

## Common Concerns Related to Flour Fortification



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#### Agenda

Concerns for discussion:

- Fortification may lead to excess consumption of folic acid and iron
- Fortifying with folic acid may cause cancer and mask B12 deficiency
- Fortifying with iron may increase the risk of iron overload in individuals with blood disorders
- Fortification should be a targeted initiative
- Food should be pure
- Mandatory fortification takes away consumer choice



# Fortification does not cause people to consume more than the tolerable upper intake level (UL) of folic acid and iron



#### What is UL?

The maximum level of total chronic daily intake of a nutrient judged to be unlikely to pose a risk of adverse health effects to humans.

	US Institute of Medicine UL for Adults	EU Scientific Committee on Food (SCF) UL for Adults
Folic Acid	1000 mcg/day	1000 mcg/day
Iron	45 mg/day	Not available



#### Sources of Folic Acid Consumption in the United States, NHANES 2003-2006 – Only Those Consuming Supplements Exceeded the Upper Limit (2.7%)

Participants	Enriched Cereal Grain Products only (ECGP)	ECGP + Ready to Eat Cereal (RTE)	ECGP + Supplements (SUP)	ECGP+ RTE + SUP
Number	Proportion Exceeding UL			
8,258	0	0	5.5 (3.0, 8.0)	9.4 (5.5, 13.3)



Yang et al. Folic acid source, usual intake, and folate and vitamin B12 status in US adults: (NHANES) 2003–2006. Am J Clin Nutr. 2010;91:64–72.

# Folic acid fortification does not cause cancer or mask B12 deficiency



### Theoretical Concerns about Folic Acid and Cancer

 High doses of supplemental folic acid reportedly enhance the inflammatory response in the human colon, which is thought to predispose individuals to colon cancer.

• Dual Role: An adequate folate level appears to protect against cancer because it is needed for gene stability. However, excessive intake of folic acid may promote cancer growth and proliferation in those individuals who have neoplasms present.



## Latest results of the VITATOPS study: relative risk of total deaths and risks of sub-type cancer incidence are not increased

	Summary RR (95% CI) Reported in
	VITATOPS (Hankey 2012)
Total deaths	0.97 (0.87-1.07)
Total cancer incidence	0.86 (0.66-1.14)
Colorectal cancer incidence	0.98 (0.44-2.18)
Breast cancer incidence	0.58 (0.21-1.62)
Lung cancer incidence	0.92 (0.48-1.80)
Prostate cancer incidence	0.63 (0.28-1.44)



MPI Science and Risk Assessment Directorate. Scientific evaluation of comments and submissions received on the future of folic acid fortification in New Zealand. August 2012.

### Folic Acid and B12 Deficiency:

- Prevalence B12 deficiency in the UK:
- ~5% in those 65-74 years of age
- ~10% in those 75 years of age and older

 It has been suggested that folic acid supplementation may mask the haematological symptoms of B12 deficiency but does not exacerbate neurological symptoms.

• Morris et al., 2007 found that when B12 blood levels are normal, high blood folate levels protect against cognitive decline.



Iron fortification may slightly increase the risk of iron overload in haemochromatosis but not in beta thalassemia



### **Blood Disorders and Iron Overload**

#### <u>Thalassemia:</u>

• Beta thalassemia is most common in persons of Mediterranean descent. The total annual incidence of symptomatic individuals is estimated at 1:10,000 in the EU.

Haemochromatosis:

- Most common among populations of European origin.
- Men affected more than women: estimated 1.8:1 3:1 ratio.

 Prevalence of the genetic defect\* in Europe is estimated 1:300 while prevalence of healthy carriers of the heterozygote mutation is estimated 1:8 in Europe.

\*homozygosity of C282Y mutation in HFE gene



1. Galanello R, and Origa R. Orphananet Journal of Rare Diseases. 2010; 5(11).

2. Merryweather-Clark AT. J Med Genet. 1997 Apr; 34(4): 275-278.

3. European Federation of Association of Patients with Haemochromatosis-http://efaph.eu/?page\_id=97

An approach targeting women before conception is less effective than fortification



## **Preconceptional Folic Acid Supplementation use in Europe**





1. Paulik E et al. Eur J Obstet Gynecol Reprod Biol. 2009 Jul; 145(1) 49-52. 4. Na

2. Nilson R et al. Am J Clin Nutr 2006; 84 : 1134-1141.

3. Pinto, E et al. Public Health Nutr. 2009 Jul; 12(7):922-931.

- 4. Navarrete-Muñoz EM. Med Clin (Barc). 2010 Nov 13;135(14):637-43.
- 5. Baykan Z et al. Arch Gynecol Obstet (2011) 283:1249-1253.
- 6. Brough L. J Hum Nutr Diet. 2009 Apr; 22(2): 100-107.

## Fortification Is More Effective than Supplementation

Supplementation	Fortification
<ul> <li>Requires personal initiative and behavior change</li> </ul>	<ul> <li>People will obtain essential vitamins and minerals by following their regular eating habits</li> </ul>
• Cost is a barrier for marginalized groups that are at the greatest risk for vitamin and mineral deficiencies	<ul> <li>Very low cost</li> </ul>
<ul> <li>Greater risk for surpassing the UL set for folic acid and iron</li> </ul>	<ul> <li>Risk for surpassing the UL for folic acid and iron are minimal</li> </ul>
• Reaches exclusive proportion of individuals, usually those with more education and of higher economic status	<ul> <li>Reaches the entire population</li> </ul>



# Flour is already processed



#### Is Bread Really 100% Pure?

- <u>Improvers</u>-increase the speed of the baking process, strengthen dough
- <u>Reducing agents</u>-break down gluten
- <u>Enzymes</u>-supplement inherent enzymes and minimize variations caused by nature
- <u>Emulsifiers</u>-improve loaf volume, crumb structure, softness
- <u>Bleaching agents</u>-enhance whiteness of flour



Labeling requirements vary by country; some may not have to be shown.

### Milling Depletes Essential Nutrients from Wheat





Bauernfeind JC, Lachance SA, eds. Nutrient Additions to Food. Trumbull, CT: Food and Nutrition Press; 1991.

Mandatory flour fortification preserves consumer choice



## **Mandatory Fortification**

- In most cases, fortification is required for the type of flour that is most commonly consumed by the population in order to ensure a public health impact and create a level playing field for millers.
- Countries frequently retain freedom of choice by permitting select flours such as pastry, organic and whole wheat to be prepared without the addition of vitamins and minerals.
- Consumers still have the option to purchase unfortified wheat flour and wheat-based products in the market



#### **Benefits of Folic Acid: For Everyone**

- Production of DNA and red blood cells
- Metabolism of homocysteine
- Maternal health during pregnancy
- Foetal development
- Cognitive development in childhood
- Prevention of cancer
- Bone health



#### Conclusions

- Fortification does not lead to excess consumption of folic acid
- Fortifying with folic acid does not cause cancer or mask B12 deficiency
- Fortifying with iron does not contribute to iron overload in beta thalassemia and may contribute slightly to the risk of iron overload in individuals with hemochromatosis. This risk is counterbalanced by the developmental benefits of iron in children
- Fortification is more effective than supplementation prior to conception
- Flour milling removes nutrients that fortification restores
- Mandatory fortification retains consumer choice

