

FDA delays decision on adding folic acid to corn masa

January 29 2016, by Jonel Aleccia, The Seattle Times

Federal regulators have delayed until April a decision on whether to allow folic acid to be added to corn-masa flour, a move experts say could help prevent birth defects like those seen in a deadly cluster in three Central Washington state counties.

The Food and Drug Administration (FDA) has notified officials with the March of Dimes that the agency will take 90 additional days beyond a mid-January deadline to continue review of a petition urging voluntary fortification of corn masa, a grain common in Latino diets. Enriched wheat and rice flours have been required to be fortified for nearly 20 years.

"The FDA has extended the time frame to allow for thorough scientific review of the data," said agency spokeswoman Lauren Sucher. "The petition remains a priority for the agency."

The delay didn't discourage Cynthia Pellegrini, March of Dimes senior vice president of public policy and government affairs, who has been waiting nearly four years for an answer. "Well, we're still alive," Pellegrini said. The FDA is allowed one 90-day delay by statute.

March of Dimes officials co-sponsored a petition in 2012 that urged the agency to add [folic acid](#), a B vitamin, to corn masa to prevent [birth defects](#) such as spina bifida and anencephaly.

Those are defects that occur when the neural tube, which forms the

brain and spine, fails to close in early pregnancy. Adequate folic acid intake is key to ensuring that the neural tube forms correctly and it's not always possible to get it through supplements or diet, health officials say.

In Washington state, cases of anencephaly - a fatal neural-tube defect - has affected more than 40 pregnancies since 2010 in Benton, Franklin and Yakima counties, about five times higher than the national rate. State health officials haven't identified a cause.

More than half the cases have occurred in Hispanic women, who are more likely than white women to have babies with the defects.

Since 1996, the FDA has required folic acid to be added to enriched cereal grains, a move that sent instances of [neural-tube](#) defects falling. But corn masa, a staple in the Hispanic diet, wasn't included at the time.

Adding folic acid to corn masa would be both safe and effective and is long overdue, Pellegrini and other advocates have said. She added that she remains hopeful that the petition will be approved.

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