



Paper for information: Folic acid modelling

Agenda Item: 2

At the SACN meeting in October 2007, Members requested sight of the latest folic acid modelling work that had been undertaken by the Agency. Please see attached paper, for information, which was used as the basis for discussion with industry on voluntary fortification.

FSA Folic Acid Modelling
Paper for Discussion
Stakeholder Meeting 5th October

This paper details a draft preliminary analysis of folic acid intakes by modelling a series of scenarios, based on the reduction of folic acid in various voluntarily fortified foods and supplements, please do not circulate.

NB: The scenarios outlined in this paper are not an exhaustive list. They are for modelling purposes only and should not be interpreted as a direction for action to be taken by Industry.

Background

1. In May 2007 the Food Standards Agency (FSA) Board agreed that mandatory fortification of bread or flour with folic acid to reduce the incidence of NTDs should be recommended to UK Health Ministers, and that this should be introduced alongside actions to control the intakes of folic acid from foods that are fortified on a voluntary basis and advice on the use of supplements. It was agreed that the overall effect would be to:
 - reduce the incidence of Neural Tube Defects (NTDs);
 - increase folic acid intakes by an average of 60-100 micrograms/day;
 - ensure numbers not achieving the reference nutrient intake (RNI) for folate do not exceed the current level
 - ensure that numbers exceeding the Upper Limit (UL)¹ for folic acid do not increase above current levels.
 - Ensure folic acid reaches those with intakes within the lowest quintile of consumers
2. The purpose of this paper is to investigate the (maximum) levels of folic acid required in voluntary fortified foods and supplements necessary to meet these objectives.

CONSUMPTION DATA

3. Over the past two years FSA have estimated folate intakes and effect of flour fortification on UK population intakes for a number of different scenarios, using data from the UK National Diet and Nutrition Survey (NDNS) (see annex 1).
4. September this year, FSA remodelled updated current UK folate consumption data, using the same methodology as the previous modelling, SACN, 2006, although some calculations and assumptions were modified and updated (annex 2) based on receipt of recent data from manufacturers and retailers of voluntary fortified foods and supplements.
5. It is important to note that this modelling combines 4 sets of NDNS data collected overtime, some of which dates back to 1995 and consumption patterns are likely to have changed since then. Although we have updated the databank to reflect voluntarily fortified products currently available (Annex 2), we are aware that consumption of fortified products such as cereal bars and milkshakes may have increased and this has not been captured in the modelling.

¹ The GL of 1mg/day for adults (EVM, 2003) was used alongside the following ULs for children (SCF, 2000): 800µg/day for 15-17 years; 600µg/day for 11-14 years; 400µg/day for 7-10 years; 300µg/day for 4-6 years & 200µg/day for 1-3 years. "Exceeding the UL" refers to each population group exceeding the GL/UL set for that age group.

6. The effect of mandatory fortification of all white and brown wheat flour (excluding wholemeal), was modelled on updated current intakes (Annex 2), at levels of 0µg, 200µg, 250µg, 300µg folic acid per 100g flour (Table 1).
7. A series of scenarios were investigated based on varying levels of folic acid within voluntarily fortified foods and supplements. Intakes were then modelled with the introduction of flour fortification of all white and brown wheat flour at 0, 200, 250, 300µg folic acid per 100g flour: The scenarios were as follows:
8. **Scenario 1b**
 - Updated current intake
 - Supplement intake capped at **200µg/day** (600µg/day for women aged 19-49years)².
9. **Scenario 2a**
 - Breakfast cereals currently fortified at **25%** RNI³ folic acid per portion reduced to **15%**.
 - Breakfast cereals currently fortified at **50%** RNI folic acid per portion reduced to **25%**.
 - Fat spreads currently fortified at **25%** RNI folic acid per portion to **15%**.
 - Other fortified products remains as they are in the NDNS databank.
10. **Scenario 2b**
 - Breakfast cereals currently fortified at **25%** RNI folic acid per portion reduced to **15%**.
 - Breakfast cereals currently fortified at **50%** RNI folic acid per portion reduced to **25%**.
 - Fat spreads currently fortified at **25%** RNI folic acid per portion reduced to **15%**.
 - Other fortified products remains as they are in the NDNS databank.
 - Supplement intake capped at **200µg/day** (600µg/day for women aged 19-49years).
11. **Scenario 3a**
 - Breakfast cereals currently fortified at 25% RNI folic acid per portion reduced to 15%.
 - Breakfast cereals currently fortified at **50%** RNI folic acid per portion reduced to **15%**.
 - Fat spreads currently fortified at 25% RNI folic acid per portion reduced to 15%.
 - Other highly fortified products reduced from current values to **15%** RNI per portion.
12. **Scenario 3b**
 - Breakfast cereals currently fortified at 25% RNI folic acid per portion reduced to 15%.
 - Breakfast cereals currently fortified at 50% RNI folic acid per portion reduced to 15%.
 - Fat spreads currently fortified at 25% RNI folic acid per portion reduced to 15%.
 - Other highly fortified products reduced from current values to 15% RNI per portion.
 - Supplement intake capped at **200µg/day** (600µg/day for women aged 19-49years).
13. **Scenario 4a**
 - Breakfast cereals currently fortified at 25% RNI folic acid per portion reduced to 15%.
 - Breakfast cereals currently fortified at 50% RNI folic acid per portion reduced to 15%.
 - Fat spreads currently fortified at **25%** RNI folic acid per portion reduced to **0%**.
 - Other highly fortified products reduced from current values to 15% RNI per portion.
14. **Scenario 4b**
 - Breakfast cereals currently fortified at 25% RNI folic acid per portion reduced to 15%.
 - Breakfast cereals currently fortified at 50% RNI folic acid per portion reduced to 15%.
 - Fat spreads currently fortified at 25% RNI folic acid per portion reduced to 0%.
 - Other highly fortified products reduced from current values to 15% RNI per portion.
 - Supplement intake capped at **200µg/day** (600µg/day for women aged 19-49years).

² Folic acid from supplements reduced to a maximum of the adult RNI of 200µg of folate per day (DH, 1991) for whole population except for women of childbearing age, for whom intake is capped at RNI for adults of 200µg of folate per day plus 400µg of folic acid as a medicinal or food supplement recommended to women who could become pregnant prior to conception and until the twelfth week of pregnancy (DH, 1992)

³ RNI for adults of 200µg of folate per day.

For summary of previous modelling see Annex 1
For methodology see SACN report on Folate and Disease Prevention, 2006
For assumptions made in this round of modelling see Annex 2.

RESULTS

Quintiles

Table 1: Effect of flour fortification on folate intake of the total population and women aged 14-49 years by quintile of folate intake.

Folic acid µg/100g flour	Current status				Scenario 1b				Scenario 2a				Scenario 2b			
	0	200	250	300	0	200	250	300	0	200	250	300	0	200	250	300
Quintile	Total population															
1	150	232	253	274	150	232	253	274	146	229	249	270	146	229	249	270
2	217	311	334	358	217	311	334	358	207	301	325	348	207	301	325	348
3	266	364	388	412	266	364	388	412	250	347	371	396	250	347	371	396
4	354	450	474	498	354	449	473	497	317	413	437	461	317	413	437	461
5	556	669	698	726	556	668	682	711	476	589	618	646	461	575	603	631
Quintile	Females aged 14-49 years															
1	133	203	221	238	133	203	221	238	130	201	218	236	130	201	218	236
2	196	275	295	315	196	275	295	315	188	267	287	307	188	267	287	307
3	248	332	353	373	248	332	353	373	232	316	337	357	232	316	337	358
4	324	410	431	453	324	410	431	453	294	380	401	422	294	380	401	422
5	500	596	620	644	500	595	619	643	440	535	560	583	439	535	558	582
Folic acid µg/100g flour	0	200	250	300	0	200	250	300	0	200	250	300	0	200	250	300
	Scenario 3a				Scenario 3b				Scenario 4a				Scenario 4b			
Quintile	Total population															
1	146	228	249	269	146	228	249	269	146	228	249	269	146	228	249	269
2	205	299	323	346	205	299	323	346	205	299	323	346	205	299	323	346
3	246	343	368	392	246	343	368	392	246	343	368	392	246	343	368	392
4	310	406	430	454	310	406	429	453	299	394	419	442	298	394	418	442
5	458	571	600	628	444	557	585	613	412	526	554	583	398	511	539	568
Quintile	Females aged 14-49 years															
1	130	200	218	235	130	200	218	235	130	200	218	235	130	200	218	235
2	186	265	285	305	186	265	285	305	186	265	285	305	186	265	285	305
3	228	312	333	354	228	312	333	354	228	312	333	354	228	312	333	354
4	287	373	394	416	287	373	394	416	276	362	383	405	276	362	383	405
5	424	520	544	567	423	519	543	566	394	489	513	537	393	488	512	536

15. Table 1 illustrates:

- For all scenarios, fortification of flour reached all quintiles of the population, including the quintiles with the lowest starting folate intakes, specifically women of childbearing age those at greatest risk of an NTD-affected pregnancy.
- Reductions made on voluntary fortification in scenarios 2a, 3a & 4a did not greatly affect intake of those consumers in the lowest quintiles.
- Supplements capped at the RNI (scenario 1b) did not affect those in the lowest quintiles of the population specifically women of childbearing age.

Table 2: Summary of 2007 modelling compared to 2006-Effects of fortification of all white and brown flour with folic acid on the UK populationⁱ

Fortification level of folic acid $\mu\text{g}/100\text{g}$ flour	Average increase in folic acid intake ⁱⁱ ($\mu\text{g}/\text{day}$)	Mean total folate intakes ($\mu\text{g}/\text{day}$)	Total number (%) in UK population with folate intakes below RNI ⁱⁱⁱ	Total number (%) in UK population with folic acid intakes above the UL ^{iv}	Number (%) of adults >19 years with intakes above UL	Number (%) >65 years with intakes above UL	Number >65 years with low vitamin B ₁₂ status with intakes above UL ^v	Number (%) NTD pregnancies prevented per year
June 06 Folate intakes (fat spreads fortified at 50% RNI per portion) (Annex 1)								
0	0	302	13,261,000 (23%)	127,000 (0.2%)	55,000 (0.1%)	11,000 (0.1%)	900	0
200	102	403	3,424,000 (6%)	404,000 (0.7%)	103,000 (0.2%)	28,000 (0.3%)	2,000	82-180 (12-20%)
300	152	454	1,888,000 (3%)	773,000 (1.3%)	176,000 (0.4%)	38,000 (0.4%)	2,500	114-261 (16-29%)
November 06 Folate intakes (fat spreads fortified at 25% RNI per portion) (Annex 1)								
0	-14	287	13,261,000 (23%)	67,000 (0.1%)	38,000 (0.1%)	8,000 (0.1%)	800	0 ^{vi}
200	88	389	3,424,000 (6%)	194,000 (0.3%)	65,000 (0.1%)	9,000 (0.1%)	900	82-180 (12-20%)
300	138	440	1,888,000 (3%)	435,000 (0.7%)	77,000 (0.2%)	9,000 (0.1%)	900	114-261 (16-29%)
September 07 Updated current intakes (See Annex 2)								
0	0	309	12,461,000 (22%)	106,000 (0.2%)	31,000 (0.07%)	8,000 (0.1%)	800	0
200	97	406	3,685,000 (6%)	378,000 (0.7%)	72,000 (0.2%)	8,000 (0.1%)	800	75-163 (11-18%)
250	121	430	2,819,000 (5%)	570,000 (1.0%)	79,000 (0.2%)	14,000 (0.2%)	1,100	94-204 (13-23%)
300	145	454	2,284,000 (4%)	803,000 (1.4%)	106,000 (0.2%)	17,000 (0.2%)	1,400	108-240 (15-27%)
Scenario 1b Updated current intakes with cap on supplements^{vii}								
0	-3	306	12,461,000 (22%)	71,000 (0.1%)	0	0	0	0
200	94	403	3,685,000 (6%)	327,000 (0.6%)	27,000 (0.06%)	0	0	75-163 (11-18%)
250	118	427	2,819,000 (5%)	519,000 (0.9%)	34,000 (0.1%)	7,000	300	93-204 (13-23%)
300	142	451	2,284,000 (4%)	725,000 (1.3%)	34,000 (0.1%)	7,000	300	108-240 (15-27%)
Scenario 2a: Levels of folic acid in fortified breakfast cereals reduced to 25% & 15% and fat spreads reduced to 15% RNI per portion								
0	-29	280	14,702,000 (25%)	44,000 (0.1%)	31,000 (0.1%)	8,000 (0.1%)	800	-21 (-3%) ^{viii}
200	67	376	4,098,000 (7%)	121,000 (0.2%)	45,000 (0.1%)	8,000 (0.1%)	800	54-122 (8-14%)
250	92	401	3,322,000 (6%)	192,000 (0.3%)	45,000 (0.1%)	8,000 (0.1%)	800	73-158 (10-18%)
300	116	425	2,519,000 (4%)	320,000 (0.6%)	69,000(0.2%)	8,000 (0.1%)	800	92-199 (13-22%)
Scenario 2b: 2a plus cap on supplements								
0	-32	277	14,702,000 (25%)	11,000 (0.02%)	0	0	0	-21 (-3%)
200	64	374	4,098,000 (7%)	75,000 (0.13%)	0	0	0	54-122 (8-14%)
250	88	398	3,322,329 (6%)	141,000 (0.2%)	0	0	0	73-158 (10-18%)
300	113	422	2,519,000 (4%)	246,000 (0.4%)	0	0	0	92-199 (13-22%)

Scenario 3a: Levels of folic acid in fortified breakfast cereals, fat spreads and highly fortified products reduced to 15% RNI per portion								
0	-36	273	15,620,000 (27%)	43,000 (0.1%)	31,000 (0.2%)	8,000 (0.1%)	800	-27 (-4%)
200	61	370	4,367,000 (8%)	91,000 (0.2%)	45,000 (0.1%)	8,000 (0.1%)	800	49-104 (7-12%)
250	85	394	3,425,000 (6%)	145,000 (0.3%)	45,000 (0.1%)	8,000 (0.1%)	800	68-149 (10-17%)
300	109	419	2,540,000 (4%)	238,000 (0.4%)	69,000 (0.2%)	8,000 (0.1%)	800	87-189 (12-21%)
Scenario 3b: 3a plus cap on supplements								
0	-39	270	15,620,000 (27%)	10,000 (0.02%)	0	0	0	-27 (-4%)
200	58	367	4,367,000 (8%)	45,000 (0.1%)	0	0	0	49-104 (7-12%)
250	82	391	3,425,000 (6%)	94,000 (0.2%)	0	0	0	68-149 (10-17%)
300	106	416	2,540,000 (4%)	163,000 (0.3%)	0	0	0	87-189 (12-21%)
Scenario 4a: Levels of folic acid in fortified breakfast cereals and highly fortified products reduced to 15% RNI per portion and fat spreads reduced to 0								
0	-47	262	15,686,000 (27%)	32,000 (0.1%)	31,000 (0.1%)	8,000 (0.1%)	800	-34 (-5%)
200	50	359	4,367,000 (8%)	51,000 (0.1%)	45,000 (0.1%)	8,000 (0.1%)	800	41-90 (6-10%)
250	74	383	3,425,000 (6%)	85,000 (0.1%)	45,000 (0.1%)	8,000 (0.1%)	800	60-131 (9-15%)
300	98	407	2,561,000 (4%)	159,000 (0.3%)	69,000 (0.2%)	8,000 (0.1%)	800	79-172 (11-19%)
Scenario 4b: 4a plus cap on supplements								
0	-50	259	15,686,000 (27%)	0	0	0	0	-34 (-5%)
200	46	356	4,367,000 (8%)	2,000 (0.004%)	0	0	0	41-90 (6-10%)
250	71	380	3,425,000 (6%)	39,000 (0.1%)	0	0	0	60-131 (9-15%)
300	95	404	2,561,000 (4%)	85,000 (0.1%)	0	0	0	79-172 (11-19%)

Results of Scenarios

16. Table 2 shows that figures for **updated current intakes** vary slightly compared to the figures presented to the Board in June 2006 due to a various changes in approaches and assumptions made (Annex 2). The main changes being: the inclusion of data for children aged 1½ to 4 years; the exclusion of children aged 0-1½ years in the population denominator; the exclusion of imported flour not subject to fortification; the slightly different approach to overage calculation for breakfast cereals, fat spreads and supplements and updated folic acid values for various fortified products. These changes resulted in:
- An increased mean intake;
 - A decrease in percentage **below the RNI**;
 - Increased numbers exceeding the UL (potentially explained by inclusion of children aged 1½ to 4 years, see Annex 2);
 - Decrease in number of adults exceeding the UL (potentially explained by a different method of measuring overage, see Annex 2);
 - No change in adults over 65 years with low B12 status exceeding the UL;
 - At 200µg/100g fortification a lower reduction in NTD risk (potentially explained by a reduced increase in folic acid from flour, as imported flour is excluded see Annex 2).
17. Reducing folic acid in voluntary fortified and supplements resulted in the following reduction in folic acid intake, prior to flour fortification:
- Scenario 2a: an average decrease of 29µg folic acid a day;
 - Scenario 3a: an average decrease of 36µg folic acid a day;
 - Scenario 4a: an average decrease of 47µg folic acid a day;
 - Introducing a cap on supplements resulted in an additional average decrease of about -3µg folic acid a day for each of the scenarios above (Scenarios 1b, 2b, 3b, 4b,).
18. Scenario **2a**, flour fortified at 200µg folic acid /100g resulted in:
- A population average **increase** of 67µg folic acid a day;
 - A decrease in percentage **below the RNI** from 22% to 7%;
 - An increase in the number **exceeding the UL** from 106,000 to 121,000;
 - The same number (800) adults >65 years with **low vitamin B₁₂ status exceeding the UL**;
 - A reduction in **NTD risk** of 8-14% per year.
19. Scenario **2a**, flour fortified at 250µg folic acid /100g resulted in:
- An population average **increase** of 92µg folic acid per day;

- An decrease in the number with intakes **below the RNI** from 22% to 6%;
 - An increase in number **exceeding the UL** from 106,000 to 192,000;
 - The same number (800) adults >65 years with **low vitamin B₁₂ status exceeding the UL**;
 - A reduction in **NTD risk** of 10-18% per year.
20. Scenario **2b**, flour fortified at 250µg folic acid /100g resulted in:
- A population average **increase** of 88µg folic acid per day;
 - A decrease in the number with intakes **below the RNI** from 22% to 6%;
 - An increase in number **exceeding the UL** from 106,000 to 141,000;
 - No adults aged over 19 years **exceeding the UL**;
 - No adults aged 65 years and above with **low vitamin B₁₂ status exceeding the UL**;
 - A reduction in **NTD risk** of 10-18% per year.
21. Scenario **3a**, flour fortified at 250µg folic acid /100g resulted in:
- A population average **increase** of 85µg folic acid per day.
 - A decrease in the number with intakes below the **RNI** from 22% to 6%.
 - An increase in number **exceeding the UL** from 106,000 to 145,000
 - The same number (800) adults >65 years with **low vitamin B₁₂ status exceeding the UL**
 - A reduction in **NTD risk** of 10-17% per year.
22. Scenario **3b**, flour fortified at 250µg folic acid /100g resulted in:
- A population average **increase** of 82µg folic acid per day.
 - A decrease in the number with intakes below the **RNI** from 22% to 6%.
 - A decrease in number **exceeding the UL** from 106,000 to 94,000;
 - An Increase in the number of children aged under 19 years **exceeding the UL** from 75,000 (106,000=current total-31,000=current adults) to 94,000;
 - No adults aged over 19 years **exceeding the UL**
 - No adults aged 65 years and above with **low vitamin B₁₂ status exceeding the UL**
 - A reduction in **NTD risk** of 10-17% per year
23. Scenario **4a**, flour fortified at 250µg folic acid /100g resulted in:
- A population average **increase** of 74µg folic acid per day.
 - A decrease in the number with intakes below the RNI from **22% to 6%**.

- A decrease in number **exceeding the UL** from 106,000 to 39,000.
- The same number (800) adults >65 years with **low vitamin B₁₂ status exceeding the UL**
- A reduction in **NTD risk** of 9-15% per year.

24. Scenario **4b**, flour fortified at 250µg folic acid /100g resulted in:

- A population average **increase** of 71µg folic acid per day.
- A decrease in the number with intakes below the RNI from **22%** to **6%**.
- A decrease in the number **exceeding the UL** from of 106,000 to 39,000
- A decrease in the number of children aged under 19 years **exceeding the UL** 75,000 (106,000=current total-31,000=current adults) to 39,000;
- No adults aged over 19 years **exceeding the UL**
- No adults aged 65 years and above with **low vitamin B₁₂ status exceeding the UL**
- A reduction in **NTD risk** at 9-15%.

25. Scenario **4b**, flour fortified at 300µg folic acid /100g resulted in:

- A population average **increase** of 95µg folic acid per day.
- A decrease in the number with intakes below the RNI from **22%** to **4%**.
- A decrease in the number **exceeding the UL** from of 106,000 to 85,000
- A decrease in the number of children aged under 19 years **exceeding the UL** 75,000 to 85,000;
- No adults aged over 19 years **exceeding the UL**
- No adults aged 65 years and above with **low vitamin B₁₂ status exceeding the UL**
- A reduction in **NTD risk** at 60-131 per year (11-19%).

SUMMARY

26. Table 2 shows:

- The number of individuals with intakes below the RNI was not greatly affected by reducing folic acid from voluntary fortified products, but was notably reduced following the introduction of folic acid from fortified flour.
- At the current level of intake 31,000 adults exceeded the UL, of which 8,000 were aged 65 years and over. This did not change with a reduction of folic acid from voluntary fortified products scenarios 2a, 3a, 4a, because those individuals captured in the survey were exceeding the UL due to supplement intake.

- When supplement intake was capped at the RNI (200µg per day, 600µg for women of childbearing age) in scenarios 1b, 2b, 3b, 4b, the number of adults exceeding the UL remains at 0 for all levels of flour fortification.
- Reducing the amount of folic acid from supplements to a maximum of the RNI per day for adults (200µg per day, 600µg for women of childbearing age) did not affect the number with intakes below the RNI or NTD risk.
- Reducing folic acid from voluntary fortified products reduced the number of children under the age of 19 exceeding the UL.

References

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European Scientific Committee on Food. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Folate 2000. Online at http://ec.europa.eu/comm/food/fs/sc/scf/out80e_en.pdf

Expert Group on Vitamins and Minerals. *Safe Upper Levels for Vitamins and Minerals*. FSA: London, 2003

Scientific Advisory Committee, Folate and Disease Prevention London: TSO, 2006.

above.

minus reduction in fortification of fat spreads and breakfast cereals.

with total folate intakes below the RNI respective for each age group (DH, 1991). Figures rounded to the nearest 1,000.

with folic acid intakes above the tolerable upper intake level, respective for each age group (SCF, 2001). Figures rounded to the nearest 1,000.

Figures rounded to the nearest 100.

consumed by individuals with high natural folate intakes, therefore women of childbearing age at most risk of dietary-related NTD i.e those with the greatest reduction in folic acid in fat spreads.

the whole population with the exception of women aged 14-49 years, intake from supplements capped at 600µg. Note, an overage of 15% is applied to those with intakes above the tolerable upper intake level.

the increased NTD risk by extrapolating for decreased folate intake (SACN, 2006).