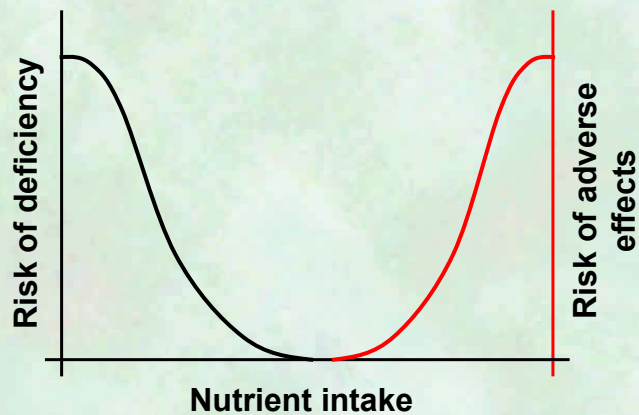


## Responsible food fortification: folic acid

Dr Alison Tedstone  
Food Standards Agency  
May 09

## Risk- benefits of increasing nutrient intake



## Folate

- is a B vitamin – essential for health (needed for cell division)
- folic acid is a synthetic form of folate
- folic acid is used in supplements and in food fortification
- Reference Nutrient Intake (RNI) is 200µg for adults
- safe Upper Level (UL) 1000µg (based on masking vitamin B12 deficiency)

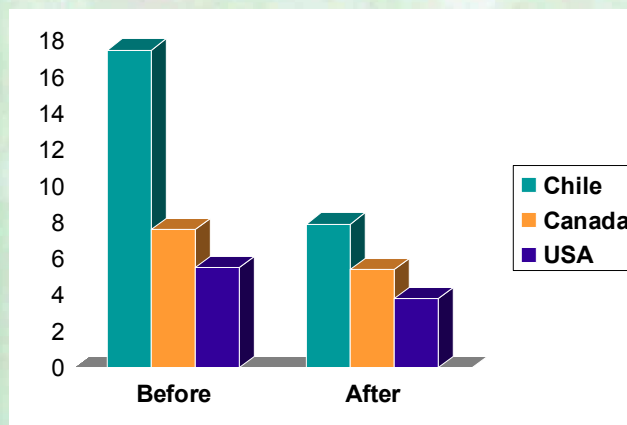


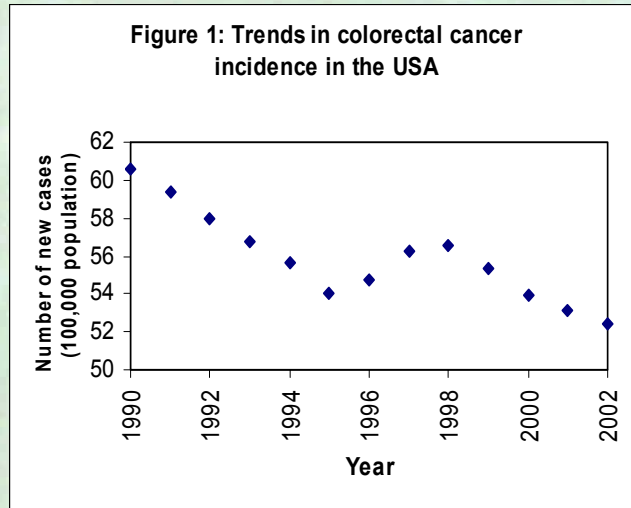
Women who might get pregnant need an extra 400 µg folic acid until the 12<sup>th</sup> week of pregnancy

## Neural tube defects (NTDs)

- Poor folate status increases the risk of NTD effect pregnancy
- NTD risk reduced by improving folate status (e.g. taking a folic acid supplement)
- 700-900 pregnancies affected per year in UK

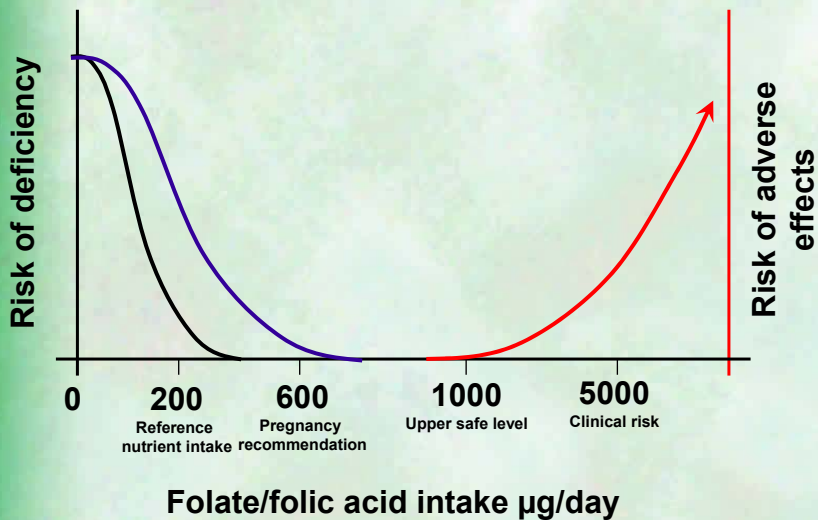
### NTD pregnancy rates in countries before and after mandatory fortification of grains (mainly wheat flour products)





National Cancer Institute, USA, 2005

## Risk and benefits of folate and folic acid



# Examples of voluntary fortification

## Breakfast cereal

NUTRITION INFORMATION TYPICAL VALUES	Per 30g with 125ml Semi-Skimmed Milk	Per 100g	
Energy	722 kJ 171 kcal	1560 kJ	368 kcal
Protein	6.7g	8.1g	
Carbohydrate of which sugars	28.7g 12.3g	75.1g 21.6g	
Fat of which saturates	3.2g 1.5g	3.9g 1.1g	
Fibre	2.0g	6.5g	
Sodium	0.2g	0.5g	
Salt Equivalent	0.5g	1.2g	

Vitamins & Minerals		%RDA*		%RDA*
Vitamin C	43.6 mg	70%	138 mg	230%
Thiamin (B1)	0.4 mg	25%	1.2 mg	85%
Riboflavin (B2)	0.6 mg	35%	1.4 mg	85%
Niacin	4.7 mg	25%	15.3 mg	85%
Vitamin B6	0.5 µg	25%	1.7 µg	85%
<b>Folic Acid (Folacin)</b>	<b>51 µg</b>	<b>25%</b>	<b>170 µg</b>	<b>85%</b>
Vitamin B12	0.79 µg	79%	0.85 µg	85%
Pantothenic acid	1.9 mg	30%	5.1 mg	85%
Calcium	285 mg	35%	450 mg	55%
Iron	3.6 mg	25%	11.9 mg	85%

\*Recommended Daily Allowance (RDA) according to the EC Nutrition Labelling Directive 90/496/EEC. A 30g serving of Nestlé Cheerios provides 25% of the RDA of seven vitamins and iron, 70% of the RDA of vitamin C and 35% of the RDA of calcium.

## Low fat spread

NUTRITION INFORMATION	
Typical values	per 100g
Energy	1331kJ/324kcal
Protein	0.1 g
Carbohydrate	2.5 g
- of which Sugars	Trace
Fat*	35.0 g
- of which Saturates	9.0 g
monounsaturates	8.0 g
polyunsaturates, of which	17.5 g
-Omega 3** fatty acids	3.0 g
-Omega 6 fatty acids	14.5 g
trans	0.5 g
Fibre	Trace
Sodium	0.4 g
Salt (based on sodium)	1.0 g
Vitamin A	800µg (100% RDA)
Vitamin D	7.5µg (150% RDA)
Vitamin E	20mg (200% RDA)
Vitamin B6	5mg (250% RDA)
<b>Folic acid</b>	<b>1000µg (500% RDA)</b>
Vitamin B12	5µg (500% RDA)

\*excluding 7.5g sterols which do not contribute to the energy level. \*\*from plants.  
RDA=Recommended Daily Allowance

## Currently in the UK

- 23% people have folate intakes below RNI (35% for young and around 50% old women)
- 75% pregnancies not protected with a folic acid supplement
- 127,000 people exceed UL for folic acid

## Folate and Disease Prevention

Scientific Advisory  
Committee on Nutrition

2006

**Recommended mandatory fortification of flour  
with folic acid alongside action to control  
voluntary fortification and advice on the  
appropriate use of supplements**

## 2007 Food Standard Agency advised:

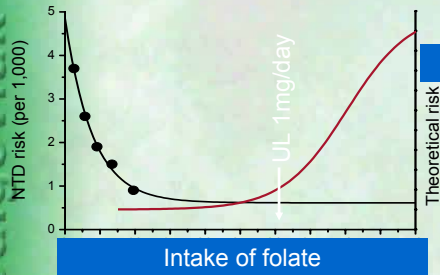
- Mandatory fortification of flour with folic acid
- Control voluntary fortification of food with folic acid
- Provide guidance on the use of supplements containing folic acid

**This combined approach should:**

- Reduce the number of NTD-affected pregnancies by 11-18%.
- Not increase the number of people with intakes above UL for folic acid
- Reduce the proportion of people with intakes below the RNI from to 5%

# Risk-benefit response to folic acid

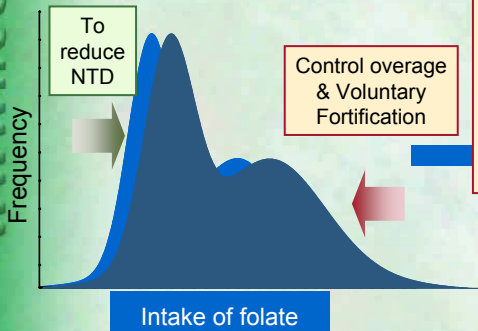
slide from Paul Haggarty



Effect of mandatory fortification of flour with folic acid in the UK

To avoid risk of very high intakes need:

- greater control of voluntary fortification of other foods.
- control of overage in food fortification



## 2008 update:

- **Decision on mandatory fortification deferred – more advice on cancer risk requested**
- **In the meantime, modelling has indicated that there should be:**
  - A status quo on voluntary fortification
  - Reduction of levels in fat spreads
  - Controls on high dose supplements

## Voluntary fortification

### Recent analysis has:

- assessed the effect of current levels of voluntary fortification and supplement use
- modelled changes in levels of voluntary fortification of MAIN food sources
- modelled the effect of capping the level of folic acid in supplements

## Data used for modelling:

- **National Diet and Nutrition Survey (NDNS)**- Toddlers 1992, Young People aged 4-18 years 1997, Adults 2000, Elderly 1994
- **Nutrient Databank** – Folic acid levels updated using retailer/manufacture information
- **Market Share Information** – Retailer/manufacture information, TDS

## Main sources of folic acid:

- Breakfast cereals
- Fat spreads
- Marmite/Bovril
- Supplements

### Also:

- Ovaltine/Horlicks
- Milkshake powders
- Cereal bars
- Soya milk

# High-dose supplements

- NDNS: some adults are exceeding UL of 1mg folic acid per day from supplement intake alone.
- 62% of folic acid containing supplements contain doses above the adult RNI of 200ug/day<sup>1</sup>

Supp. type	Level of folic acid for 938 products			
	0-100µg	101-200µg	201-400µg	+400µg
Adult's folic acid	0	0	35	2
Adult's multivitamins	75	209	463	74
Children's multivitamins	56	18	4	2
<b>TOTAL</b>	<b>131</b> (14%)	<b>227</b> (24%)	<b>502</b> (54%)	<b>78</b> (8%)

Table 1: Levels of Folic Acid in supplements



<sup>1</sup> Data from supplements industry trade associations

# Scenarios

Scenario	Folic acid level (% RNI)			Cap on supplements?
	Breakfast cereals	Fat spreads	Marmite/Bovril	
Current intake	25% or 50%	25%	50%	No
1b	25% or 50%	25%	50%	Yes (200ug/day)
1c	25% or 50%	25%	50%	Yes (400ug/day)
2a	15% or 25%	15%	50%	No
2b	15% or 25%	15%	50%	Yes (200ug/day)
2c	15% or 25%	15%	50%	Yes (400ug/day)
3a	All at 15%	15%	15%	No
3b	All at 15%	15%	15%	Yes (200ug/day)
3c	All at 15%	15%	15%	Yes (400ug/day)
4a	All at 15%	0%	15%	No
4b	All at 15%	0%	15%	Yes (200ug/day)
5	25% or 50%	15%	50%	Yes (400ug/day)

## Scenario 5: comparison

Average increase in FA intake ( $\mu\text{g}/\text{day}$ )	Mean total folate intakes ( $\mu\text{g}/\text{day}$ )	% in UK with folate intakes below RNI	Total number in UK with FA intakes above the UL	Number >65yrs with low vitamin B <sub>12</sub> status with intakes above UL	Number (%) NTD pregnancies prevented per year
<b>Estimated Current Intakes (September 07)</b>					
-	309	22%	106,000	800	0
<b>Desired outcome</b>					
-	-	<22%	<106,000	<800	0
<b>Scenario 1b: Cap on supplements at 200<math>\mu\text{g}/\text{day}</math> (600<math>\mu\text{g}/\text{day}</math> for women aged 14-49years)</b>					
-3	306	22%	71,000	0	0
<b>Scenario 1c: Cap on supplements at 400<math>\mu\text{g}/\text{day}</math> (800<math>\mu\text{g}/\text{day}</math> for women aged 14-49years)</b>					
-1	308	22%	74,000	0	0
<b>Scenario 3c</b> Breakfast cereals reduced to 15% RNI; Fat spreads reduced from 25% to 15% RNI per portion Cap on supplements at 400 $\mu\text{g}/\text{day}$ (800 $\mu\text{g}/\text{day}$ for women aged 14-49years)					
-37	272	27%	12,000	0	-27 (-4%)
<b>Scenario 5</b> Fat spreads reduced from 25% to 15% RNI per portion Cap on supplements at 400 $\mu\text{g}/\text{day}$ (800 $\mu\text{g}/\text{day}$ for women aged 14-49years)					
-9	300	22%	32,000	0	0

## EU controls on food fortification:

- Proposals expected September 2009 to set maximum level of vitamins and minerals supplements and fortified food

### *Intended to:*

- Harmonises legislation to allow free movement of fortified foods
- Protects consumers by lists of approved vitamins and minerals (and sources) and maximum safe levels
- Creates procedure for review and control of other substances on safety grounds

## Responsible food fortification needs:

- Risk benefit analysis of effects of different levels of nutrient intake on the population and subgroups
- Controls on amounts added and what foods and products can be fortified

*This needs up to date information on:*

- Science on the nutrients effects on health (benefits and risks)
- Nutrition survey data on food consumption patterns, nutrient intake from foods and supplements
- Composition data on foods (also market share information, overage etc)
- Careful modelling of effects on high and low consumers
- Being alert of changes in science, food supply, consumption patterns
- Good communication with and between industry
- Mechanisms to allow frank discussions that allow innovations while safe guarding consumers

## Summary

### Food fortification

- Is very common
- Can benefit to some (reducing the risk of deficiency)
- Can put others at risk
- Risk/ benefit balance can change as science develops, products come on and off the market
- Is difficult to managed in a modern food chain
- Over all impact can is difficult to assess
- Is not currently tightly controlled (by legislation/ voluntary agreement)