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FAILURE TO FORTIFY

How companies are neglecting to take a simple step that could save Latino/a/e lives

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Terminology

CSPI is an inclusive organization and seeks to foster an environment where all staff, collaborators, and populations that we work with feel a sense of belonging and are affirmed. In this report, we use the gender-inclusive terminology "Latino/a/e." However, throughout the report, we may also use the terms "Hispanic" and "Mexican American" when describing data from previous studies in order to accurately describe the population as it was referenced by the author(s) of each study.

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Executive Summary

Neural tube defects (NTDs) are severe defects in a fetus's or newborn baby's neural tube, the structure that forms the early brain and spine. The most common types of NTD are spina bifida (1,400 U.S. births per year), which can cause mild to severe disabilities, and anencephaly (800 U.S. births per year), which results in stillbirth or infant death. The risk of NTD is significantly reduced when people who may become pregnant consume adequate amounts of folic acid (a synthetic form of folate, or vitamin B9). For this reason, the United States began adding folic acid to staple foods including enriched breads, enriched flours, enriched pastas, enriched rice, enriched corn meal, and breakfast cereals in 1998.

Before the fortification policies of 1998 rates of NTDs were significantly higher in the Latino/a/e population. As of 2011, rates of NTDs among Latino/a/e people in the United States were still higher, at 7 NTDs per 10,000 births, compared to 5 NTDs per 10,000 births in White and Black populations. Potential reasons for this difference include lower intake of folic acid from dietary supplements among Latino/a/e people and higher prevalence of genetic variations that lead to altered folate metabolism.

Corn masa flour is the main ingredient in foods such as corn tortillas, tamales, pupusas, and empanadas that are staples in the foodways of Mexico and several other Latin American countries. Researchers and advocates have proposed that adding corn masa flour to the list of fortified foods could help increase folic acid intake and help address the elevated rate of NTDs in the U.S. Latino/a/e population. In response to a regulatory petition submitted by a diverse coalition of nonprofit and industry stakeholders, the U.S. Food and Drug Administration (FDA) issued a rule in 2016 allowing folic acid to be voluntarily added to corn masa flour. In a preamble to the rule, FDA predicted that corn masa fortification would lead to an increase in folic acid intake among Mexican American women of reproductive age from 164 mcg/d to 206 mcg/d. Unfortunately, recent data show the predicted impact has not been realized. Success of the policy hinged on the food industry's willingness to fortify corn masa foods with folic acid on a voluntary basis. As we share in this report, the industry has largely failed to take this essential step, leaving their customers cut off from the health benefits of fortification.

This report provides background on NTDs and U.S. fortification policy, followed by an analysis of food manufacturers' uptake of FDA's voluntary corn masa fortification rule. To undertake this analysis, we obtained a list of products and their ingredients from *Everything Food Inc.*, a company that claims to maintain "the nation's largest, most robust food database." We also reached out to corn masa flour companies to confirm the accuracy of the corn masa flour data. Our final sample included 59 corn masa flour products and 476 corn tortilla products sold across the United States between 2018-2022, as well as a comparison group of wheat flour and wheat tortilla products. We found that 8 of the corn masa flour products (14%) and none of the corn tortilla products (0%) contained folic acid. By comparison, 401 of 505 wheat flour products (79%) and 731 of 865 wheat tortilla products (85%) contained folic acid. Notably, although Gruma Corporation was involved in petitioning FDA for the voluntary corn masa fortification rule, the company is still not adding folic acid to all of its products. Walmart was also involved in the petition, but did not add folic acid to any of its 5 store-brand corn masa flour and tortilla products in our sample.

To increase folic acid intake and help close the racial/ethnic gap in NTD rates, manufacturers should fortify more of their corn masa flour and corn tortilla products. Retailers should strive to stock more fortified corn masa products. FDA should issue a guidance for industry addressing frequently asked questions and common barriers to folic acid fortification of corn masa. Consumers who could become pregnant should seek fortified corn masa products and follow advice from health authorities to take a daily supplement with 400 to 800 mcg of folic acid.

Neural Tube Defects & Folic Acid

WHAT ARE NEURAL TUBE DEFECTS?

Neural tube defects (NTDs) are severe defects in fetus's or newborn baby's neural tubes, the structure that forms the early brain and spine.[1] During embryological development, the two sides of the flat structure containing neural tissue fold toward one another forming a tube. NTDs occur when this neural tube does not close properly. There are several different types of NTDs with varying levels of severity. The two most common NTDs are spina bifida and anencephaly.[2]

Spina bifida is a birth defect that may cause mild to severe physical and intellectual disabilities, depending on how and where the spine and spinal cord are affected.[3] Approximately 1,400 babies in the United States are born with spina bifida each year,[2] most of whom have mild forms of the condition. Even among those with more severe forms, about 75 percent survive and thrive into adulthood.[4]

In anencephaly, a baby is born without parts of their brain and skull.[5] Anencephaly occurs in approximately 800 births in the United States each year,[2] and almost all babies that are born with this NTD die in utero or shortly after birth.[5]

The causes of these conditions are largely unknown, but genetic and environmental factors appear to play a role. A study from the 1970s estimated that genetics account for 60-70% of risk for NTDs.[6,7] A 2015 review article summarized several potential environmental contributors, including folate deficiency, maternal use of anticonvulsant therapy, maternal obesity, and maternal diabetes.[7] However, the authors of this review note that the mechanisms behind the association between these environmental factors and NTDs are not well understood and non-genetic factors appear to mainly influence NTD risk in the presence of a predisposing genotype.

One of the most effective strategies to prevent NTDs is ensuring that people consume enough folate (also known as vitamin B9) before and during early pregnancy.[8] Folate is critical for DNA synthesis, and for cell growth and differentiation.[9] While it is necessary in all stages of life, there is an increased need for folate in pregnancy when the placenta and fetus undergo rapid cell division.[10]

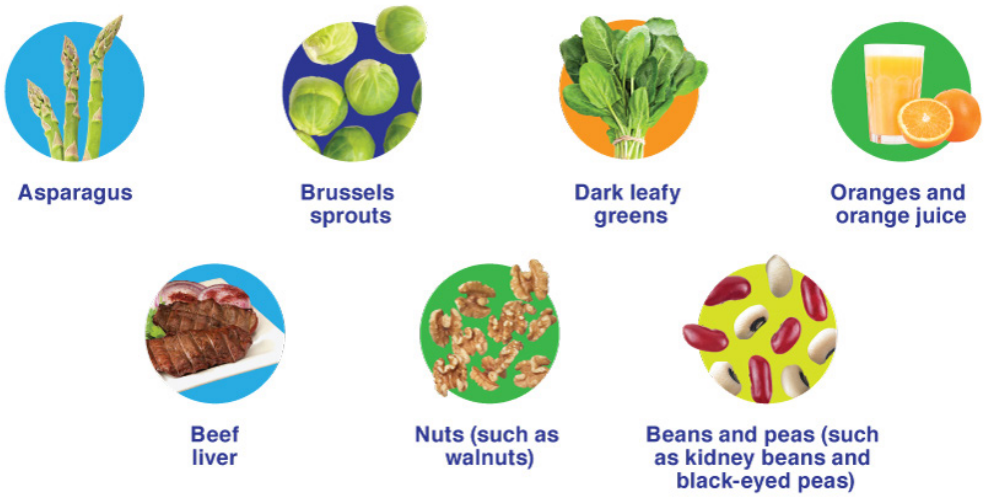
Figure 1. Visible defects in babies born with spina bifida (left) and anencephaly (right)

Sources:
https://apps.who.int/iris/handle/10665/127941; https://www.cdc.gov/ncbddd/birthdefects/anencephaly.html

CONSUMING ENOUGH FOLATE OR FOLIC ACID

Folate is naturally present in a wide variety of foods, including vegetables, fruits, nuts, beans, meat and seafood, eggs, dairy, and grains.[11] Some of the foods with highest naturally occurring folate levels include beef liver, spinach, black eyed peas, brussels sprouts, and asparagus.[11]

Figure 2. Foods with naturally occurring folate



Source: https://www.fda.gov/food/new-nutrition-facts-label/folate-and-folic-acid-nutrition-and-supplement-facts-labels

The Dietary Guidelines for Americans (DGA) recommend consuming 400 micrograms (mcg) of Dietary Folate Equivalents (DFE) per day for adults who are not pregnant and 600 mcg DFE for people who are pregnant.[12] To reduce the risk of NTDs, the DGA, the National Academy of Medicine, the U.S. Preventive Services Task Force, and the U.S. Centers for Disease Control and Prevention (CDC) recommend that all people capable of becoming pregnant consume 400 to 800 mcg of folic acid (a synthetic form of folate) from a dietary supplement or fortified foods each day, in addition to folate obtained from a varied diet.[12-14] The availability of fortified foods is particularly critical because nearly half of pregnancies in the United States are unplanned,[15] so many people do not begin taking supplements with folic acid prior to pregnancy.[16]

Folic acid is added to foods including enriched breads, enriched flours, enriched pastas, enriched rice, enriched cornmeal, and fortified breakfast cereals.[17] Folic acid, rather than folate, is used in these fortified foods because it is much more bioavailable, meaning that in the same amounts, a greater proportion of folic acid is absorbed and used in the body compared with naturally occurring folate.[18]

Figure 3. Foods with folic acid

Source: https://www.fda.gov/food/new-nutrition-facts-label/folate-and-folic-acid-nutrition-and-supplement-facts-labels

A large body of evidence, including randomized controlled trials, has demonstrated that supplementation with folic acid around the time of conception leads to a major reduction in the risk of NTDs.[19] A foundational study from 1991 of 1,195 pregnant women with a prior NTD-affected pregnancy (half receiving 4,000 mcg of folic acid prior to conception and through the first trimester, half receiving a placebo) found that folic acid supplementation prevented 72 percent of NTDs (relative risk for babies born to women in the treatment vs. control groups = 0.28, 95% confidence interval 0.12-0.71).[20] Findings from observational studies comparing the prevalence of NTDs among women who did or did not take folic acid before or during pregnancy,[21-23] as well as a randomized controlled trial in which women took a multivitamin that included 800 mcg of folic acid,[24] suggest that these findings are generalizable to women who have not had a prior NTD-affected pregnancy.

While, in general, people in the United States consume adequate amounts of folate, people who may become pregnant are at risk for insufficient folate intake. In 2017-March 2020, average daily folic acid from foods and supplements was 221 mcg among females aged 20-39 (far lower than the 400-800 mcg recommended), with only 18 percent reporting any folic acid intake from dietary supplements.[25] When combined with natural folate from foods, mean DFE in this group was 569 mcg per day.[25]

Folic Acid Fortification Policy in the United States

MANDATORY VERSUS VOLUNTARY FORTIFICATION

Food fortification is one of the most cost-effective ways to prevent and control micronutrient deficiencies. Unlike urging people to purchase and take dietary supplements or to seek out foods high in specific vitamins and minerals, fortification of staple foods comes at little or no cost to individuals and requires no individual behavior modification. It is also inexpensive for industry. In late 2015, the cost of adding folic acid to flour in the United States was estimated at $0.50 per ton of flour, equivalent to less than five cents per person per year.[26,27]

Fortification in the United States dates back to the 1920s when iodine was added to salt to prevent goiter.[28] Today, some countries require the addition of specific amounts of nutrients to specific foods, referred to as "mandatory fortification." For example, in Australia, all wheat flour that is sold as suitable for making bread must contain at least 2 mg/kg of folic acid and at least 6.4 mg/kg of thiamin.[29]

The United States does not have this same type of mandatory fortification. Instead, "mandatory fortification" in the United States actually refers to fortification requirements, developed by FDA, for versions of food staples like flour, bread, and pasta that are labeled "enriched."[28] Many staple foods have "standards of identity" (SOI) which FDA establishes through a rulemaking process for the purpose of ensuring that foods align with consumer expectations.[30] SOI typically include requirements for ingredients and production methods. For example, the SOI for bread, rolls, and buns requires that bakery products sold under these names are made "by baking mixed yeast-leavened dough prepared from […] farinaceous [*i.e.*, starchy] ingredients."[31] Some foods have separate SOI for enriched versions of the food. For example, the SOI for "enriched bread, rolls, and buns" specifies that bread, rolls, and buns labeled "enriched" must conform to the SOI for "bread, rolls, and buns" *plus* contain 1.8 mg of thiamin, 1.1 mg of riboflavin, 15 mg of niacin, 0.43 mg of folic acid, and 12.5 mg of iron per pound.[32] Fortification is required for bread, rolls, and buns that are labeled "enriched," but unenriched versions of those products may remain on the market. In this way, there are no true mandatory fortification requirements in the United States, and the choice of whether to fortify foods is left to the discretion of food manufacturers.[28]

Separately, FDA also has some "voluntary fortification" policies that allow food manufacturers to add nutrients to ordinary foods that are not labeled "enriched."[33] For example, vitamin D can be added to fruit juices and milk,[34] neither of which has an enrichment standard. Theoretically, policies that establish enrichment standards and those that allow fortification without a new SOI could be means to the same end of increasing micronutrients in the food supply. However, in practice, fortification appears to be less likely to be adopted by manufacturers when permitted through voluntary fortification policies rather than incorporated into enrichment standards. This was the leading reason why FDA chose to promote folic acid fortification by amending the SOI of enriched products (discussed further in the next section) instead of issuing voluntary fortification rules. The agency stated in a 1996 rulemaking:

> "FDA has concluded that in order for a fortification program to be effective, fortification must be mandatory for the enriched cereal-grain products. FDA is concerned that if it made fortification voluntary, and voluntary fortification were not widespread, there would be only a negligible increase in the daily folate intake of the target group, and the intent of this rulemaking would have been defeated. FDA finds that there is a public health need for women in their childbearing years to have adequate folate intake, and that the only way that it can ensure that they will have such an intake is through mandatory fortification."[35]

DEVELOPMENT OF U.S. ENRICHMENT STANDARDS AND ADDITION OF FOLIC ACID

FDA introduced the first U.S. enrichment policy in 1941, when the agency established a SOI for enriched wheat flour.[36] The goal of this policy was to address specific disease syndromes resulting from nutrient deficiencies, like pellagra due to niacin (vitamin B3) deficiency and beriberi due to thiamin (vitamin B1) deficiency, by adding nutrients to an inexpensive staple ingredient commonly consumed by a large proportion of the population.[37] At that time, the SOI for enriched wheat flour required that minimum levels of thiamin (1.66 mg), niacin (6 mg), riboflavin (1.2 mg), and iron (6 mg) must be added to each pound of flour in order for it to be labeled as "enriched."[38]

That same year, President Franklin D. Roosevelt organized the National Nutrition Conference for Defense in order to improve the nutritional status of young men enlisting for service in World War II.[37,39] The conference was attended by nutritionists, physicians, industry scientists, consumer groups, and representatives from government agencies, and enrichment of flour and bread as a means to improve Americans' diets was a key topic of discussion. The FDA enrichment standards and conference discussions were pivotal in eliciting support for enrichment from the baking and milling industry.[40] By the middle

Fortification and Enrichment

Food fortification and enrichment both refer to the addition of vitamins or minerals to foods to correct or prevent nutrient deficiencies. While fortification refers to the addition of nutrients that are not naturally present in foods, enrichment refers to adding back nutrients that were lost during processing. For example, milk—which does not contain any naturally occurring vitamin D— is often fortified with vitamin D. Milk was selected as the vehicle for addressing vitamin D deficiency because of its high content of calcium and phosphorous, whose absorption is aided by vitamin D, and because milk is considered a staple in many people's diets. Whole grains contain B vitamins, but refined grains are enriched with B vitamins that they lose during processing. Because folic acid is a synthetic form of folate and is never found naturally in foods, foods with folic acid are always considered to be "fortified with folic acid," even if the synthetic nutrient is added, in part, to replace folate that was lost during processing.

Source: Quick JA, Murphy EW. The Fortification of Foods: A Review. Agriculture Handbook No. 598. 1982.

of 1942, an estimated three-quarters of white bread in the United States was enriched with thiamin, niacin, riboflavin, and iron.[40]

Between the 1950s and the 1970s, FDA developed additional SOI for enriched grain products, such as enriched bread, rolls, and buns,[32,41] enriched macaroni and noodle products,[42] enriched corn grits,[43] enriched corn meals,[44] and enriched rice.[45]

In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA), which directed FDA to determine if there was sufficient evidence for food manufacturers to make health claims linking folic acid in their products to a reduction in risk of NTDs.[46] After considering the available evidence and potential risks, FDA authorized a health claim for folate in 1996.[47] The new rule allowed claims such as "Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect."[47]

The attention to NTDs and folic acid opened a debate about the best way to supply folic acid to the population. This led to FDA updating the SOI for several enriched foods in 1996 to require that grain products labeled as enriched must contain 140 mcg of folic acid per 100 g of enriched product, effective in 1998.[35]

IMPACT OF FOLIC ACID FORTIFICATION ON NTDS

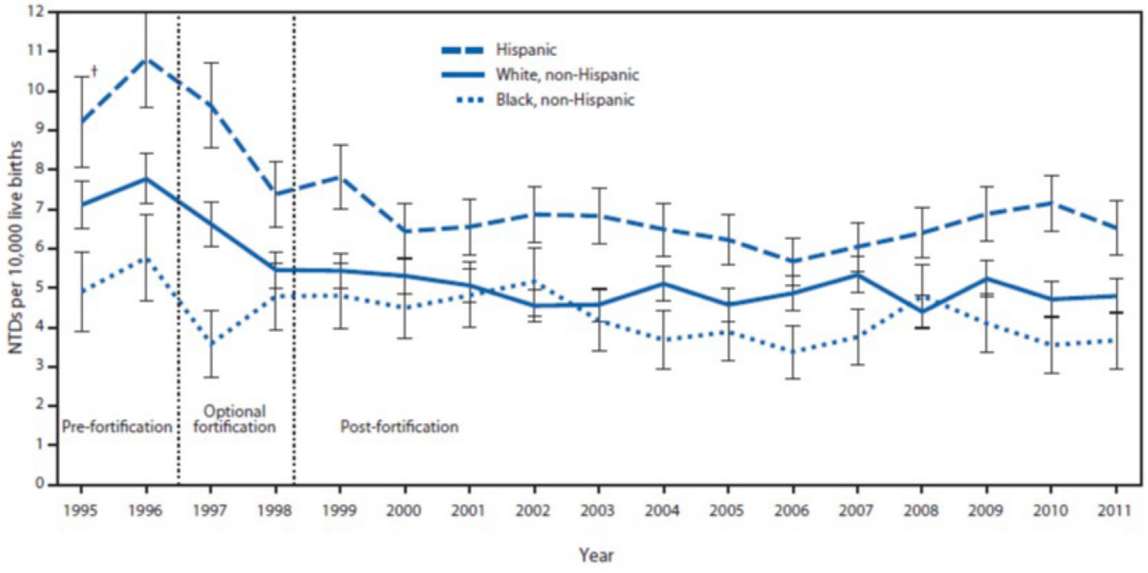
Fortification of cereal flours with folic acid starting in 1998 led to a 28 percent reduction in rates of NTDs in the United States, preventing an estimated 1,326 births with NTDs each year (*see* Figure 4).[48] This public health intervention had an enormous impact without requiring any change in behavior from consumers. Countries such as Canada, Costa Rica, Chile, Argentina, Brazil, and South Africa have reported similar decreases in NTD incidence following folic acid fortification of staple foods.[49] As of 2022, 69 of 91 countries with mandatory fortification standards for wheat flour include folic acid in their standards,[50] though uptake of folic acid fortification by manufacturers has been less widespread in many of these countries compared to the United States.[51]

Understanding the Higher Rates of NTDs among Latino/a/e Americans

NEURAL TUBE DEFECT RATES BY RACE/ETHNICITY

While the rates of NTDs declined in all racial and ethnic subgroups (Hispanic, White, and Black) following the implementation of folic acid fortification in 1998, rates of NTDs were highest among babies born to Hispanic women before fortification policies were implemented, and these disproportionately higher rates of NTDs persisted after the implementation (Figure 4). As of 2011, approximately 7 per 10,000 babies born to Hispanic mothers were born with NTDs compared with 5 per 10,000 babies born to non-Hispanic White and Black mothers.[48] Two factors, among several, that could explain this gap are differences in intake of folic acid and genetic variations that lead to an altered metabolism of folate.

Figure 4. Prevalence of NTDs (anencephaly and spina bifida) in the United States before and after folic acid fortification of enriched foods, by maternal race/ethnicity, 1995–2011

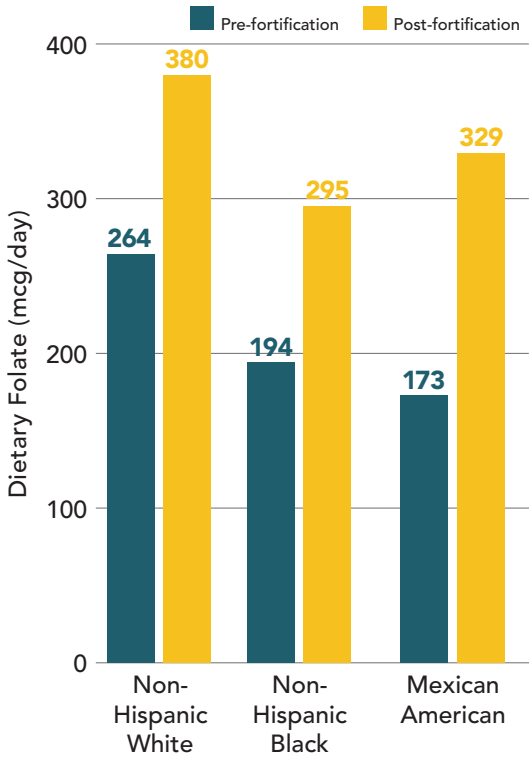


Source: Williams et al (2015)

FOLATE AND FOLIC ACID INTAKE BY RACE/ETHNICITY

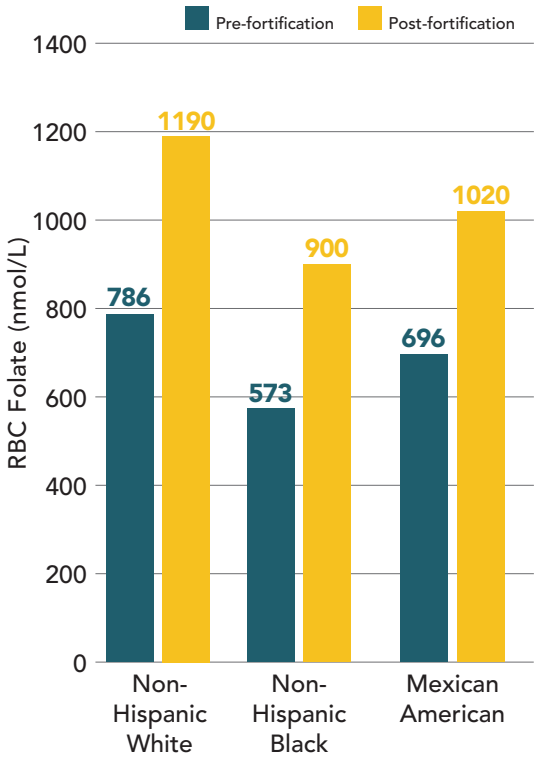
National dietary intake data from before and after the U.S. folic acid fortification policies were implemented in 1998 show that the median intake of folate was lower among non-Hispanic Black and Mexican American women aged 15 to 44 years old compared to non-Hispanic White women ages 15 to 44 in the pre-fortification period. These intakes increased by at least 100 mcg/day across racial and ethnic subgroups (*see* Figure 5).[52] However, a gap in intake levels remained, with Black and Mexican American women aged 15 to 44 consuming a median of 295 mcg/day and 329 mcg/day, respectively, compared to 380 mcg/day among non-Hispanic White women, based on data from the 1999-2000 National Health and Nutrition Examination Survey (NHANES).[52] Similarly, red blood cell (RBC) folate concentrations, a marker of folate status, was lower during the pre-fortification period for non-Hispanic Black people and Mexican-American people compared to non-Hispanic White people ($p<0.001$ for test comparing group means across race/ethnicity categories) and increased in those groups after 1998 (*see* Figure 6).[53] However, data from NHANES 1999-2010 show that non-Hispanic White persons had statistically significantly higher mean RBC folate concentrations (1190 ± 10 nmol/L) compared to non-Hispanic Black (900 ± 5 nmol/L) and Mexican American persons (1020 ± 10 nmol/L) ($p<0.001$).[53]

Figure 5. Median total folate intake from food and supplements in women aged 15-44 years of age, pre-fortification (NHANES 1988-1994) and post-fortification (NHANES 1999-2000), by race/ethnicity



Source: Bentley et al (2006)

Figure 6. Mean red blood cell folate concentrations in people aged ≥4 years, pre-fortification (NHANES 1988-1994) and post-fortification (NHANES 1999-2010), by race/ethnicity



Source: Pfeiffer et al (2012)

The latest dietary intake data from NHANES 2017-2020 show that these differences in folic acid and DFE intake by race and ethnicity persist (*see* Table 1).[54] Lower average DFE intake among Black, Hispanic, and Asian adults compared to non-Hispanic White adults appears to stem primarily from differences in use of dietary supplements, as opposed to differences in intake of folate from foods. Mean folic acid intake from fortified foods and mean DFE from all foods (*i.e.* fortified foods plus foods with naturally occurring folate) were similar or higher among Hispanic adults compared with non-Hispanic White and Black adults. But White adults obtained 57 to 72 percent more folic acid from supplements, on average, than Black, Asian, and Hispanic adults. Twenty-eight percent of non-Hispanic White adults report getting some folic acid from supplements, compared with 18 percent of non-Hispanic Black adults, 20 percent of non-Hispanic Asian adults, and 15 percent of Hispanic adults.[54]

Table 1. Mean Folic Acid Intake, Mean Dietary Folate Equivalents, and Proportion Getting Any Folic Acid from Supplements Among People in the United States Aged ≥20 Years in 2017-March 2020 (Prepandemic), by Race, Ethnicity, and Income

	NH White	NH Black	NH Asian	Hispanic	<131% FPL	131-350% FPL	>350% FPL
Mean Folic Acid Intake (mcg)							
Food	155	148	166	163	164	170	148
Supplement	151	90	96	88	83	125	151
Food + Sup	306	238	262	251	248	296	299
Mean DFE (mcg)							
Food	472	435	540	509	474	491	477
Supplement	257	153	163	150	142	213	257
Food + Sup	729	588	703	659	616	705	735
Any Folic Acid from Supplements							
	28% (SE 1.4)	18% (SE 1.3)	20% (SE 1.4)	15% (SE 1.2)	15% (SE 1.4)	24% (SE 1.6)	29% (SE 1.6)

Sources:
https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1720/Table_38_SUP_RAC_1720.pdf
https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1720/Table_40_SUP_POV_1720.pdf
NH=non-Hispanic; FPL=Federal Poverty Level; Sup=Supplement; DFE=Dietary Folate Equivalents

Lower intake of folic acid from dietary supplements among Hispanic women may be driven, in particular, by lower supplement use among Hispanic women who are less acculturated (*i.e.*, less assimilated into U.S. culture). One study of NHANES data from 2001-2008 found that total folic acid intake from foods and supplements among Mexican American women aged 15-44 who reported mostly speaking Spanish at home (224 mcg folic acid/day), or speaking both English and Spanish (206 mcg), was statistically significantly lower than total folic acid intake among non-Hispanic White women (332 mcg) ($p<0.05$), but there was no statistically significant difference in folic acid intake between Mexican American women who primarily spoke English at home (283 mcg) and non-Hispanic White women.[55] Again, these differences appeared to be attributable to differences in the use of dietary supplements, as there was no difference in intake of folic acid from fortified foods between non-Hispanic White women and Mexican American women, regardless of acculturation factors, whereas there were considerable differences in the use of supplements containing folic acid. Only 14 percent of Mexican American women who primarily spoke Spanish at home reported using dietary supplements with folic acid, compared with 30 percent of Mexican American women who primarily spoke English at home and 37% of non-Hispanic White women.[55]

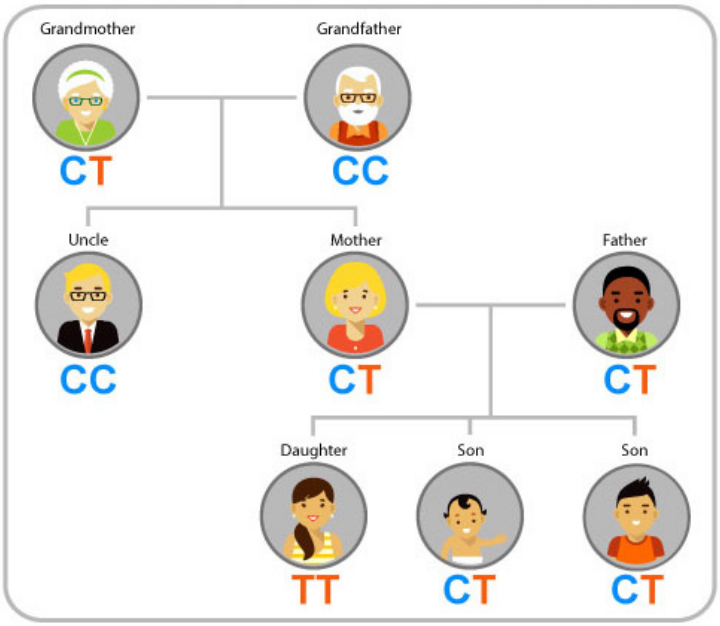
Another factor that likely contributes to lower folic acid supplement use among Latina women is access to preconception counseling on folic acid supplementation. Hispanic women are less likely than non-Hispanic White women to receive such counseling,[56] and preconception counseling has been associated with higher likelihood of daily folic acid supplementation. A study of 4,426 pregnant women in Maryland found that preconception counseling was associated with 4.5 times higher odds (95 % CI 3.66–5.62) of preconception daily folic acid use.[57]

Socioeconomic factors may also play a part in lower folic acid supplementation rates among Latinas. Table 1 shows that the likelihood of using supplements with folic acid increases with income, and Hispanic women are more likely to have low incomes compared to non-Hispanic White women (18.5% of Hispanic women aged 18 to 44 years live below the poverty level, compared with 10.4% of non-Hispanic White women in this age group).[58,59]

Studies have also found that having less than a high school education is associated with lower-than-recommended folic acid intake levels,[55] lower likelihood of taking folic acid daily,[60] and lower likelihood of having heard of or read about folic acid,[60] and Hispanic women are more likely than non-Hispanic White women to have attained less than a high school education (28.3 percent versus 6.2 percent, respectively).[61] These associations demonstrate that lack of financial means to purchase dietary supplements or lack of education about folic acid could play a role in the lower rates of folic acid intake among Latina women.

MTHFR GENE VARIATIONS

Figure 7. Genotypes for the MTHFR 677C>T Variant



Source: https://www.cdc.gov/ncbddd/folicacid/mthfr-gene-and-folic-acid.html

Another factor potentially contributing to higher rates of NTDs among Latino/a/e people in the United States is higher prevalence of certain variants of a gene involved in folate metabolism. The MTHFR gene, which stands for the methylenetetrahydrofolate reductase gene, allows the body to make the MTHFR enzyme which is required by the body to process folate.[62] One common variant of the MTHFR gene is called MTHFR 677C>T. People with the MTHFR 677C>T variant have a T allele instead of a C allele for one or both alleles making up the MTHFR677 gene (*see* Figure 7). People with the MTHFR 677CT genotype (1 copy of the MTHFR C>T variant) or MTHFR 677TT genotype (two copies of the MTHFR 677C>T gene variant, one from each parent) have a reduced capacity to process folate. A 2015 meta-analysis found that people with the MTHFR 677TT genotype have 16% lower blood folate concentrations (95% CI 12, 20) and people with the MTHFR 677CT genotype have 8% lower blood folate concentrations (95% CI 4, 12) compared to people with the most common DNA sequence (MTHFR 677CC).63 The MTHFR 677C>T genotype is also associated with significantly greater odds of having a NTD.64 While the MTHFR 677C>T variant is found across racial and ethnic groups, one study found that it occurred in 19.4% of Mexican Americans (95% CI: 16.7, 22.3) compared with 11.6% of non-Hispanic White individuals (95% CI: 9.6, 14.0) and only 1.2% (95% CI: 0.7, 2.0) of non-Hispanic Black individuals.[65]

Folic acid supplementation appears to moderate differences in RBC and plasma folate due to the MTHFR 677 TT genotype, and could potentially moderate the link between MTHFR 677C>T and NTDs.[66] Ironically, while logic might suggest that people with difficulty processing folate would consume more folic acid to ensure enough makes it into the blood, online misinformation may lead people with MTHFR variants to believe they need to avoid folic acid. Misleading claims that people with the MTHFR 677C>T variant should not consume folic acid, or should only consume supplemental forms of folate such as 5-methyltetrahydrofolate (5-MTHF) instead of folic acid, are pervasive on the internet.[67-69] This misinformation is most often disseminated by companies and individuals looking to profit by selling alternative supplements or treatments. As CDC warns:

> "You might have read or heard that folic acid is not safe if you have one or two copies of the MTHFR C677T variant. This is not true. Even if you have one or two copies of the MTHFR C677T variant, your body can safely and effectively process all different types of folate, including folic acid."[62]

Furthermore, folic acid is the only type of folate that has been definitively shown to help prevent NTDs.[62] All people who could become pregnant should consume 400 mcg of folic acid per day, regardless of MTHFR 677C>T variations.[62]

In conclusion, higher prevalence of the MTHFR genotype could contribute to higher prevalence of NTDs among Latino/a/e people, both through biological mechanisms contributing to lower blood folate levels as well as through online misinformation that may cause people with the genotype to avoid folic acid. Increased folic acid intake could help close the gap in NTD outcomes between Latino/a/e people versus other racial and ethnic groups.

Photo: Liliana/stock.adobe.com.

Homemade Corn Tortillas

Time: 30 minutes

Servings: 4 (12-16 tortillas)

INGREDIENTS

2	cups corn masa flour with folic acid
½	teaspoon salt
1½	cups warm water

INSTRUCTIONS

1. Add 2 cups of corn masa flour and ½ teaspoon salt to a mixing bowl. Add 1 cup of the warm water and stir until the water is absorbed. Add the rest of the water incrementally until the flour melds into a dough. Use your hands to knead the dough into a cohesive ball.
2. If the dough is sticking to your hands, add a few sprinklings of corn masa flour to dry it out. If the dough is crumbly, add splashes of water until it becomes cohesive.
3. Separate the dough into golf ball sized chunks. This will make tortillas approximately 4 inches across.
4. Line each side of each dough ball with plastic wrap. Flatten the dough balls using a flat-bottomed pan or a tortilla press, and then remove from the plastic.
5. Heat a skillet or comal to medium-high heat.
6. Add a tortilla to the skillet. Flip it after 10 seconds. Then cook each side for about a minute or until light brown spots are forming on the underside.
7. Continue cooking the rest of the tortillas. Once cooked, you can keep them warm by wrapping them in a tea towel or using a dedicated tortilla warmer.
8. Serve immediately and store leftovers in an airtight container in the fridge. To reheat, cook in a dry skillet over medium heat until warm and crispy.

Adapted from: https://www.mexicanplease.com/homemade-corn-tortillas/ (Patrick Calhoun)

Corn Masa: A Gap in U.S. Fortification Policy

THE ROLE OF CORN MASA FORTIFICATION IN ADDRESSING THE NTD GAP

Corn masa flour—a treated corn flour that is the main ingredient in foods such as tortillas, tamales, pupusas, and empanadas that are staples in the foodways of Mexico and some other Latin American countries—was not included in the U.S. folic acid fortification and enrichment standards of the 1990s. These standards built on previously established SOI, and FDA never developed SOI for corn masa flour or corn tortillas, likely in part because at the time they were not considered staple foods in the United States.[36] However, since 1940, the Hispanic population has grown from only 1.4 percent of the U.S. population to 18.7 percent in 2020,[70,71] and NHANES 2017-2018 data show that more than half of Hispanic women aged 12-49 years in the United States consume corn masa.[72] While data show that Hispanic and non-Hispanic adults get similar amounts of folic acid from foods, demonstrating that the lack of corn masa fortification

is not the cause of lower folic acid intake and higher rates of NTDs among Latino/a/e people, folic acid fortification of corn masa flour could be a targeted intervention for increasing folic acid intake in this population and could help to bridge the gap in NTD outcomes.

Researchers have used modeling studies to predict the benefits of adding folic acid to corn masa products for Latino/a/e people in the United States. One study by researchers from CDC predicted that corn masa fortification could prevent 30 Hispanic babies from being born with spina bifida (6% decrease) and 10 Hispanic babies from being born with anencephaly (4% decrease) each year.[73] Another study posited that fortifying corn masa flour would have the greatest benefits for Mexican American women with lower acculturation because Mexican American women who report speaking Spanish at home are more likely to consume corn masa flour compared to those who speak English at home and, as previously discussed, Mexican American women with Spanish language preference also consume less folic acid.[55,74] This study estimated that corn masa fortification would lead to a 30.5 percent increase in median folic acid intake among Mexican American women with less acculturation, and an 8.3 percent increase among Mexican American women with more acculturation, as well as 3.9 and 4.6 percent increases among non-Hispanic White and Black people in the United States, respectively.[74]

FDA'S 2016 RULE ALLOWING VOLUNTARILY FORTIFICATION OF CORN MASA

In 2012, a working group, which consisted of Gruma Corporation (a major producer of corn masa flour and corn masa-containing products sold in the U.S.), March of Dimes, American Academy of Pediatrics, National Council of La Raza (now UnidosUS), Royal DSM (an ingredients supplier), and the Spina Bifida Association, submitted a food additive petition to FDA requesting that the agency allow folic acid to be added to corn masa flour.[75] Walmart was also involved in developing and supporting the petition, and the group received technical assistance and support from CDC's National Center on Birth Defects and Developmental Disabilities.[76] The working group submitted a food additive petition, as opposed to petitioning FDA to develop a new SOI for "enriched corn masa flour," because the food additive petition was considered a quicker and less expensive approach, especially given that there was no pre-existing SOI for "corn masa flour" to amend . However, it was still a substantial undertaking. In order to submit the petition, the working group had to provide information about folic acid intake by sub-population groups such as children and older adults, and the potential for excess folate intake from supplements and fortified foods; address potential safety concerns; propose how the agency should measure impact; and provide evidence of the stability of folic acid in corn masa flour.[76] After producing all the requisite information and responding to follow-up questions from the agency, FDA approved the food additive petition in 2016.

In 2016, FDA also promulgated a final rule allowing folic acid to be voluntarily added to corn masa.[77] The rule states that folic acid may be added to corn masa flour at a level not to exceed 0.7 mg of folic acid per pound of corn masa flour. This fortification level—the same level as was requested in the food additive petition—is similar to the amount required in enriched grain products via the final rule amending the SOI for other flours in 1996 (that rule required 140 mcg of folic acid per 100g of enriched product, which translates to roughly 0.6 mg per pound).[35]

LACK OF UPTAKE OF 2016 RULE BY INDUSTRY

When FDA issued its final rule allowing voluntary corn masa fortification, it estimated that this rule would lead the median daily total folic acid intake among non-pregnant Mexican American women aged 15-44 to increase from 164 mcg to 206 mcg.[77] Unfortunately, the voluntary rule has not yet had its predicted impact. A study by researchers at CDC found that, in 2017-2018, median daily total folic acid intake among

Hispanic women of reproductive age was still only 161 mcg.[72] This study also found that between 2011-2016 (pre-corn masa fortification policy) and 2017-2018 (post-corn masa fortification policy), there was no change in red blood cell folate concentration among Hispanic women of reproductive age, and consequently no change in model-based estimated NTD rates.[72]

Figure 8. Social media advertisement for the #FindFolicAcid campaign

Source: https://twitter.com/emoryrollins/status/1090250746304569344

Two studies have examined whether consumers have access to fortified corn masa foods. It is possible to tell if folic acid has been added to a food because FDA requires that all added vitamins and minerals, including folic acid, must be declared in a product's ingredients list.[78] One study identified 20 corn masa flour and 21 corn tortilla products from 11 grocery stores in Atlanta in December 2017 and found that only two of the corn masa flour products and none of the corn tortilla products were labeled as containing folic acid.[79] After testing two bags of each of the two fortified products, they found that one of the four bags had an insufficient concentration of folic acid (only 0.7 mcg/g, equivalent to about 0.3 mg/lb, far below the 0.7 mg/lb set forth in the voluntary standard).[79] Another study found that found that only 3 of 43 unique corn masa flour and tortilla products identified through a national #FindFolicAcid social media campaign in January 2019 contained folic acid (all 3 were corn masa flour products, not corn tortillas).[80] These studies suggest that the intended effects of the policy may have not been realized because manufacturers have failed to begin voluntarily adding folic acid to their corn masa products.

Assessment of Manufacturers' Uptake of Voluntary Corn Masa Fortification

In order to examine the current state of corn masa fortification in the United States, we conducted a marketplace analysis. Our objective was to assess the food industry's uptake of the 2016 voluntary corn masa fortification rule by examining the prevalence of folic acid fortification of corn masa and to comparing the proportion of corn masa products that contain folic acid to the proportion of wheat products that contain folic acid. We used wheat products as a comparison group because there is considered to be widespread and sufficient fortification of wheat flour, demonstrating the feasibility of fortification and a level of uptake towards which producers of corn masa products should strive.

METHODS

We obtained a list of Universal Product Code (UPC) records for corn masa and wheat flour products from *Everything Food Inc.*, a company that claims to maintain "the nation's largest, most robust food database."[81] For each UPC, our dataset included product information including Category Name, Company Name, Brand Name, UPC Number, Item Description, Ingredients Text, and Last Modified date for each product. We did not have access to the Nutrition Facts or labeling claims for these products.

We included products last modified between January 2018 and January 2022, ensuring ample time after publication of FDA's 2016 rule for companies to have begun adding folic acid. Given that products and ingredients can go by different names, we searched for products with the terms "masa," 'corn masa," "corn masa flour," "masa harina," "nixta masa," "corn tortillas," or "corn flour tortillas" in the Item Name, or "corn masa," "white corn masa," "corn treated with lime," "corn treated with hydrated lime," "corn treated with calcium hydroxide," or "corn" and "lime" in the Ingredients Text. We excluded corn masa products containing folic acid from enriched ingredients other than fortified corn masa flour (e.g., products containing a mix of corn masa and enriched wheat flour) in order to avoid misclassifying products as containing fortified corn masa.

To identify wheat flour and wheat tortilla products for comparison, we searched for products with "flour" or "tortilla" in the Item Name and "wheat flour," "bleached wheat flour," "enriched flour," "bleached enriched wheat flour," "enriched bleached flour," or "unbleached flour" in the Ingredients Text. We excluded products made with whole wheat from our sample of wheat products, limiting our analysis to refined wheat products, as there is no fortification or enrichment standard for whole wheat flour. We also excluded products that had missing or incomplete Ingredients Texts.

If there were multiple products with the same UPC and same Last Modified date, we excluded duplicates from our analysis (there were no products with duplicate UPCs and different Last Modified dates). In our original protocol, we planned to exclude duplicates with the same Company Name, Brand Name, and Item Description, only including the most recent. However, we decided against this approach after realizing there was variation in the level of detail provided in Item Descriptions between companies and brands, and therefore doing so may have led to unintentional exclusion of products that were actually distinct but had the same Item Descriptions.

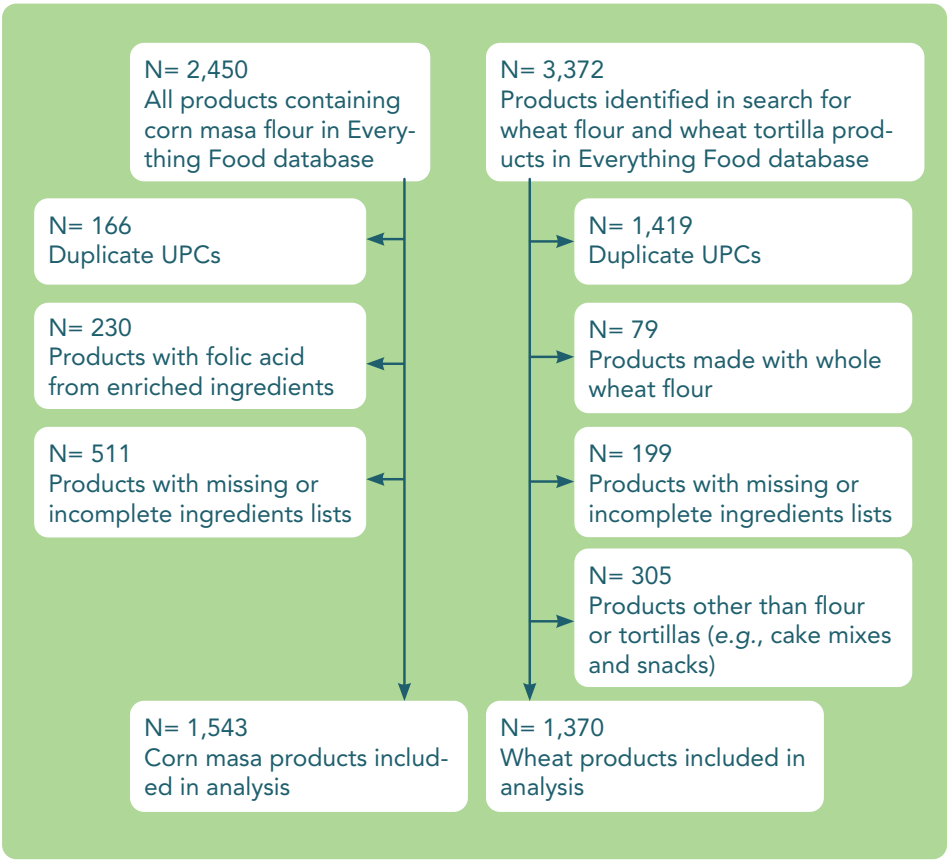
We produced descriptive statistics representing the total number of unique UPCs in five product categories (corn masa flour, corn tortilla, other corn masa flour products, wheat flour, and wheat tortillas), and the numbers and proportions of UPCs with folic acid in each of those product categories. We also produced descriptive statistics representing the total number of corn masa flour and corn tortilla products from each unique company, and the proportion of these products that were fortified with folic acid. We contacted each company with a corn masa flour product in our dataset via email or phone to confirm that our findings accurately reflect their current product offerings. Companies were given at least two weeks to respond. If a company responded with updated product information (number of unique products currently sold, and number of these currently containing folic acid), we amended our findings.

For corn masa flour products that contained folic acid, we conducted searches of company and retailer websites for images of Nutrition Facts labels to assess the amount of folic acid per pound, if disclosed (a quantitative disclosure of the amount of folic acid is only required in certain cases, such as when the packaging includes a marketing claim about the nutrient; otherwise, it may be provided on a voluntary basis[82]). To compare to the maximum level permitted in the voluntary standard (0.7 mg folic acid per pound[77]), we converted the labeled folic acid content reported in % DV or mcg DFE per serving to mg folic acid per pound of flour.

RESULTS

After exclusions, our sample included 1,543 unique corn masa products and 1,370 unique wheat products (*see* Figure 9). Of the 1,543 corn masa products, 62 were corn masa flour, 476 were tortillas, 451 were tortilla chip products including tortilla chips, tostadas, or taco shells, 48 were tamales, 203 were other types of prepared food (*e.g.*, enchiladas, burritos, taquitos), and 303 fell into other categories, such as snacks, salads, or dressings/dips/sauces. Of the 1,370 wheat flour products, 505 were wheat flour and 865 were tortillas.

Figure 9. Inclusion and exclusion of corn masa flour products and wheat flour products



The 62 corn masa flour products in our sample came from 17 different companies. One of these companies went out of business in 2022 and another had no website or contact information available online. We reached out to the remaining 15 companies and received responses from two (Gruma and Masa Brosa). After amending our sample based on information provided by Gruma and Masa Brosa, our sample included 59 unique corn masa flour products.

Eight of the 59 corn masa flour products (14%) and none of the 476 corn tortillas (0%) contained folic acid (*see* Table 2). In contrast, 401 of the 505 wheat flour products (79%) and 731 of the 865 wheat tortilla products (85%) contained folic acid. Of 1,005 corn masa flour-containing products that were not flour or tortillas contained folic acid, including six taco shells, five tostadas, three prepared foods ("Chicken Enchilada," "Chicken Taco," and "Pizza" with a corn masa crust), one tortilla chip, and two other foods ("Burrito Seasoning Mix" and "Rice Dry Mix"), only 17 (1.7%) contained folic acid.

Table 2. Percentage of corn masa and wheat flour products containing folic acid following publication of the 2016 voluntary corn masa fortification rule, by product type

Product Type	Total Products N	Products with Folic Acid n(%)	
Corn Masa Products (N=1,543)			
Corn Masa Flour	59	8	13.6%
Tortilla	476	0	0.0%
Other	1,005	17	1.7%
Tortilla Chip Product*	451	12	2.7%
Tamales	48	0	0.0%
Prepared Food	203	3	1.5%
Other	303	2	0.7%
Wheat Flour Products (N=1,370)			
Wheat Flour	505	401	79.4%
Tortilla	865	731	84.5%

*includes tortilla chips, tostadas, and taco shells

The eight corn masa flour products with folic acid came from three companies: five were from Gruma, two were from Masa Brosa, and one was from The Quaker Oats Company. Only five out of 10 corn masa flour products from Gruma, two out of six corn masa flour products from Masa Brosa, and one of two corn masa flour products from The Quaker Oats Company had folic acid (*see* Appendix).

The 476 corn tortilla products, none of which contained folic acid, were from 134 different companies. The other 17 corn masa products in our sample that contained folic acid came from 8 different companies: Ahold Delhaize; Entertainment Production House, Inc; Giant Food; Gruma; Kroger/Fred Meyer; Mars Wrigley; My Fit Foods; and UTZ Quality Foods, Inc. Our sample also included corn masa products that did not contain folic acid from five of these companies. One of eight corn masa products in our sample from Ahold Delhaize (13%), two of five products from Giant Food (40%), five of 257 products from Gruma (2%), two of 24 products from Kroger (8%), and one of six products from UTZ Quality Foods, Inc (17%) contained folic acid. Among the other three companies, two had only one product each in our sample, and the third—My Fit Foods— had two products in our sample, both of which contained folic acid.

Given Walmart's involvement in advocating for the 2016 voluntary corn masa rule, it is worth noting that our sample also included 19 corn masa products from Walmart store brands (one corn masa flour, four tortillas, three tortilla chip products, seven prepared foods, and four others), none of which contained folic acid. Walmart did not respond to our emails requesting confirmation that our findings accurately reflect their current product offerings, but the Great Value brand Instant Corn Masa Flour product currently available at Walmart.com does not appear to contain folic acid.[83]

We were able to obtain quantitative folic acid contents for fortified corn masa flour products from Gruma, Masa Brosa, and The Quaker Oats Company on Walmart.com and Publix.com. Gruma's 4.4 lb bag of Maseca brand instant corn masa flour and Masa Brosa's 4 lb bag of Instant Corn Masa each had 15 percent of the new Nutrition Facts label's Daily Value for folate, or 40 mcg folic acid, per 30g serving, equivalent to approximately 0.6 mg folic acid per pound (*see* Figure 10). Quaker's 4 lb 6 oz bag of Corn Tortilla Mix had 10% of the old Nutrition Facts label's Daily Value for folic acid per 31g serving, equivalent to approximately 0.6 mg folic acid per pound (*see* Figure 11). However, the 4 lb 6 oz bag of Corn Tortilla Mix listed on QuakerOats.com, with a Nutrition Facts label updated on September 9, 2022, did not disclose folic acid in its ingredients list or Nutrition Facts. We were not able to obtain quantitative folic acid contents for

any of the other corn masa products, either because we could not locate the products or their Nutrition Facts labels on company or retailer websites, or because the products did not disclose this information on their labels.

Figure 10a. Folic acid content of Maseca Instant Corn Masa Flour, 4.4 lb bag on Walmart.com

Source: https://www.walmart.com/ip/MASECA-Traditional-Instant-Corn-Masa-Flour-4-Lb/10291185

Figure 10b. Folic Acid Content of Masa Brosa Instant Corn Masa Flour, 4 lb bag on Publix.com

Source : https://delivery.publix.com/landing?product_id=114472&retailer_id=57&postal_code=32829&region_id=662500170

Figure 11. Folic acid content of Quaker Corn Tortilla Mix, 4 lb 6 oz bag, Walmart.com and QuakerOats.com

Nutrition Facts
Información Nutrimental

Serving Size 1/4 cup (31 g/ approx. 2-6" baked tortillas)
Tamaño de la Porción 1/4 taza (31 g aprox. 2-6" tortillas preparadas)
Servings Per Container about 64
Porciones Por Envase: aproximadamente 64

Amount Per Serving / Cantidad Por Porción	
Calories / Calorías 110	
Calories from Fat / Calorías de Grasa 15	
	% Daily Value* % Valor Diario**
Total Fat / Grasa Total 1.5g	**2%**
Saturated Fat / Grasa Saturada 0g	**0%**
Trans Fat / Grasa Trans 0g	
Cholesterol / Colesterol 0mg	**0%**
Sodium / Sodio 0mg	**0%**
Total Carbohydrate / Carbohidratos Totales 24g	**8%**
Dietary Fiber / Fibra Dietética 3g	**10%**
Sugars / Azúcares 0g	
Protein / Proteína 3g	
Vitamin A / Vitamina A	0%
Vitamin C / Vitamina C	0%
Calcium / Calcio	4%
Iron / Hierro	4%
Thiamin / Tiamina	8%
Riboflavin / Riboflavina	4%
Niacin / Niacina	4%
Folic Acid / Ácido Fólico	10%

Ingredients: Corn treated with lime water and specially ground, niacin*, reduced iron, thiamin mononitrate*, riboflavin*, folic acid*. (450-1-14)
*One of the B Vitamins.

Ingredientes: Maíz tratado con agua de cal y especialmente molido, niacina*, hierro reducido, mononitrato de tiamina*, riboflavina*, ácido fólico*. (450-1-14)
*Una de las vitaminas B

Source: https://www.walmart.com/ip/Quaker-Corn-Masa-Harina-70-4-oz/483970100, September 15, 2022

Nutrition Facts

About 64 servings per container
Serving Size
1/4 Cup/Approximately 2-6 Inch Baked Tortillas (31 g)

Amount Per Serving	
Calories	**120**
	% Daily Value*
Total Fat 1g	**1%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0g	
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Total Carbohydrate 24g	**9%**
Dietary Fiber 2g	**7%**
Total Sugars 0g	
Includes 0g Added Sugars	**0%**
Protein 3g	
Vitamin D 0mcg	0%
Calcium 40mg	2%
Iron 0.5mg	2%
Potassium 80mg	0%

Ingredients: Ground corn treated with lime.

Source: https://www.quakeroats.com/products/tortilla-mix/masa-preparada, September 15, 2022

DISCUSSION

This study examined a large national sample of corn masa products on the market at least two years after FDA began permitting folic acid fortification of corn masa flour, and confirmed that there has been minimal uptake of voluntary fortification by manufacturers of corn masa products. Our finding that 8 out of 59 (14%) of corn masa flours in our sample contained folic acid was consistent with the finding from a 2018 study that 2 of 20 (10%) corn masa flours in Atlanta grocery stores contained folic acid.[79] As with previous studies from 2018 and 2019, we did not find a single corn tortilla product with folic acid.[79,80] Our results also show that, compared to wheat flour and wheat tortillas, folic acid fortification of corn masa is substantially lagging.

With few fortified corn masa flour products and no fortified corn tortillas on the market (based on our large sample), people who rely on these foods as staples in their diets are less likely to consume the level of folic acid recommended for NTD prevention. This is particularly concerning given that Latino/a/e people in the United States are more likely to consume these foods and face higher rates of NTDs. There is a great need for access to culturally appropriate foods that are fortified with folic acid.

We applaud the companies Gruma, Masa Brosa, and Quaker for offering fortified corn masa flour, as well as Ahold Delhaize, Entertainment Production House, Inc, Giant Food, Kroger, Mars Wrigley, My Fit Foods, and UTZ Quality Foods, Inc for offering other fortified corn masa products. However, we encourage these producers to begin fortifying more of their corn masa products, as most of these companies had other, non-fortified corn masa products in our sample, and it is unclear whether Quaker's fortified corn masa flour remains on the market.

We understand that companies may face barriers to folic acid fortification of corn masa products. In an informal poll of manufacturers conducted by a trade association and shared with CSPI via email, one manufacturer reported that they grind whole corn to make their own corn masa and have had difficulty extrapolating the FDA guideline of 0.7 mg folic acid per pound of corn masa flour to determine the right fortification level for their process. Another manufacturer reported a lack of availability of fortified corn masa from their ingredient supplier. Other manufacturers noted concerns regarding the impact of folic acid on product quality, the need for label changes, and consumer demand for simple labels with recognizable ingredients.

Despite these barriers, our findings show that companies are fully capable of fortifying corn masa products with folic acid. Additional evidence of feasibility comes from Mexico, where corn masa flour is required by law to be fortified with folic acid.[84] Despite some ongoing issues with enforcement and uptake by smaller producers, much of the corn masa flour and corn tortillas sold in Mexico is fortified, and corn tortillas represent the single greatest food source of folic acid in people's diets.[85]

We have called special attention to Gruma and Walmart, as these two companies were involved in the initial push to pass the voluntary corn masa fortification rule. Our sample included several corn masa flour products from Gruma's Maseca brand that had folic acid, but several other Maseca products that did not. According to Gruma, their fortified corn masa flour products currently account for 85 percent of the company's corn masa flour sales.[86] Nevertheless, the company expects to "complete the migration of [its] remaining corn masa flour products" in 2023 and 2024.[86] Given that Gruma already produces fortified corn masa flour, it is not clear why the company has not already begun using fortified flour as an ingredient in its tortillas. In an email to CSPI, the company stated: "We expect for all of our core corn tortillas to be fortified by the end of 2024."[86] None of Walmart's 19 corn masa flour products in our sample contained folic acid, and the company did not respond to our email inquiry.

LIMITATIONS

Our study had several limitations. First, the products in Everything Food's database were collected from across the country but were not necessarily a comprehensive or nationally representative sample of corn masa and wheat flour products sold in the United States. For example, previous studies from 2018 and 2019 found that some Masa Brosa-brand corn masa flour in U.S. supermarkets contained folic acid,[79,80] but none of the Masa Brosa-brand corn masa flour products in the Everything Food database (all from 2020) contained folic acid. We corrected these data based on information provided by Masa Brosa, but were unable to verify the contents of the database for other companies that did not respond to our outreach or producers of other corn masa and wheat products who we did not reach out to.

We were unable to weight our data by the market share of each brand or company because we could not find reliable market share data on the U.S. corn masa flour or corn tortilla markets. Therefore, we were unable to assess the proportion of corn masa and flour product purchases that contain folic acid.

Next, we only excluded duplicate UPCs and not products with the same Brand Name and Item Name but different UPCs, which could have resulted in some brands being over-represented in our data, with multiple versions of the same product that were assigned different UPCs due to minor changes, such as changes in branding or package size.

The data from Everything Food may have contained errors affecting our findings. For example, some wheat products in the database listed "enriched flour" as an ingredient without listing all the micronutrients added through enrichment. However, labeling regulations require that products with enriched ingredients list all added micronutrients in their ingredients lists.[78] These items were considered to have incomplete ingredients lists and were excluded from our analysis. In the wheat tortilla category, 18% of wheat tortillas were excluded for this reason.

Call to Action

There is an urgent need for action to increase folic acid intake among Latino/a/e people who may become pregnant in the United States. Many different stakeholders have a role to play.

MANUFACTURERS

Manufacturers should add folic acid to all corn masa products sold in the United States. They should let their ingredients suppliers know that they are interested in purchasing fortified corn masa or, if they produce their own corn masa ingredients, they should fortify the corn masa flour in-house. If questions about feasibility and regulatory compliance arise, manufacturers should recognize these as surmountable barriers and reach out to FDA for technical assistance. Manufacturers should also consider participating in educational campaigns to raise awareness of the importance of folic acid, particularly to Latino/a/e consumers.

INGREDIENTS SUPPLIERS

Ingredients suppliers should make available corn masa flour that is fortified with 0.7 mg folic acid per pound and advertise its availability to customers. If possible, suppliers should sell fortified corn masa flour at no additional cost to avoid disincentivizing manufacturers from purchasing it.

RETAILERS

Retailers should commit to carrying fortified corn masa products and communicate such commitments to food manufacturers and consumers. They should leverage their purchasing power to push manufacturers to expand access to fortified corn masa foods. They may also participate in educational campaigns to raise awareness of the importance of folic acid.

FDA

FDA should host a listening session to learn about barriers to fortification facing corn masa manufacturers and ingredient suppliers. Following the listening session, the agency should issue a guidance for industry responding to frequently asked questions and addressing common barriers. FDA should consider potential labeling solutions to overcome barriers to fortification. FDA should also communicate to manufacturers about the label claims they are permitted to use (*e.g.*, "fortified" or "enriched") to communicate the nutritional benefits of their fortified corn masa products.

DGA

The 2020-2025 DGA urge that "individuals who eat refined grains should choose enriched grains."[12] The DGA should consider amending this advice to urge that individuals who eat refined grains should look for grain products that list "folic acid" in the ingredients.

U.S. SURGEON GENERAL

The U.S. Surgeon General should issue a call to action for the food industry to increase the availability of corn masa products fortified with folic acid.

CLINICIANS

Health care providers should encourage all people who may become pregnant to take a multivitamin supplement containing folic acid. Given the gap in access to preconception folic acid counseling by race and ethnicity,[56] and the higher prevalence of MTHFR variants among some Latino/a/e populations,[65] providers should especially make sure to engage in such conversations with their Latino/a/e patients.

CONSUMERS

Consumers—especially those who are or may become pregnant—should look for the words "folic acid" when buying corn masa flour and corn masa products. They can always check if a product contains folic acid by looking at the ingredients list, but some products make it even easier by declaring folic acid on the front of the package (*see* Figure 12). Given the apparent absence of fortified corn tortillas on the market, we recommend that consumers choose enriched wheat tortillas or make corn tortillas from scratch using fortified corn masa flour until fortified ready-made corn tortillas become available. Consumers who are or may become pregnant should also take a multivitamin supplement containing folic acid to reach the 400 to 800 mcg per day recommended by the DGA, the National Academy of Medicine, the U.S. Preventive Services Task Force, and the CDC.12-14

Figure 12. Folic acid disclosure on Maseca Corn Masa Flour package

Source: https://www.walmart.com/ip/MASECA-Traditional-Instant-Corn-Masa-Flour-4-Lb/10291185

Conclusion

While increased fortification of corn masa flour may not address the root causes of elevated NTD rates among Latino/a/e populations, such as lower rates of supplement use and higher prevalence of genetic variants that affect folate metabolism, an increased intake of folic acid through corn masa products could help bridge the gap in folic acid intake and potentially result in reduced NTD rates. Companies should prioritize this simple step that could save Latino/a/e lives.

We call on manufacturers and ingredient suppliers to implement FDA's voluntary rule and add folic acid to all of their corn masa products, and look forward to commending the first company to bring a fortified corn tortilla product onto the U.S. market.

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Appendix

PERCENTAGE OF CORN MASA FLOUR AND CORN TORTILLA PRODUCTS CONTAINING FOLIC ACID, BY COMPANY

Company	N with Folic Acid	Total	% with Folic Acid
Corn Masa Flour	**8**	**59**	**13.6%**
Gruma (Azteca Milling L.P.)	5	10	50.0%
Masa Brosa	2	6	33.3%
The Quaker Oats Company	1	2	50.0%
Barry Farm	0	1	0.0%
Bob's Red Mill Natural Foods, Inc	0	10	0.0%
Casa Cardenas	0	1	0.0%
Don Pancho	0	1	0.0%
Gold Mine Natural Foods Co	0	1	0.0%
Goya Foods, Inc.	0	2	0.0%
Kroger	0	1	0.0%
La Predilecta	0	1	0.0%
Larissa Veronica	0	17	0.0%
Manitou Trading Company	0	2	0.0%
Ole Mexican Foods, Inc.	0	1	0.0%
OliveNation LLC	0	1	0.0%
The Moran Group Incorporated	0	1	0.0%
Walmart	0	1	0.0%
Corn Tortillas	**0**	**476**	**0.0%**
Ahold USA, Inc	0	2	0.0%
Albuquerque Tortilla Co.	0	1	0.0%
Aldi	0	1	0.0%
Alejandro's Tortilla & Bakery	0	1	0.0%
Associated Wholesale Grocers, Inc	0	1	0.0%
Atotonilco Tortilleria	0	1	0.0%
Authentasty	0	1	0.0%
Azteca Foods, Inc	0	2	0.0%
Bashas Corporate	0	3	0.0%
Best's Foods	0	1	0.0%
Bimbo Bakeries USA, Inc	0	21	0.0%
Bokados	0	1	0.0%
Broghies	0	1	0.0%
Brookshire Grocery Company	0	2	0.0%
Butter Krust Baking Co.	0	1	0.0%
Buy Low	0	2	0.0%
Cabo Loco	0	1	0.0%
Cafe Hon, Inc	0	1	0.0%
Casa Cardenas	0	1	0.0%
Casa Valdez	0	1	0.0%

CASERA STYLE	0	1	0.0%
Catallia Mexican Foods LLC	0	1	0.0%
Celia's	0	1	0.0%
Chef Garcia Mexican Foods	0	1	0.0%
Chica Bella, Inc	0	2	0.0%
Crook-Miller Co.	0	1	0.0%
Cruz	0	2	0.0%
Del Rey Tortilleria, Inc.	0	1	0.0%
Diana's Mexican Food Products, Inc	0	2	0.0%
Don Miguel Mexican Foods, Inc	0	1	0.0%
Don Pancho	0	19	0.0%
El Comal	0	1	0.0%
El Encanto, Inc	0	4	0.0%
El Maizal Tortilleria Inc.	0	4	0.0%
El Milagro Of Atlanta	0	1	0.0%
EL Milagro Products	0	5	0.0%
El Paisano	0	1	0.0%
El Popocatepetl Industries Inc	0	1	0.0%
El Tortillero LLC	0	1	0.0%
Fiesta	0	6	0.0%
Food City	0	1	0.0%
Food For Life	0	1	0.0%
Frescados	0	2	0.0%
Generic	0	1	0.0%
Giant Eagle, Inc	0	1	0.0%
Giant Food	0	2	0.0%
Globo Foods Ltd.	0	1	0.0%
Glutenfreeda Foods, Inc.	0	2	0.0%
Golden Flake Snack Foods, Inc.	0	1	0.0%
Gonzalez Northgate Market	0	1	0.0%
Goya Foods, Inc	0	2	0.0%
Gruma (includes Guerrero Tortilleria, Mission Foods)	0	125	0.0%
Grupo Salvatex	0	1	0.0%
Guerrero Tortilleria	0	1	0.0%
H-E-B	0	4	0.0%
Hacienda Mexican Foods LLC	0	7	0.0%
Hannaford SuperMarket	0	3	0.0%
Harbar LLC	0	5	0.0%
Hereford Tortilla Factory	0	5	0.0%
Hola Nola	0	2	0.0%
Jodi Cosmetics, Inc.	0	1	0.0%

Kroger	0	4	0.0%
La Bonita Ole	0	1	0.0%
La Campera	0	1	0.0%
La Cocina De Josefina	0	1	0.0%
La Comadre	0	1	0.0%
La Favorita	0	2	0.0%
La Mexicana Grocery	0	1	0.0%
La Primera Tortilla Factory	0	1	0.0%
La Ranchera	0	1	0.0%
La Real	0	1	0.0%
La Rosa Tortilla Factory, Inc	0	1	0.0%
La Tapatia	0	4	0.0%
LA Tol Teca	0	1	0.0%
La Tortilla Factory, Inc	0	27	0.0%
La Tumba Todo	0	1	0.0%
Laura Lynn	0	1	0.0%
Lompoc Tortilla Shop	0	1	0.0%
Los Altos	0	1	0.0%
Los Amigos Tortillas Manufacturing	0	1	0.0%
Los Angeles	0	1	0.0%
Los Arcos Grocery	0	1	0.0%
Lyle Style	0	1	0.0%
Madrid Santa Fe Trading	0	1	0.0%
Maizada	0	1	0.0%
Mama Lola's	0	1	0.0%
Mama Lupe's	0	3	0.0%
Masienda Bodega	0	1	0.0%
Megamex Foods	0	1	0.0%
MexAmerica Foods, Inc	0	1	0.0%
Mi Abuelita Bonita Tortillas	0	1	0.0%
Mi Pueblo	0	3	0.0%
Mi Rancho	0	6	0.0%
Moctec Enterprises, Inc	0	1	0.0%
Montecito	0	1	0.0%
Northgate Gonzalez Markets Corporate	0	6	0.0%
Nuevo Grille	0	1	0.0%
O.M. Distributors	0	1	0.0%
Old Mill	0	1	0.0%
Ole Mexican Foods, Inc	0	35	0.0%
One Degree Organic Foods	0	1	0.0%
Pepito	0	6	0.0%
Premium Brands Holdings Corp.	0	1	0.0%

Raley's Supermarkets	0	4	0.0%
Reser's Fine Foods	0	4	0.0%
Romero's Food Products, Inc	0	9	0.0%
Roundy's	0	2	0.0%
Safeway	0	5	0.0%
San Antonio	0	2	0.0%
Santa Fe Tortilla Company	0	1	0.0%
Schnucks	0	1	0.0%
Siempre Autentico	0	2	0.0%
Sinaloa	0	3	0.0%
Snyder's-Lance, Inc	0	2	0.0%
Supervalu, Inc	0	1	0.0%
Surito	0	1	0.0%
Taco Loco	0	1	0.0%
Target	0	2	0.0%
The Great Western Tortilla Company	0	1	0.0%
The Kellogg Company	0	1	0.0%
Three Sisters Nixtamal	0	1	0.0%
Topco Associates LLC	0	2	0.0%
Tortilla Fresca	0	1	0.0%
Tortilla King, Inc	0	2	0.0%
Tortilla Land	0	3	0.0%
Tortillas Mexico	0	6	0.0%
Tortillas Montes	0	1	0.0%
Tortillas Tita	0	1	0.0%
Tortilleria	0	1	0.0%
Tortilleria Los Comanches	0	1	0.0%
Trader Joe's	0	6	0.0%
Walmart	0	4	0.0%
Wegmans	0	2	0.0%
Whole Foods Market, Inc	0	2	0.0%
Wisoman Foods Inc.	0	1	0.0%
Missing Brand	0	2	0.0%