces of peanut"
AP30-lot B	Negative	ND	ND	Advisory: "may contain traces of peanut"
AP35-lot A	Positive	220 (3.4)	360 (4.4)	Advisory statement
AP35-lot B	Positive	210 (0.6)	550 (3.8)	Advisory statement
AP44-lot A	Positive	5 (11)	14 (9.2)	Advisory statement
AP44-lot B	Positive	4 (5.0)	9 (3.2)	Advisory statement
AP45-lot A	Positive	20 (3.4)	32 (7.4)	Advisory statement
AP45-lot B	Positive	12 (3.4)	22 (5.8)	Advisory statement
AP50-lot A	Positive	25 (4.7)	29 (7.3)	Advisory statement
AP50-lot B	Negative	ND	ND	Advisory statement
FP3-lot A	Negative	ND	ND	Peanut free
FP3-lot B	Negative	ND	ND	Peanut free
NSP2-lot A	Positive	15 (7.4)	17 (5.5)	No statement for peanut
NSP2-lot B	Positive	53 (11)	130 (13)	No statement for peanut
NSP15-lot A	Positive	28 (3.4)	65 (14)	No statement for peanut (includes "may contain nuts, wheat and soy")
NSP15-lot B	Positive	9 (0.4)	21 (0.2)	No statement for peanut (label changed and includes no statements)
NSP18-lot A	Positive	110 (1.7)	170 (2.2)	No statement for peanut (includes "produced in a facility that uses nuts and all products may contain traces of nuts")
NSP18-lot B	Positive	24 (7.4)	68 (14)	No statement for peanut (includes "produced in a facility that uses nuts and all products may contain traces of nuts")

[a] Chocolate products with different lot numbers or expiration dates are denoted by capital letters A, B, or C.
[b] Positive results were obtained when peanut concentrations were ≥LOQ (2.5 ppm) with the Veratox ELISA.
[c] ND, not determined.

determined with the Veratox and RIDASCREEN FAST assays, respectively (Supplemental Table 2).

Table 3 presents an overview of the ranges of peanut concentrations in the chocolate products as measured with both ELISAs organized by label category. Within the advisory statement category, peanut concentrations in positive samples (4.3 of 51 samples) were 4 to 280 ppm with the Veratox ELISA and 9 to 550 ppm with the RIDASCREEN FAST ELISA (Table 3 and Supplemental Table 2). Because three lots were tested for product AP11, the fractional positive rate (0.3) represented the fact that one of the three samples was positive for peanut (Tables 3 and 4). Manufacturers of the chocolates used a variety of advisory statements on their products. The term "traces of peanut" was found on the labels of 13 chocolate products, and 2 other product labels indicated that the chocolates "may have residual amounts of peanuts" as part of their advisory statement language (Table 3). All but one sample bearing the "may contain traces of peanut" or "residual peanut" phrase tested negative for peanut. Two lots of product AP30 were tested for peanut; lot A was positive at 280 and 440 ppm of peanut with the Veratox and RIDASCREEN ELISAs, respectively, and lot B was negative (Table 4). The peanut concentrations found with the two ELISAs were typically slightly different. These differences may be owing to dissimilarities in the extraction efficiencies and recoveries associated with the methods, the ability of the antibodies used in the two kits to detect proteins present in the chocolate samples, and the nature of the peanut present in the chocolate: cultivar of peanut, form of peanut (e.g., particulate, peanut butter, or defatted peanut), and peanut roasting conditions *(16)*. All nine dark chocolate products categorized as peanut free or allergen free were negative for the presence of peanut (Table 3 and Supplemental Table 2). Some of the labels (six of nine) indicated that the products were manufactured in dedicated allergen-free or peanut-free or nut-free facilities.

Among the 18 dark chocolate bars bearing no statement regarding the presence of peanut, 3 tested positive for peanut (Table 3). For each of these three products, multiple lots purchased in consecutive years were tested, and all lots were positive for peanut (Table 4). Peanut concentrations for these

samples were <170 ppm with both test kits: 9 to 110 ppm with the Veratox ELISA and 17 to 170 ppm with the RIDASCREEN FAST ELISA (Supplemental Table 2). For all three of these chocolate products that were positive for peanut, the labels included the term "nuts" but not the word "peanut." Sample NSP2 (lots A and B) had no statement about peanut or nuts. Sample NSP15-lot A had no statement for the presence of peanut but had a "may contain nuts, wheat and soy" statement. Lot B of the same chocolate bar, which was purchased at a later time, had a different label that included no advisory statements. The third chocolate product in this category was NSP18 (lots A and B). Despite the lack of the term "peanut" on the packaging, both lots had a label stating that they were "produced in a facility that uses nuts and all products may contain traces of nuts." The presence of peanut in these chocolate samples may be attributed to cross-contact of tree nuts with peanuts. Two other chocolate products in this category also referenced "possible traces: milk, nuts" but tested negative for peanut.

DISCUSSION

Survey of milk in dark chocolate. Numerous recalls have taken place owing to the presence of milk and other allergens in chocolate and other confectionary products *(10)*. Dark chocolate may be produced on the same processing line as chocolate products containing milk, and equipment such as enrobers and hold tanks used for production of chocolate are not designed for easy access and cleaning. Because chocolate products have been implicated in *Salmonella* outbreaks, water use in chocolate manufacturing facilities is limited; hence, wet cleaning procedures are not commonly used for most equipment in chocolate production facilities *(5, 15)*. Food contact surfaces in chocolate manufacturing facilities are more frequently dry cleaned by scraping and by flushing lines with cocoa butter, dark chocolate, or other materials. All of these factors contribute to a higher risk of cross-contact for dark chocolate products *(15)*.

This survey was conducted to evaluate dark chocolate products that were not explicitly labeled as containing milk for the presence of this food allergen. The results provide information on the effectiveness of allergen control procedures used in the production of dark chocolate. Although an attempt was made to obtain chocolate samples from all regions of the United States, this survey represents only a snapshot of the big picture regarding the prevalence of undeclared allergens in this high-risk product. Limitations of the survey included the small sample size (88 products) and evaluation of only two or three lots from a small subset of products. Collection of the chocolate products at more time points and from different production runs would have provided additional information regarding the effectiveness of cleaning and sanitation procedures and cross-contact problems over time. Relatively few dairy-free and/or allergen-free dark chocolate manufacturers exist in the United States.

In general, the results of this survey confirmed previous findings and suggest that the presence of undeclared milk in dark chocolate products continues to be problematic. A study conducted before implementation of FALCPA revealed undeclared milk at 3 to >10,000 ppm of casein in some dark chocolate products and cited milk-allergic consumer complaints associated with some of these products *(14)*. Similarly, in a separate Dutch study, Spanjersberg et al. *(26)* investigated undeclared milk in dark chocolate sprinkles and found total milk protein concentrations of up to 3,547 ppm.

Of the 88 dark chocolate bars analyzed for undeclared milk, the majority had some type of advisory statement on the product label, but the specific statements differed considerably. Of the dark chocolate products bearing an advisory statement alone, 77% tested positive for milk at concentrations of 16 to >17,000 ppm. Chocolate bars indicating that the product may contain "traces of milk" had a fairly high percentage (67%) of positive results for milk, at concentrations of 3 to 6,700 ppm.

Although the term "trace levels" is undefined, the amount of allergen required to trigger a reaction differs among individuals, and published scientific data pertaining to the lower concentration threshold for allergic reactions to milk are limited. In one study, accidental ingestion of 23 to 24 μL of milk in a lemon sorbet sample resulted in an anaphylactic reaction in a 3-year-old milk-allergic child *(17)*. In another report, an anaphylactic reaction occurred in a 9-month-old infant due to ingestion of soy infant formula contaminated with 196.2 ± 3.9 ppm of milk protein *(18)*.

The findings of our study are similar to those reported by Crotty and Taylor *(7),* who examined the use of three specific forms of milk advisory labels on a variety of food products and found 3.7 to 15,000 ppm of milk in 82% of the dark chocolate products surveyed. Ford et al. *(8)* investigated advisory labels for egg, milk, and peanut in a variety of food categories and found an overall frequency of milk contamination of 10% in products bearing an advisory label, with milk concentrations of 4 to 222 ppm *(8)*.

In addition to the term "traces of milk," the word "vegan" is used occasionally on product packaging. Although this term is not defined by regulation, consumers generally understand that a vegan product should not contain any animal-derived ingredients such as milk or eggs. Several dark chocolate bars evaluated in this survey had the term "vegan" on the label but elsewhere on the packaging was an advisory statement referencing the possible presence of milk. Other chocolate bars simply had contradictory claims stating that the product was dairy free or lactose free but also included an advisory statement about milk. Chocolates bearing statements of this kind were classified as belonging to the label categories "advisory plus vegan" or "advisory plus dairy free or lactose free," and 88 and 67% of the samples in these categories tested positive for milk, respectively.

Survey samples of dark chocolate bars placed in the "no statement" category had no reference to milk in any form on the label, but 33% of these products tested positive for milk at 60 to 3,400 ppm. The samples with undeclared milk that had advisory statements for peanuts, tree nuts, and other allergens but not for milk were also a concern. Although

consumer behavior varies greatly, milk-allergic consumers will most likely interpret the complete omission of milk on the product label and the inclusion of precautionary statements listing other allergens as an indication that the dark chocolate product is safe for them. In another limited retail survey, Hefle and Lambrecht *(14)* investigated the presence of undeclared milk in products, including dark chocolate, in response to complaints by milk-allergic individuals and found casein concentrations of 3.6 to >10,000 ppm in the dark chocolate samples.

In a Dutch study of undeclared allergens in food products, the lack of guidance for use of precautionary or advisory statements on packaging was also noted, and dark chocolate sprinkles with no precautionary label for the possible presence of milk was responsible for a severe reaction in a milk-allergic individual *(26)*. Analysis of the dark chocolate sprinkles revealed 1,765 ppm of milk protein. Testing of multiple lots of the same brand of dark chocolate sprinkles revealed that milk protein was present in each sample at 100 to 3,547 ppm.

To minimize accidental cross-contact exposure to allergens among different products, a few food processors indicate on the product packaging the use of dedicated processing lines or allergen-free facilities. All chocolates citing production in a dedicated facility tested negative for milk in the present study. Other manufacturers use the dairy-free or allergen-free claims with no explanation. In this study, a majority (85%) of the chocolates in the dairy-free or allergen-free category were negative for milk. However, 2 (15%) of the 13 total samples were positive for undeclared milk at concentrations >1,000 ppm. Additional lots of one of these two chocolate products were obtained at a later date. By that time, the labels had changed to include a statement that the product was produced on equipment shared with products containing milk. Although relatively few dairy-free or allergen-free chocolate manufacturers with dedicated facilities exist, the results of this survey suggest that dark chocolate products in this category pose a lower risk to milk-allergic individuals.

Evaluation of the lot-to-lot variability of four dark chocolate products revealed that milk was either consistently present or consistently absent. To determine whether the unintended presence of milk in chocolate was due to production issues, insufficient cleaning of shared equipment, or other deficiencies, additional lots should be tested and the allergen control plan should be evaluated along with an on-site examination of the manufacturing procedures.

The results of this study confirmed that a high proportion of dark chocolate products contain milk at concentrations associated with allergic reactions in sensitive individuals. Because the term "traces of milk" is currently not defined, milk-allergic consumers should be cautious of chocolate products bearing this label statement owing to the ambiguity regarding milk allergen content. Similarly, products that have contradictory and confusing statements such as advisory statements combined with a vegan, dairy-free, or lactose-free statement had a high probability of containing milk. Some chocolate products with no advisory statement for milk but statements for other allergens also contained milk. Dark chocolate can be a high-risk food for milk-allergic individuals, particularly when products have an advisory statement on the package.

Survey of peanut in dark chocolate. From September 2013 to September 2014, 29% of the allergen-related recalls in the United States for foods in the chocolate, confections, and candy category were attributed to the presence of undeclared peanut, i.e., a lower percentage than the 50% of recalls resulting from undeclared milk *(29)*. The differences in recall reports between undeclared milk and undeclared peanut in dark chocolate may be attributed to the manufacturing process for chocolate products containing these allergenic ingredients. Milk chocolate and dark chocolate are often produced on the same line. Milk is added early in the manufacturing process for milk chocolate, thus contaminating major pieces of equipment with milk and resulting in frequent cross-contact situations. In contrast, peanuts are often introduced into the production line toward the end of processing, typically as an inclusion *(5)*. Another possible explanation for the lower number of peanut- versus milk-associated recalls may be because of the heightened awareness of peanut as an allergen and greater controls surrounding the production of products with peanuts.

The results from 78 chocolate bar products for the presence of undeclared peanut indicated that all 9 products displaying an allergen-free or peanut-free label were negative for peanut (<2.5 ppm). Although advisory statements for peanut were present on the majority (65%) of the chocolate bars, only 8% tested positive for peanut, suggesting that manufacturers label for peanut out of an abundance of caution or that adequate controls exist to prevent contamination of chocolate products with peanut. The lower percentage of positive results for peanut in the chocolate survey may also be attributed to the particulate nature of peanut inclusions. Sampling for peanut in this form may have a lower positive rate, but risks still exist for the peanut-allergic individual.

This survey also included dark chocolates with no statement specifying the word "peanut" on the product packaging, and 17% of these products tested positive for peanut. Some chocolates in the category "no statement for peanut" that tested positive for peanut used the term "nuts" instead of "peanut" on the label. The ambiguity surrounding the use of "nuts," which can refer to either peanut and/or tree nuts, can further complicate label interpretation by the consumer. Our findings indicated a higher proportion of chocolates testing positive for undeclared peanut compared with a study published before FALCPA, in which negative ELISA results for peanut were obtained for all 32 chocolate products (all produced in North America) surveyed *(31)*. Although our survey indicates a higher prevalence of undeclared peanut in dark chocolate products than reported by Vadas and Perelman *(31)*, our results support the Reportable Food Registry reports indicating an increasing number of recalls for undeclared allergens in chocolate products.

Despite the small number of dark chocolate bar products included in our survey, the results confirm that undeclared peanut may be present in dark chocolate. Dark

chocolates can be a high-risk food for consumers with peanut allergy, especially when the product labels contain an advisory statement. Similar to the results of the milk survey, the lowest risk for undeclared peanut allergens was associated with products manufactured in dedicated or allergen-free facilities.

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SUPPLEMENTAL MATERIAL

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