

FDA to review fortifying corn flour with folic acid to prevent birth defects

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The federal Food and Drug Administration has agreed to review a long-delayed petition to fortify corn masa flour with folic acid, a move advocates say is crucial to preventing devastating birth defects like those seen in an ongoing cluster of cases in Washington state and other cases in the nation's growing Hispanic population.

Officials with the March of Dimes, which co-sponsored the [petition](#) in 2012, said the FDA has received results of recent tests to validate the stability of the B vitamin when added to foods such as tortillas and corn chips.

"We are pleased to have moved the process forward on our citizen petition to fortify corn masa flour with folic acid," Cynthia Pellegrini, March of Dimes senior vice president of public policy and government affairs, said in an email. "We and our co-petitioners look forward to working with the FDA on this critically important issue for mom and baby health, especially in Hispanic communities."

On the FDA website, the status of the petition has been changed from "held in abeyance" to "under review." Public comments will be accepted until mid-January.

The FDA required the tests, conducted by Utah food scientists in June, before the agency would consider the petition aimed at halting severe birth defects such as spina bifida and anencephaly, particularly in Hispanic communities.

In Washington state, a cluster of anencephaly - a condition in which babies develop in utero missing all or part of the brain and skull - has affected at least 40 pregnancies since 2010 in three of the state's counties. Despite an ongoing investigation, state and federal health officials have found no cause for the cluster and no way to stop the rare and fatal disorder.

Adequate folic acid is necessary to ensure proper formation of the neural tube, which creates the brain and spinal cord early in fetal development. If the tube doesn't close properly, it can cause [spina bifida](#), or, in severe cases, anencephaly.

Folic acid supplements and fortification of foods are the only known way to reduce or prevent the defects.

The FDA had tabled the petition that would allow manufacturers to fortify corn flour with folic acid, the same way the vitamin has been added to enriched wheat and rice flours for years.

Since 1996, the FDA has required that cereal-grain products identified as enriched must be fortified with folic acid. After the regulation took effect, cases of neural-tube defects in the U.S. plunged by 35 percent.

Fortification eliminated about 10,000 defects in a decade, making it one of the top 10 public-health interventions of the 21st century's first decade.

But corn masa, a staple grain in the Hispanic diet, was overlooked at the time. The corn flour wasn't as common then as it is now in the U.S., and wasn't defined in a way to be classified as an enriched grain.

Since then, the U.S. Hispanic population has surged. A quarter of all U.S. babies are now born to Hispanic mothers, who have a 20 percent

increased risk of neural-tube defects.

Fortifying corn masa flour with folic acid could prevent an average of 40 neural-tube defects a year in Hispanic women and perhaps as many as 120 nationwide, according to the Centers for Disease Control and Prevention (CDC).

The test results are promising, according to Michael Dunn, the Brigham Young University food scientist who led the study. Although he can't discuss the results now, while they're under FDA review, he has previously said the folic [acid](#) remained reasonably stable in stored corn flour and showed little loss in baked tortillas and, surprisingly, fried chips.

The new review is no guarantee of FDA approval, however. Agency officials could ask for more time to consider the petition, or they could reject the proposal, March of Dimes officials noted.

But advocates say it's a move long overdue. Dr. Godfrey Oakley, an Emory University epidemiology professor who previously headed the birth-defects division at the CDC, lobbied for fortification in the mid-1990s and wants to see it added to corn masa, too. "They should have an expedited way to approve the petition and get [folic acid](#) into corn masa flour as fast as possible to prevent babies from having [birth defects](#)," he said.

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