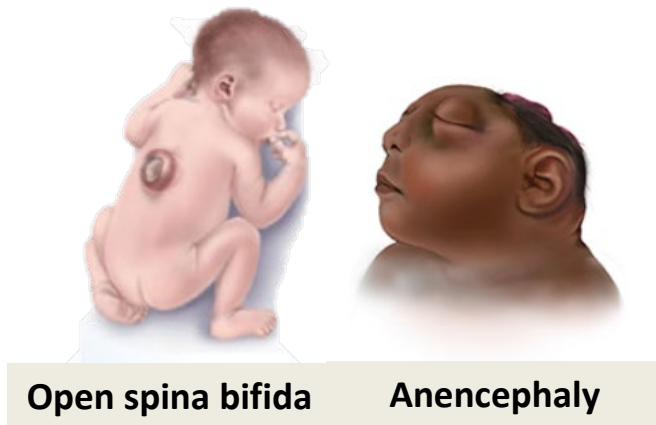


# Folic Acid Fortification of Corn Masa Flour

U.S. Food and Drug Administration

September 24, 2024

# What are Neural Tube Defects (NTDs)?



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](http://www.cdc.gov/folicacid)

# 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  $\mu\text{g}/100\text{ g}$  or 140  $\mu\text{g}/100\text{ g}$ , 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](mailto:Corn_Masa_Inquiries@fda.hhs.gov).
- **New FDA Resource Site:** [Fortifying Corn Masa Flour Products with Folic Acid](#)

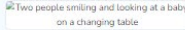
# Folic Acid Educational Resources for Hispanic/Latina Communities

**Folic Acid**  
EXPLORE TOPICS

SEARCH

MAY 16, 2024

## From Heritage to Health Toolkit

**KEY POINTS**  
Use this toolkit to raise awareness about the importance of folic acid among Hispanic/Latina women.  


### Overview


This toolkit includes resources in English and Spanish to reach Hispanic/Latina women and healthcare professionals. The following resources are included:

- Graphics
- Videos
- Sample messages


Download the graphics and videos, and copy their sample messages to post on your various platforms.

### From Heritage to Health materials


SEARCH



**Children of the Future**  
Hispanic/Latina women are more likely to have a child born with a neural tube defect.  
FEBRUARY 20, 2024



**Choose Folic Acid — Start Taking It Today!**  
Taking 400 mcg of folic acid each day is especially important for Hispanic women.  
FEBRUARY 20, 2024



**Did You Know?**  
Make sure you're taking care of yourself and your future baby by getting enough folic acid.  
FEBRUARY 20, 2024

## LAS LATINAS

somos unas madres extraordinarias.

Entonces, ¿por qué es más común que tengamos bebés con ciertos defectos de nacimiento graves del cerebro y la columna vertebral?

**¿Por qué es tan importante el ácido fólico para las latinas?**  
Los estudios muestran que, comparadas con otras mujeres, las latinas tienen más bebés con ciertos defectos de nacimiento del cerebro y la columna vertebral.

**¿Cuándo se producen estos defectos de nacimiento y por qué?**

- Se producen en las primeras semanas del embarazo, cuando se forman el cerebro y la columna vertebral.
- De modo que suceden mucho antes de que usted se entere de que está embarazada.
- Tomar ácido fólico todos los días antes de quedar embarazada ayuda a prevenir los defectos de nacimiento del cerebro y la columna vertebral.
- Debido a que muchos embarazos no son planificados, todas las mujeres en edad fértil deberían tomar una vitamina que contenga 400 microgramos (mcg) de ácido fólico todos los días.

**¿Cuáles son estos defectos de nacimiento graves?**

- El defecto de nacimiento más común es espina bífida. Este problema afecta la columna vertebral. Causa la pérdida del movimiento en la parte baja del cuerpo (parálisis).
- Otro tipo de defecto de nacimiento grave es la anencefalia. Este problema afecta el cerebro y puede causar la muerte del bebé.

Anencefalia      Espina bífida

**CDC**

**¿Qué puedo hacer para prevenir ciertos defectos de nacimiento del cerebro y la columna vertebral?**

- Tomar todos los días una vitamina que contenga ácido fólico.
- Tomar ácido fólico a diario antes y durante el embarazo ayudará a prevenir muchos defectos de nacimiento graves del cerebro y la columna vertebral.

**Supplement Facts**

Folic Acid	
Amount Per Serving	% Daily Value*
400 mcg	100%
<b>% Daily Value</b> is based on a diet of other people's mistakes.	

**¿Cómo puedo obtener suficiente ácido fólico?**

- Casi todos los multivitáminas que se venden tienen la cantidad que usted necesita. Si las multivitáminas le sientan mal, trate tomarlas junto con alguna comida o a la hora de acostarse.
- Puede tomar pastillas de ácido fólico. Estas son pequeñas y fáciles de tragar. También puede tomar multivitáminas masticables.
- Puede comprar ciertos tipos de cereales enriquecidos con ácido fólico. Lea las etiquetas para averiguar cuánto ácido fólico hay en cada ración. Las mujeres deberían tratar de obtener 400 mcg de ácido fólico al día para ayudar a prevenir los defectos de nacimiento graves del cerebro y la columna vertebral.

Aunque haya tenido un bebé saludable antes...



Así que recuerda, al buscar vitaminas, asegúrate de buscar **ácido fólico** en la etiqueta.

0:54 / 1:02

**Folic acid is the **only** form of folate that has been shown to help prevent birth defects.**

When it comes to your family's future, choose **folic acid**. **Start taking it today!**

**#PowerToPrevent**

**CDC**