Confidential: Embargoed Until 11:00 am ET, October 16, 2018. Do Not Distribute

Letters

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Availability of Corn Masa Flour and Tortillas Fortified With Folic Acid in Atlanta After National Regulations Allowing Voluntary Fortification

In 1996, the US Food and Drug Administration (FDA) required all enriched cereal grains to be fortified with folic acid at a concentration of 1.40 µg/g.¹ Since then, there has been a significant reduction in the prevalence of spina bifida and anencephaly.² The regulation did not include fortification of corn masa flour, a staple food for many Hispanic people.³ Hispanic women of reproductive age are less likely to take prenatal folic acid supplements, have lower blood folate concentrations, and have a higher prevalence of spina bifida and anencephaly than non-Hispanic women.^{4,5} To address this disparity, the FDA published regulations allowing voluntary fortification of corn masa flour and tortillas in April 2016.^{1,6} Our objective was to determine the availability of folic acid-fortified corn masa flour and tortilla products in Atlanta, Georgia, 20 months after the FDA permitted voluntary fortification.

Methods | In December 2017, we visited 11 grocery stores (Buford Highway Farmer's Market, Supermercado Chicago, Walmart [n = 2], Aldi [n = 2], Kroger [n = 3], and Publix [n = 2]) in northeast Atlanta that cater to a large concentration of Hispanic residents. We identified all products on the store shelves labeled "corn masa" and soft corn "tortillas," and from their nutritional labels, recorded whether the product was fortified with folic acid. Products labeled "cornmeal," "corn flour," or "wrap" without "masa" or "tortilla" on the label were excluded.

We sought to validate the labeling by measuring folate concentrations in selected products. We purchased 2 bags, with different production dates, of each product labeled as fortified with folic acid, and purchased 1 bag of each product not fortified with folic acid. We tested all bags labeled as fortified as well as an equal number of unfortified bags of corn masa flour, ensuring that each color of masa (blue, yellow, and white) and several producers were represented. We arbitrarily chose 5 corn tortilla products for testing, each from a different producer. As positive controls, we tested 2 "enriched" all-purpose flour and 2 "enriched" yellow cornmeal products. We sent coded, duplicate samples to a commercial research laboratory (Covance Laboratories) to test folate content in the products. Samples were analyzed using the standard microbiological method for folate concentration in foods. Summary statistics, including means and SDs, were analyzed using SAS software, version 9.4 (SAS Institute Inc).

Results | Forty-one corn masa flour and tortilla products were identified during our survey of grocery store shelves. Only 2 of 20 corn masa flour products (10%) and none of the 21 soft corn tortilla products (0%) identified were labeled as containing "folic acid." The mean folate concentration in the 4 bags of fortified corn masa flour tested was 1.28 (SD, 0.47) μ g/g; the folate content was accurately labeled in 3 of these bags, while the fourth bag had an insufficient concentration (approximately 0.7 μ g/g). The mean folate concentration in 4 bags of unfortified corn masa was 0.47 (SD, 0.30) μ g/g and was 0.12 (SD, 0.01) μ g/g in unfortified corn tortillas. The positive controls had a mean folate concentration of 1.43 (SD, 0.62) μ g/g for "enriched" flour and 0.98 (SD, 0.39) μ g/g for "enriched" cornmeal (**Table**).

Discussion | Twenty months after the FDA issued national regulations permitting voluntary fortification, all soft corn tortillas and most corn masa flour products were not fortified with folic acid in a convenience sample of grocery stores in northeast Atlanta. The laboratory analysis confirmed that folic acid content in fortified products was generally accurately labeled. The concentration of folic acid in unlabeled products, especially corn tortillas, was very low.

This study was conducted in 1 city but examined national brands; therefore, voluntary fortification could be low nationally. The FDA aimed to achieve widespread fortification of corn masa products to prevent health disparities among Hispanic people. If the study findings are generally representative, achieving this goal will require complete fortification of corn masa products. Until then, Hispanic women of reproductive age should eat only corn masa products and tortillas fortified with folic acid and take daily vitamin supplements containing 400 µg of folic acid.

Ben Redpath, BS, BA Vijaya Kancherla, PhD Godfrey P. Oakley Jr, MD, MSPM

Author Affiliations: Department of Epidemiology, Emory University Rollins School of Public Health, Atlanta, Georgia.

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Corresponding Author: Vijaya Kancherla, PhD, Department of Epidemiology, Emory University Rollins School of Public Health, 1518 Clifton Rd NE, Atlanta, GA 30322 (vkanche@emory.edu).

Author Contributions: Mr Redpath and Dr Kancherla had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

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Product Type	Product Name	Description of the Product	Producer	Advertised Folic Acid Level on the Nutrition Labels	Folic Acid Concentration in the Product, µq/q ^b
Enriched all-purpose flour (positive control)	Gold Medal	Enriched unbleached all-purpose flour	General Mills	10% Daily value	2.16
					1.72
	Kroger	Enriched unbleached all-purpose flour	Kroger	10% Daily value	0.908
					0.916
Enriched cornmeal (positive control)	Goya	Enriched fine yellow cornmeal	Goya Foods Inc	15% Daily value	1.31
					1.31
	Quaker	Enriched yellow cornmeal	The Quaker Oats Company	10% Daily value	0.732
					0.569
Corn masa flour	Masa Brosa ^c	Instant blue corn masa (bag 1)	Masabrosa LLC	1.33 µg/g (40 µg per 30-g serving; 15% daily value)	1.61
					2.13
	Masa Brosa ^c	Instant blue corn masa (bag 2)	Masabrosa LLC	1.33 µg/g (40 µg per 30-serving; 15% daily value)	0.787 ^d
					0.658 ^d
	Maseca ^c	Instant white corn masa flour (bag 1)	Azteca Milling LP (Gruma)	1.33 µg/g (40 µg per 30-g serving; 15% daily value)	1.19
					1.52
	Maseca ^c	Instant white corn masa flour (bag 2)	Azteca Milling LP (Gruma)	1.33 µg/g (40 µg per 30-g serving; 15% daily value)	1.15
					1.22
	Masa Brosa	Instant white corn masa	Masabrosa LLC	Not labeled	0.217
					0.248
	Maseca	Amarillo: instant yellow corn masa flour	Azteca Milling LP (Gruma)	Not labeled	0.276
					0.389
	Minsa	Nixtamalized blue corn masa mix	Minsa Corporation	Not labeled	1.05
					0.803
	Torti Masa	White corn masa flour	Azteca Milling LP (Gruma)	Not labeled	0.278
					0.489
Corn tortilla	La Banderita	Yellow corn tortillas	Ole Mexican Foods Inc	Not labeled	0.109
	Pueblo Lindo	White corn tortillas	Aldi Inc	Not labeled	0.139
	Great Value	Soft corn tortillas (white)	Walmart Stores Inc	Not labeled	0.114
	Mission	White corn tortillas	Gruma Corporation	Not labeled	0.110
	Kroger	White corn tortillas	Kroger	Not labeled	0.105

Abbreviations: LLC, limited liability company; LP, limited partnership.

^a Summary findings of mean folate levels (μg/g) in the products tested (with or without folic acid included in the nutrition label): Enriched all-purpose flour: mean, 1.43 (SD, 0.62); median, 1.32; and range, 0.91-2.16. Enriched yellow cornmeal: mean, 0.98 (SD, 0.39); median, 1.02; and range, 0.57-1.31. Corn masa flour (with folic acid): mean, 1.28 (SD, 0.47); median, 1.21; and range, 0.66-2.13. Corn masa flour (not labeled): mean, 0.47 (SD, 0.30); median, 0.33; and range, 0.22-1.05. Corn tortilla (not labeled): mean, 0.12 (SD, 0.01); median, 0.11; and range, 0.11-0.14.

^b All products except the corn tortillas were analyzed in duplicate; hence, there are 2 folic acid concentration values for each of these products. The mean of these 2 values may better represent the contents of the entire bag.

^c Two separate samples of Masa Brosa Instant Blue Corn Masa and Maseca Instant White Corn Masa Flour were tested in duplicate because they advertised folic acid level on their nutritional labels.

^d Insufficient concentration of folic acid.

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