



# Flour Fortification Initiative

A PUBLIC-PRIVATE-CIVIC INVESTMENT IN EACH NATION

## Effectiveness, Safety and Economics of Fortifying Flour with Folic Acid

The Flour Fortification Initiative (FFI) encourages countries to add folic acid to flour to reduce the rate of major birth defects called neural tube defects (NTDs). Fortifying flour with folic acid is a reliable method of delivering this essential nutrient via commonly consumed foods. This public health intervention is effective and safe, and it saves millions of dollars annually in health care costs.

### Effective

All people need folic acid, a form of vitamin B<sub>9</sub>, to produce and maintain new cells and decrease the risk of folate deficiency anemia. Folate, the natural form of folic acid, can be found in legumes, beef liver, green leafy vegetables, some fruits, and whole grains, but it is difficult for people to get enough folate through their diet.

Women especially need folic acid to reduce the risk of having a child with a NTD. If folic acid is taken before conception and in the early stages of pregnancy, it can prevent 50 to 70%<sup>1</sup> of NTDs which affect more than 300,000 infants worldwide annually.<sup>2</sup> Countries which track birth defects nationally report varying prevalence of NTDs, such as 12.6 per 10,000 births in Cuba, 9.59 per 10,000 births in Norway, and 4.9 per 10,000 births in Hungary.<sup>3</sup>

The most common NTD is spina bifida in which the spine does not form correctly. In mild cases, permanent loss of some sensation or movement occurs. Severe cases include paralysis and varying degrees of loss of bowel and bladder control. Some spina bifida symptoms can be treated with surgeries and therapy, but spina bifida cannot be cured. Another NTD is anencephaly in which the brain does not form properly, and this causes the infant to die within a few days after birth.

Women who may become pregnant are encouraged to take folic acid supplements, but women who do not plan to get pregnant may not follow this advice and unplanned pregnancies are common. Also, some women are not exposed to health education campaigns or do not have prenatal care, so they are not aware that they should take folic acid in their child-bearing years. Other women may know that folic acid is important, but

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<sup>1</sup> Facts About Folic Acid, Centers for Disease Control and Prevention, <<http://www.cdc.gov/ncbddd/folicacid/about.html>> accessed 30 December 2009.

<sup>2</sup> March of Dimes Global Report on Birth Defects: The Hidden Toll of Dying and Disabled Children. 2006: Executive Summary, 2. March of Dimes Birth Defects Foundation, White Plains, New York.

<sup>3</sup> Annual Report 2008 with data for 2006. International Clearinghouse for Birth Defects Surveillance and Research, Italy. Incidence of anencephaly, spina bifida, and encephalocele are included in the country's NTD rate.



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they do not have access to supplements. The critical time for folic acid intake is before conception and in the early days of pregnancy, and many women may not even realize they are pregnant in time to take folic acid to prevent a NTD. Flour fortification, on the other hand, regularly delivers an extra supply of this critical nutrient through staple foods made with fortified flour.

The number of NTDs that can be prevented through flour fortification varies based on how much folic acid is added to flour and the baseline incidence rate. In Costa Rica, where wheat and corn flour are both fortified, the national level of NTDs dropped by 35% after fortification began.<sup>4</sup> South Africa began fortifying flour in October 2003 and saw a 30.5% decline in NTD prevalence in less than two years.<sup>5</sup> In Canada, a study in seven provinces from 1993 to 2002 evaluated NTD rates before fortification, during partial fortification, and during full fortification. The study revealed a 46% decline in NTDs due to fortification. The percent decrease was higher in areas where the baseline rate was higher.<sup>6</sup>

## Safe

While the effectiveness of reducing NTDs by fortifying flour with folic acid is well established, some researchers question whether consuming too much folic acid has undesirable consequences such as cancer promotion and progression of nerve damage in people who are deficient in vitamin B<sub>12</sub>.

Three organizations – the Institute of Medicine National Academies of Science in the U.S. and Canada, the Scientific Committee on Food in the European Union, and the Conseil Supérieur d'Hygiène Publique de France – have set the upper level of daily folic acid intake at 1000 micrograms.<sup>7</sup> In addition, the Expert Group on Vitamin and Minerals of the Food Standards Agency of the United Kingdom noted that no adverse effects were observed at 1000 micrograms of daily intake.<sup>8</sup> Each group noted that 5000 micrograms

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<sup>4</sup> Tacsan, L. et al., The Costa Rican Experience: Reduction of Neural Tube Defects Following Food Fortification Programs. *Nutrition Reviews* 62 June 2004:S40-S43.

<sup>5</sup> Sayed, Abdul-Rauf, et al., Decline in the Prevalence of Neural Tube Defects Following Folic Acid Fortification and Its Cost-Benefit in South Africa. *Birth Defects Reserch (Prt A): Clinical and Molecular Teratology* 2008:82:211-216.

<sup>6</sup> De Wals, et al., Reduction in Neural Tube Defects after Folic Acid Fortification in Canada. *The New England Journal of Medicine* 357 July 12, 2007:135-142.

<sup>7</sup> A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances, Report of Joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) Technical Workshop on Nutrient Risk Assessment (2005: Geneva, Switzerland) Annex 3, 151.

<sup>8</sup> Ibid.



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per day was the lowest level at which adverse effects were observed, and the critical adverse effect at that rate was masking the anemia of vitamin B<sub>12</sub> deficiency.<sup>9</sup>

Exceeding 1000 micrograms daily is associated with taking excessive folic acid supplements, not with consuming fortified foods. People in the United States get folic acid from at least three sources: foods made with enriched flour, ready-to-eat fortified foods such as breakfast cereals, and vitamin supplements. Yet a population-based study of U.S. adults found that less than 3% exceeded 1000 micrograms a day.<sup>10</sup> None reached that level by eating fortified foods; they only exceeded 1000 micrograms a day if they consumed more than 400 micrograms from supplements daily.<sup>11</sup>

There is no evidence that folic acid intake at levels in fortified foods in the United States and in levels recommended to prevent NTDs causes harm, including progression of nerve damage in people with vitamin B<sub>12</sub> deficiency, creating excess intake in children, problems with unmetabolized folic acid, blunting of anti-folate therapy, twinning and miscarriages.<sup>12</sup> Improved folate status has been associated with protecting against some cancers, but more research is needed regarding whether people who take high dose supplements have more cancer risk.<sup>13</sup>

In December 2006, England's Scientific Advisory Committee on Nutrition (SACN), a committee of independent scientific experts, recommended mandatory flour fortification with folic acid. In October 2007, the Chief Medical Officer asked SACN to reconsider its recommendation in light of newly published studies associating folic acid with colorectal cancer. In 2009, SACN issued a statement saying the "new evidence does not provide a substantial basis to change its previous recommendation for the introduction of mandatory fortification with folic acid."<sup>14</sup>

Also in 2009 the United States Preventive Services Task Force published an update of its 1992 recommendations and continued to urge women who might become pregnant to take at least 400 micrograms of folic acid daily. The update noted that folic acid from

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<sup>9</sup> Ibid.

<sup>10</sup> Yang, Q. et al., Folic Acid Source, Usual Intake, and Folate and Vitamin B-12 Status in US Adults: National Health and Nutrition Examination Survey (NHANES) 2003-2006. *The American Journal of Clinical Nutrition*, 2009; October: 10.3945/ajcn.2009.28401.

<sup>11</sup> Ibid.

<sup>12</sup> Johnston, R., Will Increasing Folic Acid in Fortified Grain Products Further Reduce Neural Tube Defects Without Causing Harm? Consideration of the Evidence. *Pediatric Research* 63 (2008): 2-8. Also, Folic Acid in the Prevention of Birth Defects. Public Health Grand Rounds, U.S. Centers for Disease Control and Prevention, <<http://www.cdc.gov/about/grand-rounds/archives/2010/02-February.htm>> accessed 25 February 2010.

<sup>13</sup> Ibid.

<sup>14</sup> Folic Acid and Colorectal Cancer Risk Update, Food Standards Agency, <<http://www.food.gov.uk/news/newsarchive/2009/oct/folicacid>> accessed 29 December 2009.



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supplementation at usual doses, even “in light of mandatory food fortification,” is not associated with serious harms, including carcinogenic effects.<sup>15</sup>

In April 2008, the Flour Fortification Initiative (FFI) convened an international workshop to review flour fortification recommendations. The workshop involved nearly 100 leading nutrition, pharmaceutical and cereal scientists and milling experts. They agreed that fortifying flour with folic acid, when appropriately implemented, does not appear to pose a public health risk.<sup>16</sup> Based on findings of the workshop and its own core group of evaluators, the World Health Organization (WHO) issued “Recommendations on Wheat and Maize Flour Fortification Meeting Report: Interim Consensus Statement” that affirms the use of folic acid and other nutrients in flour fortification.<sup>17</sup> The consensus statement reflects the position of the Food and Agriculture Organization of the United Nations (FAO), the United Nations Children’s Fund (UNICEF), the Global Alliance for Improved Nutrition (GAIN), the Micronutrient Initiative (MI), and FFI.

## Economical

In addition to being effective and safe, fortifying flour with folic acid is economical. In Chile it is estimated that the flour fortification program prevented 109 live births of infants with spina bifida in one year. Comparing the costs of surgical treatment and rehabilitative services for 109 children with the cost of adding folic acid to flour, the country’s savings represent average averted costs of nearly 12 dollars for every dollar spent on fortification.<sup>18</sup> In the United States, fortification is credited with preventing 1000 NTDs a year. There the annual fortification costs are approximately US\$ 3 million, and direct medical costs averted are US\$ 145 million per year; consequently US\$ 48 is saved for every dollar spent on fortification.<sup>19</sup> South Africa found that it saved 30 rand for every one rand spent on fortification when it calculated the cost of treating a child with spina bifida during the first three years of life.<sup>20</sup>

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<sup>15</sup> Folic Acid for the Prevention of Neural Tube Defects: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine* 5 May 2009:626—631.

<sup>16</sup> Flour Fortification with Iron, Folic Acid, Vitamin B12, Vitamin A, and Zinc: Proceedings of the Second Technical Workshop on Wheat Flour Fortification. *Food and Nutrition Bulletin* 31 March 2010:S24.

<sup>17</sup> World Health Organization, Recommendations on Wheat and Maize Flour Fortification Meeting Report: Interim Consensus Statement <[http://www.who.int/nutrition/publications/micronutrients/wheat\\_maize\\_fort.pdf](http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fort.pdf)> accessed 21 December 2009.

<sup>18</sup> Llanos, A., et. al., Cost-effectiveness of a Folic Acid Fortification Program in Chile. *Health Policy* 83 2007:295-303.

<sup>19</sup> Mulinare, J., Folic Acid in the Prevention of Birth Defects. Public Health Grand Rounds, U.S. Centers for Disease Control and Prevention, <<http://www.cdc.gov/about/grand-rounds/archives/2010/02-February.htm>> accessed 25 February 2010.

<sup>20</sup> Sayed, A., et.al., Decline in the Prevalence of Neural Tube Defects Following Folic Acid Fortification and Its Cost-Benefit in South Africa. *Birth Defects Research* 82 2008:211-216.



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Once the milling infrastructure is in place to fortify flour, it is cost effective to fortify flour with other nutrients in addition to folic acid. Flour is also routinely fortified with iron, thiamine, riboflavin, and niacin. Some countries also add vitamin D, vitamin B<sub>12</sub>, vitamin A, and zinc to flour. Many studies have established that fortifying flour with folic acid and iron costs less than 25 US cents per person per year.

## Conclusion

The majority of concerns about folic acid are related to daily higher doses caused by supplements taken in excess. The conclusive evidence is folic acid prevents many NTDs, and that flour fortification, when appropriately implemented, effectively and safely delivers folic acid. The cost of adding folic acid to flour is minimal, especially when compared to the economic burden NTDs place on a health care system and the financial and emotional drain on a family whose child has a birth defect that may have been prevented.