FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Folic Acid Fortification of Corn Masa Flour

U.S. Food and Drug Administration

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What are Neural Tube Defects (NTDs)?

Open spina bifida Anencephaly

NTDs are serious birth defects that affect the brain and spine.

The neural tube closes before many women realize they are pregnant.

Taking folic acid before and during pregnancy is crucial to help prevent NTDs.

IMPACT OF FOLIC ACID FORTIFICATION IN THE U.S.

Folic acid has been added to foods labeled as "enriched," such as breads, pastas, rice and cereals. Adding folic acid to foods is called folic acid fortification.

Folic acid in foods helps prevent about

1,300

neural tube defects

annually in the U.S.

Folic acid fortification of enriched cereal grain products in the U.S. saves more than

$600 million each year.

www.cdc.gov.folicacid

CS321235-B

Hispanic/Latina Women in the US Have the Highest Risk of Having a Baby Affected by an NTD

Hispanic women **have lower folate levels** than non-Hispanic White women and are **less likely to take folic acid supplements**.

Compared to non-Hispanic White women, Hispanic women are **less likely to know about folic acid and eat fortified foods**.

Limited adoption of voluntary corn masa flour fortification affects access to fortified products for Hispanic groups, many who rely on corn masa flour for their staple foods.

Folic Acid Fortification History

Institute of Medicine's Food and Nutrition Board recommended that all women who can become pregnant get 400 mcg of folic acid daily, in addition to getting folate from a varied diet, to reduce the risk of having a baby with an NTD.

U.S. Preventive Services Task Force 400–800 µg/day of folic acid from supplements. Grade A: highest level of confidence.
The recommendation was reaffirmed in August 2023.

1992

US Public Health Service recommended that all women who could become pregnant get 400 mcg of folic acid daily to prevent NTDs.

1998

FDA mandated folic acid fortification of enriched cereal grains.

2016

FDA allowed voluntary fortification of corn masa flour.

2017

Fortification Policy

Establishes a uniform set of principles to serve as a model for the rational addition of essential nutrients to foods, specifically to:

- Prevent or correct a demonstrated deficiency
- Restore naturally occurring nutrients lost during processing, storage, or handling
- Provide a balance of nutrients in proportion to total caloric content of the food
- Add a nutrient to a food at the level found in a comparable traditional food

Standards of Identity for Enriched Foods

Historically, one tool FDA has used to promote rational fortification of the food supply, particularly in refined grain products

- Enrichment is not mandatory
- For certain categories of foods, such as flours, bread, and pasta, there are standards of identity (SOI) for unenriched and enriched products
- Products that are labeled as enriched (e.g., enriched flour) must meet the enrichment requirements of the standard
- The enriched standards dictate the addition of specific nutrients (iron, thiamin, riboflavin, niacin, and folic acid) at specified levels
- There is no SOI for corn masa flour, either enriched or unenriched

1996 Final Rule for Enriched Grain Products to Include Folic Acid: Considerations

- FDA considered addition of folic acid to cereal-grain products, fruit juices, and dairy products.
- FDA's analysis showed that when fortification included fruit juices and dairy products in addition to cereal grain products, intakes by consumers in some non-target groups exceeded the safe upper limit of 1 mg/day even at the lowest level of fortification.
- However, when fortification is limited to cereal grain products at levels of 70 µg/100 g or 140 µg/100 g, estimates of daily intakes did not exceed the safe upper limit.
- As a result of its analysis, FDA determined that fortification should be limited to cereal-grain products and not extended to dairy products and fruit juices.

FDA Regulation of Food Additives

- Section 409 of the FD&C Act requires that a food additive be shown to be safe before marketing. Under 21 CFR 170.3(i), a food additive is "safe" if "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."
- Safety Standard – Reasonable Certainty of No Harm
- For approval of a new food additive, a food additive petition must be submitted
- The petitioner has the burden to submit all relevant safety data concerning the proposed use of the additive

Food Additive Petition

- FDA received a food additive petition in 2012 requesting that we amend the food additive regulations to allow addition of folic acid to corn masa flour (CMF)
- The petitioners included a major tortilla manufacturer (Gruma Corp.) and public health organizations (Spina Bifida Assoc., March of Dimes, American Acad. of Pediatrics, and the National Council of La Raza)
- Goal of petition was to increase folic acid intake for U.S. women of childbearing age who regularly consume CMF as a staple in their diet (in particular, for women of Latin American descent) to help reduce the incidence of NTDs in this population

Food Additive Petition- continued

- In 2016, FDA approved the use of folic acid in CMF at levels not to exceed 0.7 mg/lb, and amended our regulations in 21 CFR 172.345
- FDA conducted an exposure analysis as part of the petition review, considering the total dietary exposure for folic acid including from currently fortified foods, dietary supplements, and from the petitioned use
- FDA considered safety issues such as the masking effect of folic acid on vitamin B12 deficiency, and concluded that the requested level of CMF fortification is safe
- FDA relied upon the IOM's ULs for various age ranges, including 1 mg/day for adults ages 19 years and up

Exposure Estimate Details

- Folic acid exposure was estimated for the U.S. population stratified by gender, race/ethnicity, and age.

- Since fortification has been targeted to U.S. women of childbearing age, our exposure estimate focused on exposure resulting from the fortification of CMF products with folic acid on women of childbearing age (15-44 years, non-pregnant) by race/ethnicity

- Since the impact of fortification varies by age, we considered the U.S. population subgroups at risk for over-fortification (e.g., children and older adults)

Food Additive Regulation

§ 172.345 Folic acid (folacin).

(i) Folic acid may be added to corn masa flour at a level not to exceed 0.7 milligrams of folic acid per pound of corn masa flour.

Fortification of CMF as Described in Petition

- Folic acid may be added to corn masa flour at a level not to exceed 0.7 milligrams of folic acid per pound of corn masa flour.
- The petition describes CMF manufacturing:
  - Cook whole kernel corn with lime and water to produce nixtamal, steep in alkaline, wash, grind, dry and sift to produce CMF
  - Fortification with folic acid added in continuous system (like with wheat flour), added as a premix to ground, dried CMF at appropriate levels

Uses of Folic Acid Fortified CMF Considered in Exposure Assessment

- Corn or cornmeal snacks (chips, puffs, twists)
- Cornmeals (mush, dumpling, sticks)
- Corn beverages (atole, champurrado)
- Dishes (chalupas, chilaquiles, enchiladas, flautas, gorditas, huevos rancheros, nachos, quesadilla, sope, taco, tamales, taquitos, tostada)
- Cake or flatbread (pupusas, tortillas, pone); and soups

Corn Masa in the US: Supply, Market, and Fortification

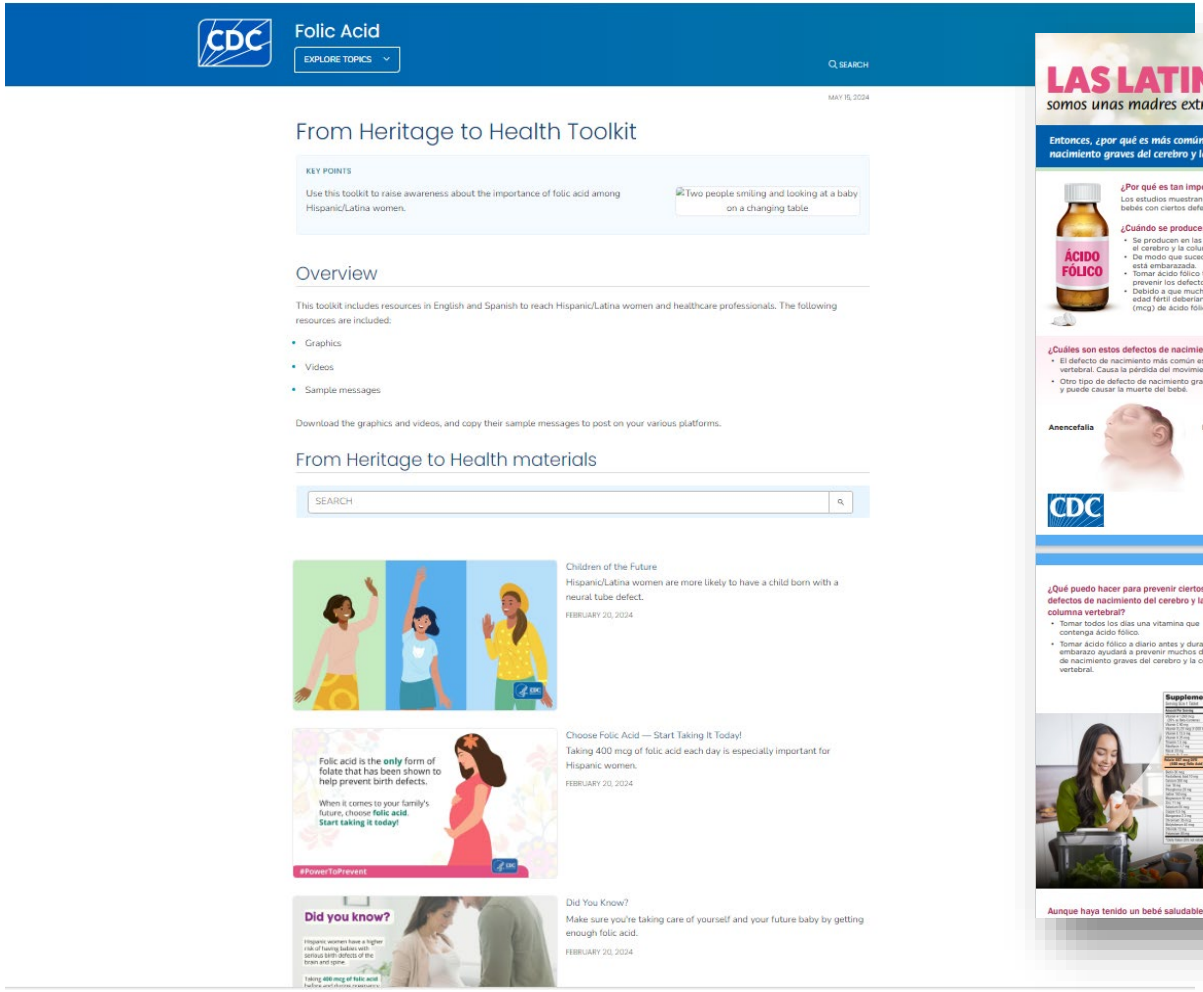
- Corn masa supply chain assessment, Food Fortification Initiative (FFI) report
  - Amount of corn ground in the US for masa production: about 2.7 million metric tons per year .
  - An estimated 6% of the total US corn masa volume contains folic acid.

- Market assessment in two majority Hispanic counties in CA and TX (FFI report pending)
  - About half (47%) of unique corn masa flour retail bags were found to be fortified with folic acid.
  - Additionally, one tostada and one tortilla brand were fortified with folic acid.

Resources

- Consumer Update: Adding Folic Acid to Corn Masa Flour May Prevent Birth Defects | FDA
- New FDA Inquiry Portal: Manufacturers who have questions about FDA regulations related to fortifying corn masa flour or other corn masa products with folic acid can contact the FDA through our inquiry portal: Corn_Masa_Inquiries@fda.hhs.gov.
- New FDA Resource Site: Fortifying Corn Masa Flour Products with Folic Acid

Folic Acid Educational Resources for Hispanic/Latina Communities



https://www.cdc.gov/folic-acid/php/toolkit_hispanic/index.html