IMPROVING FOLATE INTAKES OF WOMEN OF REPRODUCTIVE AGE AND PREVENTING NEURAL TUBE DEFECTS: PRACTICAL ISSUES

Executive Summary

1. The Board has previously agreed to recommend to UK Health Ministers the mandatory fortification with folic acid of bread or flour to reduce the incidence of neural tube defects (NTDs) and that this should be introduced alongside controls on voluntary fortification of foods with folic acid and guidance on the use of supplements. The Board is now asked to agree the detail of their advice to UK Health Ministers, specifically if wheat bread or flour should be fortified and the need for labelling.

2. This paper sets out the impact of each fortification option and the technical and implementation issues and also draws on consumer research and stakeholder views.

Board Action Required

3. Board is asked to:

- **note** their recommendation to UK Health Ministers that the incidence of NTDs would be reduced if mandatory fortification of bread or flour with folic acid is introduced in the UK;
- **note** the information on the likely impact of bread or flour fortification;
- **consider** the information on the technical and practical aspects of bread or flour fortification; and
- **agree** advice to UK Health Ministers on folic acid fortification set out in paragraph 43.

NUTRITION DIVSION
Contact:

Rosemary Hignett	Tel: 020 7276 8178
	Email: rosemary.hignett@foodstandards.gsdi.gov.uk
Alison Tedstone	Tel: 020 7276 8929
	Email: Alison.tedstone@foodstandards.gsi.gov.uk
Lynda Harrop	Tel: 020 7276 8928
	Email: Lynda.harrop@foodstandards.gsi.gov.uk

IMPROVING FOLATE INTAKES OF WOMEN OF REPRODUCTIVE AGE AND PREVENTING NEURAL TUBE DEFECTS: PRACTICAL ISSUES

Issue

1. To agree advice to UK Health Ministers on folic acid fortification of bread or flour and the need for labelling of flour products.

Strategic Aim

2. To help reduce diet-related diseases.

Background

3. In May 2007 the 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 NTDs;
    - increase folic acid intakes by an average of 60-100 micrograms/day;
    - ensure numbers not achieving the reference nutrient intake for folate do not exceed about 10 %; and
    - ensure that numbers exceeding the GL/UL for folic acid do not increase above current levels.

4. The Board, however, deferred decisions on the type of bread or flours to be recommended for fortification and the need for labelling.

5. The key decisions to be made are:

    - should wheat bread or flour be fortified;
    - if flour, should wholemeal flour be fortified;
    - should bread making wheat flours be fortified and non-bread making wheat flours exempted;
    - should organic wheat flours be exempted; and

- should wheat flours and wheat flour products fortified with folic acid be labelled?

6. This paper sets out the advantages and disadvantages of each fortification option including the costs to industry.

Bread and Flour Consumption

7. Flour and bread, including grain products, are the most commonly used vehicle in countries that have adopted mandatory fortification in order to improve folate intakes (see Board paper FSA 07/05/04)). The majority of flour consumed in the UK is as wheat bread; other products containing wheat flour such as cakes and biscuits account for a lower proportion of flour consumption (Annex 1, Tables 1-6).

8. According to National Diet and Nutrition Survey (NDNS) data, most (over 90%) women with low folate intakes consume wheat bread (Annex 1, Table 1). Women in the Low Income Diet and Nutrition Survey (LIDNS) consumed similar quantities of bread as those in the NDNS (Annex 1, Table 2).

9. Wheat flour and bread is consumed almost universally and in relatively equal amounts across all population groups (Annex 1, Tables 3 and 4; these tables also show the amount of flour-containing products other than bread consumed). Further details of flour-containing products consumed are given in Annex 1, Tables 5 and 6.

10. Nationally representative data are not available to characterise the consumption patterns of organic wheat products or the characteristics of organic consumers.

Effect of Fortification of Bread or Flour

11. In their report, *Folate and Disease Prevention,* the Scientific Advisory Committee on Nutrition (SACN) modelled the effect of folic acid fortification of all wheat flour, and of white and brown wheat flour on average intakes of folic acid (see Annex 2). The options below, on the effect of mandatory fortification, exclude current levels of folic acid in voluntarily fortified foods but include folic acid intake from supplements.

All Wheat Flour

12. This option includes all wholemeal, brown and white wheat flours used to make bread and other wheat flour products including cakes and biscuits.

13. Compared to the current situation, fortification at 300 micrograms/100 grams of all wheat flour would reduce the risk of NTD-affected pregnancies by 12-21% (i.e. 84-189 pregnancies/year) without increasing the number of people with

intakes above the tolerable upper level (UL)[1] for folic acid (119,000 compared to the current level of 127,000). The proportion of people with intakes below the Reference Nutrient Intake[2] (RNI) would be reduced from the current level of 23% (13.3 million people) to 4% (2.2 million people).

White and Brown Wheat Flour

14. This option includes all brown and white flours used to make bread and other wheat products including cakes and biscuits and excludes all wholemeal wheat flours and wholemeal wheat products.

15. Compared to the current situation fortification at 300 micrograms/100 grams white and brown wheat flour would reduce the risk of NTD-affected pregnancies by 11-18% (i.e. 77-162 NTD pregnancies/year) without increasing the number of people with intakes above the UL for folic acid (115,000 compared to the current level of 127,000). The proportion of people with intakes below the RNI would be reduced from the current level of 23% (13.3 million people) to 5% (3 million people).

White and Brown Bread making Wheat Flour

16. This option includes all brown and white flours used to make bread and excludes wholemeal wheat flour, bread made with wholemeal flour and wheat products including cakes and biscuits made with wholemeal, white and brown flour.

17. Using the model developed by SACN, the Agency has undertaken further analysis on the effect of fortification of white and brown bread making wheat flour (Annex 2). Compared to the current situation fortification at 300 micrograms/100 grams white and brown bread making wheat flour would reduce the risk of NTD-affected pregnancies by 6 - 9% (i.e. 40-78 NTD pregnancies/year); the number of people with intakes above the UL would be less than if all white and brown bread wheat flours were fortified (115,000 when white and brown wheat flours are fortified compared to 61,000 for white and brown bread making flour); and the proportion of people with intakes below the RNI would be reduced from the current level of 23% (13.3 million people) to 10% (5.6 million people).

18. To achieve similar effects as 300 micrograms folic acid being added to 100g of all white and bread wheat flours on NTD risk (i.e. 11-18% reduction), a fortification level of about 450 micrograms folic acid/100 grams would need to

[1] The UL represents the highest level of daily nutrient that is likely to pose no risk to health. UL for adults (≥18y) : 1mg/d; UL for children (Europe): 300µg/d for 4-6y; 400µg/d for 7-10y; 600µg/d for 11-14y; 800µg/d for 15-17y.

[2] The RNI is the amount of a nutrient that is considered sufficient to meet the requirements of 97.5% of the population. The RNI for adults & children: 100µg/d for 4-6y; 150µg/d for 7-10y; 200µg/d for 11y and above.

be added to bread making flour. At this level, the UL for folic acid would be exceeded by about 194,000 people; the proportion of the population not achieving the RNI for folate would be 7% (3.9 million people).

19. The effect of fortifying all bread making wheat flour (wholemeal, white and brown) has not been modelled; however it can be estimated that this would have only a small positive additional effect on NTD levels compared with only fortifying white and brown bread making flour. This is because the majority of wholemeal flour is consumed as bread and results from the SACN modelling showed that excluding fortification of wholemeal flour would have little effect on NTD risk (11-18% risk reduction at 300 micrograms/100g flour if wholemeal flour is excluded compared to 12-21% if wholemeal flour is included). Fortifying all bread making flour would help more people to achieve the RNI for folate but would also increase the number of people exceeding the UL per day for folic acid. It also would not provide an unfortified bread option for those who wish to make this choice.

20. Insufficient data is available to assess the effect of exempting organic flour from folic acid fortification on NTD risk, the proportion of those not achieving the RNI and those exceeding the UL.

Technical Implementation Issues

Wheat Flours and Breads

21. Wheat bread would be a suitable vehicle for mandatory fortification as it is consumed almost universally and in relatively equal amounts across all population groups (paragraph 9). Fortification would therefore increase folic acid consumption evenly across the population. Fortification of bread in the bakery is technically more demanding than the fortification of flour in the flour mill (see Annex 3); for example it is harder to achieve accurate fortification levels in the bakery compared to the flour mill because of the large number of recipes used to make bread.

22. The key advantage of mandatory fortification of wheat flour over fortification of bread is that:

- it makes use of existing equipment, expertise and enforcement practices, thereby minimising costs;

- white and brown wheat flour in the UK already has four nutrients added on a mandatory basis[3]. The addition of one extra nutrient to these fortificants would be relatively straightforward to implement. Current fortification

[3] The Bread and Flour Regulations 1998 require thiamine, nicotinic acid, iron and calcium to be added to white and brown flour

practice excludes wholemeal flour and, for legal reasons, imported flour. The existing Bread and Flour Regulations are not applied to imported flours;

- it is difficult to achieve accurate fortification levels in bread (see Annex 3).

23. The Republic of Ireland is exploring limiting fortification to bread making flour by turning one of their two main flour mills over to bread making flour only. We are advised that this would be more difficult in the UK as the industry is more complicated in the UK with 59 large mills, all producing a number of different flours. There is no agreed definition of bread making flour but it tends to be of a high protein content. The milling industry, however, advise that it might be possible to separate flours according to their protein content (higher protein content flours tend to be used for bread making than for cake and biscuit making). This would 'narrow' the flour fortified towards predominately bread making flour. It would not, however, achieve complete separation of bread making flour from wheat flours for other uses and would exclude some lower protein flours used in bread making. For example, 'value' breads, French style breads and chapattis are often made from flours of similar protein content to that used for biscuit making. The exclusion of 'value' and ethnic breads would be likely to reduce the impact of mandatory fortification with folic acid on incidence of NTD-affected pregnancies in the lower socio-economic groups in the UK; these groups are the most at risk of NTD-affected pregnancies (see Board paper FSA 07/05/04).

24. Fortification of bread making flour only would require capital investment in mills for modifications for new fortification equipment. The cost associated with this is approximately £20k per site, however the addition of new equipment may be impossible for certain sites due to layout of the mills and space constraints. In addition, there would be significant operational complexities created and managerial challenges in distinguishing between flours of different protein content. There are also a number of associated legal issues (Annex 3).

Wholemeal, Stone-ground and Organic Flours

25. Wholemeal wheat flour is currently not fortified with the four micronutrients already added to white and brown wheat flours (paragraph 22). The addition of folic acid to wholemeal flour would require some capital investment and re-design of flour mills (similarly to the costs set out in paragraph 24). Wholemeal wheat flour contains more natural folates than white or brown wheat flours[4].

26. A number of respondents to the Agency consultation on folate (see Board paper FSA 07/05/04) argued that traditionally milled or wholemeal flours should remain free from folic acid. The Soil Association has argued that organic white

[4] McCance and Widdowson, The Composition of Foods, 2004, 6th Edition

and brown wheat flours should also be exempted, although these flours are already fortified with the same micronutrients as other white and brown flours.

Gluten Free Flours

27. People with coeliac disease (UK prevalence of coeliacs, 1%[5]) avoid wheat products. This group do not benefit from any of the nutrients currently added to flour as the Regulations are for wheat flours only. A number of manufacturers, however, do add the nutrients on a voluntary basis to gluten free flours and flour products so that some gluten free flours and breads, are fortified to a similar extent as white and brown wheat flour currently. Any restrictions on voluntary fortification should not prevent the voluntary fortification of gluten free flour. The Board will be receiving an update on the Agency's activities to help ensure safety and choice for food allergic and food intolerant consumers after the summer and the broader nutritional needs of this subgroup of the population will be discussed in more detail in that paper.

Labelling

28. The Agency has previously carried out small scale consumer research on this issue (see Board paper FSA 07/05/04). Participants agreed that products containing folic acid should be labelled.

29. Products made with relatively high proportions of flour, such as bread, cakes and biscuits, would contain nutritionally significant amounts of folic acid, and so should be labelled to inform consumers. There is however, a need for further detailed consideration of labelling requirements, including the need to develop a *threshold* below which labelling may not be required for products containing only small amounts of flour (see Annex 4). *Threshold* levels are generally not used for ingredients (including allergens) in foods for labelling purposes. However to make a nutrient content claim, at least 15% Recommended Daily Amount[6] (RDA) for a nutrient must be present in the food. A *threshold* for folic acid labelling would need to be set at a level at or below which added folic acid was not nutritionally significant; a starting point for discussions would be 5% RNI for folate (equal to 10 micrograms of folic acid/100 grams product).

30. According to the Bread and Flour Regulations 1998, nutrients added to white and brown flour are not required to be labelled, due to a specific national provision of the Food Labelling Regulations 1996 (although some bread is labelled with these nutrients on a voluntary basis). This national provision is being reconsidered because of the EC Review of Food Labelling, which is likely to result in new EC labelling legislation by 2010 (Annex 4). The Board will be

[5] Ciclitira PJ, Johnson MW, Dewar DH, Ellis HJ (2005) The pathogenesis of coeliac disease. Mol Aspects Med. 2005 Dec;26(6):421-58.

[6] RDA is the Recommended Daily Amount used for labelling purposes in the EU. The RDA for folate is set at 200 micrograms (an equal amount to the RNI).

kept informed of this process. In the meantime manufacturers may choose whether or not to label nutrients already added to white and brown flour. A decision on labelling of mandatory folic acid added to food should be taken separately from any changes in the labelling requirements for other flour fortificants.

Trade

31. Mandatory fortification is unlikely to be a barrier to trade in flour or exports from the UK of derived products from a legal viewpoint (Annex 4). Industry is, however, concerned that importers in other countries might choose not to purchase fortified UK goods if labelling for folic acid is required. This could be in part addressed for products that contained only small amounts of wheat flour by the application of *thresholds* for folic acid labelling (paragraph 29).

32. About 4.4 million tonnes of flour is produced in the UK[7] (at a value of just under £1 billion/year), about 3% of which is exported; an amount equal to about 1% of domestic production is imported (see Annex 5 which also gives more information on production and trade). There are a large number of different wheat-containing products traded: the monetary value of exports of sweet biscuits and cakes is about 10% UK domestic production (total value of UK production is £1.5 and £1.2 billion for sweet biscuits and cakes respectively), whereas imports are roughly equal to 10% and 30% of the value for domestic sweet biscuit and cake production respectively[8]. As the effect of mandatory fortification on trade cannot be predicted so the costs of this cannot be quantified (Annex 6).

Partial Regulatory Impact Assessment (RIA)

33. On balance the cost benefit analysis shows that fortification of all white and brown wheat flour (and excluding wholemeal flour) at 300 micrograms per 100g flour is the most beneficial policy option for folic acid fortification (Annex 6). The options of fortifying flour for bread making only or bread only reach approximately half of the annual net benefits compared to fortifying all flour (excluding wholemeal).

34. In terms of administrative burdens, the fewer the number of smaller firms impacted, the lower the cost to industry. Therefore the option of fortifying bread has a much greater cost compared to the other options as there are significantly more bakeries than mills in the UK.

[7] See www.uktradeinfo.com

[8] Sweet Biscuits (October 2005) and Cakes and Cake Bars (June 2006). These Mintel reports provide retail sales data. We can estimate UK production of a given item by subtracting imports and then adding exports to the retail sales figure.

35. There are several costs and benefits which are not quantifiable such as unpredictable effect on trade in wheat products (Annex 6).

Discussion

36. Fortification of wheat flour rather than bread has significant practical advantages. For example, industry has advised that it is likely to be much harder to achieve accurate fortification level of folic acid in bread in the bakery than in flour in the flour mill (see paragraphs 21 to 23) and the following discussion therefore focuses on flour.

37. To mitigate the impact on choice, wholemeal flour could be exempted, as is the case for current wheat flour fortificants, and this would have significant practical advantages (see paragraph 22). All imported wheat flour would also be exempt (see paragraph 22).

37. In considering any further limits or exceptions to flour fortification, such as exempting non-bread making or other flours, it is necessary to take account of the impact on the public health objectives of the proposal; the potential for over-consumption of folic acid by vulnerable groups; the effect on industry; and the cost to the consumer.

38. Whilst exempting flours other than those for bread making would alleviate concerns about impact on trade in cakes and biscuits, the milling industry has highlighted that there would be significant practical difficulties and costs involved, and that some bread making flours would not then be fortified. In addition, limiting fortification to bread making flour only would lead to a less favourable balance of health and nutrition benefits (NTDs prevented and proportion achieving RNI) against risk of exceeding the UL for folic acid (see paragraph 17-18).

39. Although the organic industry has expressed the view that organic flours should remain free from folic acid (see paragraph 26), data are not available to assess the impact on public health. Whilst wholemeal wheat flours contain more folate than white or brown wheat flours[2] there is no evidence to suggest that organic white and brown flours contain more natural folate than non-organic flours. It is also not known if organic consumers have a better folate status and thus lower NTD risk than non organic consumers. In addition, although this option might seem to offer choice of a 'natural' white loaf it should be noted that the four other fortificants are added to white and brown organic flour.

40. It is important that consumers are informed that wheat breads have added folic acid. Actions to do this should include labelling of pre-packaged breads. It would also be important to label other wheat flour containing products, unless the amounts of folic acid present were not nutritionally significant. The use of a *threshold* for labelling would require EU agreement (paragraph 29) but would

offer practical advantages to industry and could also help provide accurate information to consumers who might be given the impression, if folic acid is labelled on all wheat products, that they are consuming nutritionally meaningful amounts of the nutrient.

41. Industry may also wish to take the opportunity of the introduction of labelling for folic acid to introduce voluntary labelling of the four micronutrients already added to white and brown flour. This would minimise re-labelling costs that may be required when the review of the specific exemption of these from the Food Labelling Regulations is completed by 2010 (paragraph 30).

Next Steps

42. Shortly after the Board meeting, Health Departments will be briefed and meetings arranged to inform Ministerial decisions on fortification. In addition, over the next few months discussion with industry will take place to develop implementation plans; a meeting with trade associations has been organised for July on the regulation of voluntary fortification. The Board will be provided with a progress report in about six months time.

Recommendation

43. On balance, therefore, taking into account the scientific advice, practical and technical issues and the views of stakeholders, it is recommended that the Board's advice to UK Health Ministers to introduce mandatory fortification with folic acid should include the following further provisos:

- that mandatory fortification apply to all white and brown wheat flours;
- that the folic acid contained in these products should be labelled; and
- the potential for a threshold for labelling should be explored where folic acid
- levels are not nutritionally significant, at a level of about 5% RNI folate.

ANNEX 1

CONSUMPTION DATA

1. This annex presents folate, folic acid, food and supplement consumption patterns derived from the analysis of UK National Diet and Nutrition Survey (NDNS) data. It also includes some data from the Low Income Diet and Nutrition (LIDNS) due for publication by the Agency later this year.

Consumption of wheat flour and wheat flour containing products according to levels of folate intake and income

2. Women of child bearing age with low folate intakes are more often in receipt of benefits than high folate consumers. Table 1 illustrates this using NDNS data for 19-34 year olds. Flour and bread consumption is however relatively uniform; there are no apparent trends across different levels of folate intake.

3. Table 2 compares women in the LIDNS survey with those in NDNS. It shows that a greater proportion of the LIDNS sample have intakes below the reference nutrient intake (RNI) in all age groups except the over 60s. White bread consumption was similar in both surveys.

Table 1: Consumption of wheat flour and wheat flour containing products by quintile of folate intake for women aged 19-34 years

Women aged 19-34 years	Folate intake quintiles									
	Quintile 1 (lowest)		Quintile 2		Quintile 3		Quintile 4		Quintile 5 (highest)	
Mean age (years)	26		28		28		28		28	
Percentage from benefit households[1]	*44*		*27*		*14*		*16*		*13*	
	Flour consumption (grams/day)									
Total flour consumption (grams / day) of which	55		56		67		66		56	
Flour from bread	44		40		48		51		38	
Flour from other products	11		15		18		15		18	
	Consumption of flour containing products									
	mean g/day	*% cons -umers*	mean g/day	*% cons -umers*	mean g/day	*% cons -umers*	mean g/day	*% cons -umers*	mean g/day	*% cons -umers*
White bread	63	*91*	53	*94*	64	*100*	56	*90*	37	*82*
Softgrain bread	0	*0*	0	*0*	0	*2*	2	*4*	0	*0*
Other bread	8	*31*	13	*41*	14	*53*	28	*68*	28	*70*
Pizza	6	*16*	11	*33*	16	*40*	13	*39*	15	*30*
Other cereals[2]	4	*22*	6	*31*	5	*38*	3	*34*	4	*26*
Biscuits	6	*49*	7	*63*	11	*73*	9	*70*	9	*60*
Buns, cakes, pastries and fruit pies	10	*45*	17	*65*	15	*56*	12	*52*	16	*58*
Cereal based puddings	4	*14*	3	*18*	5	*18*	7	*13*	12	*29*

Source: NDNS adults 19-64 years (2000/01)

[1] Receipt of income related benefits by the respondent or anyone else in the household

[2] The 'other cereals' food group includes products such as dumplings, Yorkshire pudding, poppadoms, pancakes, cous cous, polenta etc.

Table 2: Comparison of population mean total folate intake from food and mean daily bread consumption between the National Diet and Nutrition Survey (NDNS) series and the Low Income Diet and Nutrition Survey (LIDNS).

Age (yrs) and sex group		Data from NDNS series	Data taken from LIDNS[3]
11-18 females[4]	Mean daily folate intake (μg)	212	201
	% of the population with intakes <RNI[5]	51	56
	Mean white bread consumption (g/d)	59	56
	Mean wholemeal bread consumption (g/d)	6	5
19-34 females[6, 7]	Mean daily folate intake (μg)	249	207
	% of the population with intakes <RNI	35	59
	Mean white bread consumption (g/d)	54	47
	Wholemeal bread consumption (g/d)	10	9
35-49 females[6, 7]	Mean daily folate intake (μg)	280	208
	% of the population with intakes <RNI	26	57
	Mean white bread consumption (g/d)	50	48
	Mean wholemeal bread consumption (g/d)	15	10
65+ females[8]	Mean daily folate intake (μg)	220	220
	% of the population with intakes <RNI	48	46
	Mean white bread consumption (g/d)	46	41
	Mean wholemeal bread consumption (g/d)	22	16

The consumption of folate, wheat flour and products bread

4. Table 2 compares folate intakes as average values and proportions below the RNI (200 micrograms/day) for women from the general population assessed using NDNS data and the low income population using LIDNS data. A greater proportion of women of child bearing age in the low income group have folate intakes below recommended levels. Bread consumption levels were broadly similar in NDNS and LIDNS for different age groups of women according to folate intake (Tables 1 and 2), age and sex (Table 3) and receipt of benefits (Table 4). The consumption of flour containing products is presented according to age and sex (Table 5) and receipt of

[3] This table uses data taken from the unpublished Low Income Diet and nutrition Survey (LIDNS) which is due to be published by Food Standards Agency in 2007.

[4] Gregory J, Lowe S, Bates CJ, Prentice A, Jackson LV, Smithers G, Wenlock R & Farron M. National Diet and Nutrition Survey: young people aged 4 to 18 tears. Volume 1: Report of the diet and nutrition survey. TSO (London: 2000)

[5] Reference Nutrient Intake for folate is 200μg/day for adults and children aged 11 years and above. Department of Health. Dietary Reference Values for food Energy and Nutrients in the United Kingdom. (Report on Health and Social Subjects, No. 41). London: HSMO, 1991.

[6] Hederson L, Gregory J, & Swan G. National Diet and Nutrition Survey: adults aged 19 to 64 years. Volume 1: Types and quantities of foods consumed. TSO (London: 2002)

[7] Henderson L, Irving K, Gregory J, Bates CJ, Prentice A, Perks J, Swan G & Farron M. National Diet and nutrition Survey: adults aged 19 to 64 years. Volume 3: Vitamin and mineral intake and urinary analytes. TSO (London: 2000)

[8] Finch S, Doyle W, Lowe C, Bates CJ, Prentice A, Smithers G & Clarke PC. National Diet and Nutrition Survey: people aged 65 years or over. Volume 1: Report of the diet and nutrition survey. TSO (London: 1998)

benefits (Table 6). Tables 3-6 present data as mean values and those for low (bottom 2.5%) and high (top 97.5%) consumers.

TABLE 3: Mean wheat flour consumption (g/day) by age and sex

Source	Age and sex											
	4 – 10 yrs						11 – 18 yrs					
	Males			Females			Males			Females		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
Total flour[1], of which	22	73	147	23	63	120	16	90	194	19	70	134
Flour from bread, of which	9	46	110	9	40	83	9	62	155	9	49	109
White bread	6	37	98	4	32	76	7	50	129	6	38	91
Wholemeal bread	2	4	50	2	4	55	2	4	91	2	4	63
Granary bread	n/a	0	n/a	1	0	n/a	n/a	1	n/a	4	1	42
Brown bread	2	1	67	2	1	26	3	1	62	2	1	33
Soft grain bread	n/a	0	n/a	n/a	1	n/a	n/a	1	n/a	3	0	n/a
Other bread[2]	2	3	41	2	3	31	3	5	57	2	5	42
Flour from other foods[3]	4	27	73	4	23	50	2	28	78	3	21	57
Total flour excluding wholemeal, brown and granary breads	19	67	142	19	58	112	16	84	174	16	64	126

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Includes flour from wholemeal, brown and granary breads (1994/95)
[2] Includes products such as rye bread, ciabatta, crumpets, bagels, brioche, naan etc
[3] Includes products such as biscuits, fruit pies, buns, cakes and pastries, pizza, sponge puddings, dumplings, Yorkshire pudding, poppadoms, pancakes, etc.

Source	Age and sex											
	19 – 49 yrs						50 – 64 yrs					
	Males			Females			Males			Females		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
Total flour[1], of which	28	101	208	15	71	159	33	110	236	21	73	151
Flour from bread, of which	14	79	173	7	54	128	21	84	185	13	53	121
White bread	8	53	144	4	33	85	5	51	149	4	29	98
Wholemeal bread	3	11	111	3	8	66	5	13	92	3	10	57
Granary bread	3	2	64	3	2	51	4	3	108	n/a	2	44
Brown bread	3	2	70	3	2	63	3	3	87	3	3	68
Soft grain bread	n/a	0	n/a	n/a	0	n/a	n/a	3	n/a	n/a	1	n/a
Other bread[2]	3	11	73	3	10	61	2	10	87	2	8	60
Flour from other foods[3]	2	22	77	1	17	57	1	26	84	2	20	60
Total flour excluding wholemeal, brown and granary breads	20	86	193	10	59	130	22	90	204	9	58	140

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Includes flour from wholemeal, brown and granary breads (1994/95)
[2] Includes products such as rye bread, ciabatta, crumpets, bagels, brioche, naan etc
[3] Includes products such as biscuits, fruit pies, buns, cakes and pastries, pizza, sponge puddings, dumplings, Yorkshire pudding, poppadoms, pancakes, etc.

Source	Age and sex											
	65+ yrs (free living)						65+ yrs (institutions)					
	Males			Females			Males			Females		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
Total flour[1], of which	31	103	203	23	74	143	30	99	185	27	84	156
Flour from bread, of which	18	74	175	11	52	115	15	64	158	10	52	111
White bread	6	41	129	5	29	97	4	41	107	4	32	102
Wholemeal bread	5	17	118	6	14	91	3	11	84	2	11	75
Granary bread	9	2	85	4	2	117	n/a	0	n/a	-	-	-
Brown bread	3	3	149	4	2	74	2	5	135	2	4	54
Soft grain bread	5	1	n/a	n/a	0	n/a	-	-	-	n/a	0	n/a
Other bread	5	8	98	5	5	66	2	6	114	2	4	47
Flour from other foods	3	29	81	2	22	61	4	35	79	6	32	75
Total flour excluding wholemeal, brown and granary breads	12	79	171	8	56	125	16	82	161	18	69	141

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Includes flour from wholemeal, brown and granary breads (1994/95)
[2] Includes products such as rye bread, ciabatta, crumpets, bagels, brioche, naan etc
[3] Includes products such as biscuits, fruit pies, buns, cakes and pastries, pizza, sponge puddings, dumplings, Yorkshire pudding, poppadoms, pancakes, etc.

TABLE 4: Mean wheat flour consumption (g/day) by household receipt of benefits[1]

Source	YOUNG PEOPLE aged 4–18											
	Males						Females					
	Receiving			Not receiving			Receiving			Not receiving		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
Total flour[2], of which	9	67	157	26	86	177	20	64	134	24	68	129
Flour from bread, of which	7	44	118	12	58	137	6	41	110	10	46	98
White bread	6	39	119	7	45	114	5	33	88	5	35	87
Wholemeal bread	2	3	36	2	5	81	2	3	63	2	4	61
Granary bread	n/a	0	n/a	2	1	36	3	1	n/a	1	1	38
Brown bread	8	1	n/a	2	1	65	2	1	53	2	1	26
Soft grain bread	n/a	0	n/a	1	1	62	n/a	0	n/a	n/a	1	n/a
Other bread[3]	2	2	22	2	5	57	3	4	45	2	4	33
Flour from other foods[4]	2	23	76	4	29	76	4	22	53	3	22	55
Total flour excluding wholemeal, brown and granary breads	9	64	157	21	80	170	17	59	123	17	62	125

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Receipt of income related benefits by the respondent or anyone else in the household
[2] Includes flour from wholemeal, brown and granary breads (1994/95)
[3] Includes products such as rye bread, ciabatta, crumpets, bagels, brioche, naan etc
[4] Includes products such as biscuits, fruit pies, buns, cakes and pastries, pizza, sponge puddings, dumplings, Yorkshire pudding, poppadoms, pancakes, etc.

Source	ADULTS aged 19–64											
	Males						Females					
	Receiving			Not receiving			Receiving			Not receiving		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
Total flour[1], of which	14	95	192	32	105	222	11	63	159	16	73	157
Flour from bread, of which	13	78	161	16	81	176	8	49	127	10	55	125
White bread	13	60	147	6	51	144	5	34	101	4	32	86
Wholemeal bread	6	9	106	3	12	108	3	5	61	3	9	64
Granary bread	n/a	2	n/a	4	3	96	n/a	0	n/a	3	2	50
Brown bread	n/a	2	n/a	3	3	71	2	3	62	3	3	69
Soft grain bread	-	-	-	2	1	184	n/a	0	n/a	n/a	0	n/a
Other bread	2	6	59	3	12	79	2	7	60	2	10	60
Flour from other foods	1	16	55	2	24	81	1	14	55	2	18	57
Total flour excluding wholemeal, brown and granary breads	30	82	192	21	88	194	11	55	157	10	60	132

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Includes flour from wholemeal, brown and granary breads (1994/95)
[2] Includes products such as rye bread, ciabatta, crumpets, bagels, brioche, naan etc
[3] Includes products such as biscuits, fruit pies, buns, cakes and pastries, pizza, sponge puddings, dumplings, Yorkshire pudding, poppadoms, pancakes, etc.

Source	OLDER PEOPLE (free living) aged 65+											
	Males						Females					
	Receiving			Not receiving			Receiving			Not receiving		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
Total flour[1], of which	22	95	192	35	103	203	21	73	143	26	78	143
Flour from bread, of which	13	66	182	17	73	168	6	47	116	13	53	114
White bread	4	38	120	5	42	128	6	31	100	5	30	96
Wholemeal bread	5	12	83	3	17	117	n/a	7	71	3	14	84
Granary bread	n/a	0	n/a	9	2	85	n/a	1	n/a	4	1	123
Brown bread	n/a	6	n/a	2	4	141	n/a	3	n/a	2	3	62
Soft grain bread	-	-	-	5	1	n/a	n/a	0	n/a	n/a	0	n/a
Other bread[2]	n/a	9	101	3	8	98	n/a	5	75	3	5	60
Flour from other foods[3]	5	30	74	3	30	82	3	26	70	3	25	65
Total flour excluding wholemeal, brown and granary breads	15	77	161	12	80	170	16	62	136	9	60	133

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Includes flour from wholemeal, brown and granary breads (1994/95)
[2] Includes products such as rye bread, ciabatta, crumpets, bagels, brioche, naan etc
[3] Includes products such as biscuits, fruit pies, buns, cakes and pastries, pizza, sponge puddings, dumplings, Yorkshire pudding, poppadoms, pancakes, etc.

TABLE 5: Mean consumption of bread (g/day) by sex and age

Source	Age and sex											
	4 – 10 yrs						11 – 18 yrs					
	Males			Females			Males			Females		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
White bread	10	59	159	6	50	120	11	80	204	9	60	144
Wholemeal bread[1]	3	7	79	3	6	87	4	7	144	4	6	100
All other breads, of which	3	7	86	3	6	62	4	10	104	3	10	80
Granary	n/a	0	n/a	2	1	n/a	n/a	1	n/a	7	2	66
Brown	4	2	107	3	1	41	4	2	98	3	2	53
Softgrain	n/a	1	n/a	n/a	1	n/a	n/a	1	n/a	5	1	n/a

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Wholemeal flour not included in modelling

Source	Age and sex											
	19 – 49 yrs						50 – 64 yrs					
	Males			Females			Males			Females		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
White bread	13	83	229	6	52	134	8	81	236	7	46	156
Wholemeal bread[1]	4	17	176	5	12	105	7	21	146	5	16	91
Other breads, of which	6	20	133	5	18	110	4	24	196	3	16	109
Granary	5	3	101	5	3	81	6	5	171	n/a	3	70
Brown	5	4	112	4	4	101	4	6	138	5	5	107
Softgrain	n/a	0	n/a	n/a	0	n/a	n/a	5	n/a	n/a	1	n/a

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Wholemeal flour not included in modelling

Source	Age and sex											
	65+ yrs (free living)						65+ yrs (institutions)					
	Males			Females			Males			Females		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
White bread	9	66	204	9	46	153	7	65	169	7	51	162
Wholemeal bread[1]	8	28	187	9	22	144	4	18	133	3	18	119
Other breads, of which	8	16	192	9	11	126	4	11	208	3	8	85
Granary	14	4	134	6	2	186	n/a	0	n/a	-	-	-
Brown	4	5	236	6	4	117	4	8	214	3	7	86
Softgrain	7	2	n/a	n/a	1	n/a	-	-	-	n/a	0	n/a

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Wholemeal flour not included in modelling

TABLE 6: Mean consumption of bread (g/day) by household receipt of benefits[1]

Source	YOUNG PEOPLE aged 4–18											
	Males						Females					
	Receiving			Not receiving			Receiving			Not receiving		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
White bread	10	61	188	11	72	182	9	52	140	8	56	138
Wholemeal bread[2]	3	4	57	3	8	129	3	5	99	4	7	97
Other breads, of which	4	4	43	3	10	105	5	7	81	3	8	70
Granary	n/a	0	n/a	3	1	57	4	1	n/a	2	1	60
Brown	13	1	n/a	3	2	103	4	2	84	3	1	41
Softgrain	n/a	0	n/a	2	1	98	n/a	1	n/a	n/a	1	n/a

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Receipt of income related benefits by the respondent or anyone else in the household
[2] Wholemeal flour not included in modelling

Source	ADULTS aged 19–64											
	Males						Females					
	Receiving			Not receiving			Receiving			Not receiving		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
White bread	21	95	233	10	81	229	8	53	160	6	50	136
Wholemeal bread[1]	9	15	168	5	19	172	5	8	97	5	14	102
Other breads, of which	3	10	107	5	23	160	3	12	108	4	18	109
Granary	n/a	3	n/a	6	4	152	n/a	1	n/a	5	3	80
Brown	n/a	3	n/a	5	4	113	4	4	98	4	4	110
Softgrain	-	-	-	4	2	292	n/a	0	n/a	n/a	1	n/a

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Wholemeal flour not included in modelling

Source	OLDER PEOPLE (free living) aged 65+											
	Males						Females					
	Receiving			Not receiving			Receiving			Not receiving		
	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile	2.5 percentile	Mean	97.5 percentile
White bread	7	60	190	8	66	204	9	49	159	8	47	153
Wholemeal bread[1]	7	19	132	5	27	186	n/a	11	113	5	23	134
Other breads, of which	n/a	17	184	5	15	216	n/a	10	136	5	10	113
Granary	n/a	1	n/a	14	4	134	n/a	1	n/a	6	2	195
Brown	n/a	9	n/a	4	6	224	n/a	5	n/a	3	4	98
Softgrain	-	-	-	7	1	n/a	n/a	1	n/a	n/a	1	n/a

Sources: NDNS young people aged 4–18 (1997)
NDNS adults aged 19–64 (2000/01)
NDNS people aged 65 years and over (1994/95)

[1] Wholemeal flour not included in modelling

ANNEX 2

THE POTENTIAL IMPACT OF MANDATORY FOLIC ACID FORTIFICATION OF FLOUR AND BREAD

Modelling Exercise

1. The effect of fortifying all wheat flour (wholemeal, white, brown), white and brown wheat flour only, and white and brown bread flour only with 2 levels of folic acid on the total folate intake (including processing losses, overage, and supplement use but excluding current levels in voluntarily fortified foods) of different population age groups was investigated by modelling intake data from the National Diet and Nutrition Survey (NDNS) series.

2. The model to investigate the potential effect of folic acid fortification of all wholemeal, white, and brown flours was developed by the Scientific Advisory Committee on Nutrition (SACN) and published in their report, *Folate and Disease Prevention* (2006). The potential effect of fortification of bread making flour only was assessed by the Agency using the model developed by SACN.

3. The purpose of the modelling exercise was to explore the effect of mandatory folic acid fortification of all flour, only white/brown flour or white/brown bread flour only on the:

    - average intakes of folic acid;
    - proportion of the population with folate intakes below the recommended nutrient intake (RNI[1]);
    - risk of NTD-affected pregnancies;
    - total numbers in the population who might be exposed to levels of folic acid above the tolerable upper level (UL) per day set for folic acid[2];
    - number of people aged 65 years and over, with low vitamin B_{12} status, who might be exposed to levels of folic acid above 1 milligram/day.

4. In the UK, a Guidance Level[3] (GL) of 1 milligram/day for folic acid was set for adults, however no GLs were set for children. ULs were set for children in Europe and the USA, which were extrapolated from the UL for adults on the basis of body weight. The ULs were therefore used for the purpose of the modelling exercise in order to estimate the total proportion of the UK population (including children) who might be exposed to high intakes of folic acid.

[1] The RNI is the amount of a nutrient that is considered sufficient to meet the requirements of 97.5% of the population. The RNI for adults & children: 100µg/d for 4-6y; 150µg/d for 7-10y; 200µg/d for 11y and above.

[2] The UL represents the highest level of daily nutrient that is likely to pose no risk to health. UL for adults (≥18y) : 1mg/d; UL for children (Europe): 300µg/d for 4-6y; 400µg/d for 7-10y; 600µg/d for 11-14y; 800µg/d for 15-17y.

[3] The Guidance Level is an approximate indication of intakes that would not be expected to cause adverse effects.

5. The potential effects of mandatory folic acid fortification of all flour (wholemeal, white and brown), only white and brown flour, and only white and brown bread flour were assessed at two different levels per 100 grams of flour: 300 and 450 micrograms. After processing losses this would result in actual levels of 225 and 338 micrograms per 100 grams food respectively.

Results of Modelling Exercise

Table 1: Effects on the UK population* of mandatory folic acid fortification of ALL flour (including and excluding wholemeal) compared with white & brown BREAD flour only.

Level of folic acid micrograms/100g flour (level in food after processing)	Average increase in folic acid intake (micrograms/day)[4]	Estimated mean total folate intakes (micrograms/day)	Estimated % of people with intakes below RNI**[5]	Estimated number of people exceeding the UL of folic acid/day**[6]	Estimated number aged 65y+ with low vitamin B_{12} status exceeding 1 milligram/day folic acid***	Estimated NTD pregnancies prevented/year (% risk reduction)
Current situation *(INCLUDES folate and folic acid intake from fortified breakfast cereals and fat spreads and folic acid intake from supplements[7])*						
0	0	302	23	127,000	900	0
Folic acid fortification of ALL flour (INCLUDES wholemeal, white & brown flour) *(EXCLUDES contribution of folic acid from fortified breakfast cereals and fat spreads. INCLUDES contribution of folic acid intake from supplements)*						
300 (225) 450 (338)	98 184	404 491	4 2	119,000 660,000	900 1,400	84-189 (12-21%) 140-315 (20-35%)
Folic acid fortification of ONLY white & brown flour (EXCLUDES wholemeal flour) *(EXCLUDES contribution of folic acid from fortified breakfast cereals and fat spreads. INCLUDES contribution of folic acid intake from supplements)*						
300 (225) 450 (338)	78 154	385 461	5 3	115,000 559,000	900 900	77-162 (11-18%) 126-279 (18-31%)
Folic acid fortification of white & brown BREAD flour only *(EXCLUDES wholemeal flour and contribution of folic acid from fortified breakfast cereals and fat spreads. INCLUDES contribution of folic acid intake from supplements)*						
300 (225) 450 (338)	31 83	337 390	10 7	61,000 194,000	900 900	40-78 (6-9%) 84-174 (12-19%)

* *Based on data from the NDNS which does not include pregnant or lactating women*
** *Figures rounded to the nearest 1,000*
*** *Figures rounded to the nearest 100*

[4] Across all population groups.
[5] For each age group (DH, 1991)
[6] For each age group (European Scientific Committee on Foods, 2001).
[7] Mean of values for overage applied and not applied.

Effects of mandatory fortification including current levels of folic acid intake from voluntary fortification and supplements

6. See first section of table, headed: *Current situation.*

7. It can be seen that at current levels of folic acid intake in the UK (from voluntary fortification and supplements):

    - The average folate intake of the population is approximately 302 micrograms/day;
    - Approximately 23% of the population (13,261,000 people) have intakes below the RNI for folate;
    - Approximately 127,000 people are exceeding the UL/day set for folic acid (the largest proportion are children aged 4-10 years [57% or 72,000 children] as the ULs/day are much lower for these age groups [300-400 micrograms/day] than for adults [1 milligram/day]);
    - Approximately 900 adults aged 65 years and over with low vitamin B_{12} status are exceeding folic acid intakes of 1 milligram/day.

Effect of mandatory fortification of ALL flour: wholemeal, white and brown wheat flour (excluding folic acid intakes from fortified breakfast cereals/fortified spreads but including folic acid intake from supplements)

8. See second section of Table 1, headed: *Folic acid fortification of ALL flour*.

9. It can be seen that, mandatory folic acid fortification of all flour at 300 micrograms per 100g flour, without the contribution of folic acid intakes from fortified breakfast cereals and fortified fat spreads (but including intakes from supplements) would result in an average increase in folic acid intake of approximately 98 micrograms per day. Fortification at this level would reduce the risk of NTD-affected pregnancies (by 12-21%) without increasing the number of people with intakes above the UL (119,000 compared to the current level of 127,000) or the number of adults aged 65 years and over with low vitamin B12 status, exceeding intakes of 1 milligram per day. The proportion of people with intakes below the RNI would be reduced from the current level of 23% to 4%.

10. Mandatory fortification with folic acid at 450 micrograms per 100g of flour would further reduce the risk of NTD-affected pregnancies (20-35%) and the proportion of the population with intakes below the RNI (2%). However the number of adults aged 65 years and over, with low vitamin B12 status, exceeding intakes of 1 milligram per day would be increased (from 900 to 1,400) and the numbers with intakes above the UL per day would be substantially increased (660,000).

Effect of mandatory fortification of only white and brown wheat flour (excluding wholemeal flour and folic acid intakes from fortified breakfast cereals/fortified spreads but including folic acid intake from supplements)

11. See third section of Table 1, headed: *Folic acid fortification of only white and brown flour*.

12. It can be seen that, mandatory folic acid fortification of all white and brown flour at 300 micrograms per 100g flour, without the contribution of folic acid intakes from fortified breakfast cereals and fortified fat spreads (but including intakes from supplements) would result in an average increase in folic acid intake of approximately 78 micrograms per day. Fortification at this level would reduce the risk of NTD-affected pregnancies (by 11-18%) without increasing the number of people with intakes above the UL (115,000 compared to the current level of 127,000) or the number of adults aged 65 years and over with low vitamin B12 status, exceeding intakes of 1 milligram per day. The proportion of people with intakes below the RNI would be reduced from the current level of 23% to 5%.

13. Mandatory fortification with folic acid at 450 micrograms per 100g of flour would further reduce the risk of NTD-affected pregnancies (18-31%) and the proportion of the population with intakes below the RNI (3%). There would be no change in the number of adults aged 65 years and over, with low vitamin B12 status, exceeding intakes of 1 milligram per day, however the numbers with intakes above the UL per day would be substantially increased (559,000).

Effect of mandatory fortification of white and brown BREAD flour only (excluding wholemeal flour and folic acid intakes from fortified breakfast cereals/fortified spreads but including folic acid intake from supplements)

14. See fourth section of Table 1, headed: *Folic acid fortification of white & brown BREAD flour only*.

15. It can be seen that, mandatory folic acid fortification of all white and brown bread flour only at 300 micrograms per 100g flour, without the contribution of folic acid intakes from fortified breakfast cereals and fortified fat spreads (but including intakes from supplements), would result in an average increase in folic acid intake of approximately 31 micrograms per day. Fortification at this level would reduce the risk of NTD-affected pregnancies (by 6-9%) and the number of people with intakes above the UL (61,000 compared to the current level of 127,000). There would be no change in the number of adults aged 65 years and over with low vitamin B12 status, exceeding intakes of 1 milligram per day. The proportion of people with intakes below the RNI would be reduced from the current level of 23% to 10%.

16. Mandatory fortification of white and brown bread flour with folic acid at 450 micrograms per 100g of flour would further reduce the risk of NTD-affected pregnancies (12-19%) and the proportion of the population with intakes below the RNI (7%). There would be no change in the number of adults aged 65 years and over, with low vitamin B12 status, exceeding intakes of 1 milligram per day, however the numbers with intakes above the UL per day would be increased (from 127,000 to 194,000).

Comparison of the effects of fortifying ALL white and brown flour with fortifying white and brown BREAD flour only (excluding folic acid intakes from fortified breakfast cereals and fat spreads but including folic acid intakes from supplements)

17. It can be seen that as a result of mandatory fortification of only white and brown BREAD flour, compared with mandatory fortification of ALL white and brown flour (excluding wholemeal flour), the:

- Average increase in daily folic acid intake is reduced;
- There are less NTD-affected pregnancies prevented per year;
- There are more people with folate intakes below the RNI;
- There are less people with intakes above the UL of folic acid/day;
- The estimated number of people aged 65 years and over with low vitamin B12 status exceeding folic acid intakes of 1 milligram/day is the same.

ANNEX 3

TECHNICAL AND PRACTICAL ISSUES TO TAKE INTO ACCOUNT: FOLIC ACID FORTIFICATION

General Points

Flour and Bread Fortification

1. Bread is consumed by almost all women (98%) in relatively uniform amounts. Folic acid is also relatively stable in bread (except for soda bread).

2. There are two main potential methods for fortification of bread:

- Fortification of flour at the milling stage (either all flours, all flour except wholemeal or all flour except non bread making flours); or

- Fortification of flour at the bread making stage (either some or all breads).

3. The bread and milling industry indicates that the fortification of all flour except for wholemeal at the milling stage is the preferred option. This would build upon the existing requirements for the fortification of all flour except wholemeal in the UK with iron, calcium, thiamine and niacin[1] and so would capitalise on existing technology and regulation. Choice could be provided to consumers who want an unfortified product through wholemeal bread (which provides 40 micrograms/100 grams folate compared with unfortified white bread, which provides 25 micrograms/100 grams). Ethnic breads made by using white and brown flour would be included (white, brown and wholemeal chapatti flours are milled in the UK).

4. The baking industry has raised concerns about achieving accurate fortification levels within bread if fortification occurs at the bread making stage. They consider that this would be a problem throughout the industry although it would be a particular problem for small scale or artisan bakers. They also noted that staff training and new equipment would be needed. The results of product testing within the Republic of Ireland suggest large variation in folic acid levels of bread fortified in the bakery.

5. The Biscuit, Cake, Chocolate and Confectionary Alliance (BCCCA) would prefer fortification to be at the bread making stage so that their products are free from folic acid.

[1] The Bread and Flour Regulations require that flour should contain not less than 0.24 micrograms thiamine (vitamin B1), 1.60 micrograms nicotinic acid and 1.65 micrograms of iron per 100g of flour. These amounts are found naturally in wholemeal flour. White and brown flours must be fortified to restore their nutritional value. In addition calcium carbonate at a level of not less than 235 micrograms and not more than 390 micrograms per 100g of flour is added to all flours except wholemeal (and certain self raising varieties).

Bread Making Flour

6. The milling industry advises that bread-making flour cannot be separated easily from other flours in mills although it might be possible achieve separation of flours according to protein content. There is however no strict protein threshold for different products. Bread tends to be made from flours with a protein content of more than 9% (most bread making flour is between 9.5 and 14% protein) whereas biscuits and pastry tend to be made with flours that are between 8.5 and 10% protein. 'Value' breads, French style and ethnic breads (such as chapattis) tend to use flours of similar protein content to that used in biscuit making. Some higher protein flour is used in the manufacture of some pastries and biscuits; fruit cakes are made with an 11% protein flour. The millers also point out that they are not always aware of the destination or final use of the flour being milled and that bread, pastry and biscuit makers may use the same flours and that the fortification of bread making flour would require capital investment and be managerially complex.

7. The Republic of Ireland is currently exploring the separation of bread-making flour from other flours in the mills. They, however, have only two main flour mills and may be able to use one for the production of bread-making flour only, which will be fortified with folic acid (all wholemeal, white and brown wheat flours and blended wheat flours intended for commercial baking). Also they are not adding any other nutrients to flour by mandate. The industry is significantly more complicated in the UK; there are 59 mills.

8. In theory "bread-making flour" could be made a legally defined term for the purposes of the Bread and Flour Regulations (1998), or for other legislation. How well the term would work is to a large extent dependent on practical issues as discussed below.

9. One way would be to define by variety and/or properties, for example flour from wheat with a given minimum protein content; this could be an over-simplification (see paragraph 6). The other way might be to define the term by the use to which the flour is put, i.e. any flour which is to be used for making bread, or certain types of bread, is "bread-making flour" for the purposes of the legislation.

10. Whatever the legislative method chosen, the legislation requiring fortification will need to be notified to the Commission and other Member States in draft form (see Annex 4).

Organic Flours

11. Organic white and brown flour are not exempted from the Bread and Flour Regulations (1998); they are fortified with micronutrients to the same extent as non-organic white and brown flour. Organic flour is produced in about 6 mills in

the UK; these tend to be small mills that are specialising in organic flours. About 40,000 tonnes of organic flour is produced per year (1% of total flour production).

12. The Soil Association is keen that organic flour is not fortified with folic acid. The Republic of Ireland will be exempting organic but not wholemeal flours from their legislation.

ANNEX 4

LABELLING AND TRADE

1. If it were decided to fortify on a mandatory basis, it would be important to ensure that the regulatory framework was appropriate and that the new measure did not create unnecessary trade barriers. The new legislative requirement could be implemented by amending the UK Bread and Flour Regulations 1998 (BFR). As a national measure, this would be notifiable in draft to the Commission and to the World Trade Organisation if appropriate. The justification for the measure would be the protection of public health in the UK. A consequence of notification is that Member States and the Commission would have the option to oppose the measure being brought in. There is a standstill period of six months and, if objections are made, a decision at EU level, which could be a vote for non-implementation. Failure to comply would incur legal action in the European Courts. It is likely that any consensual schemes or statutory controls to restrict voluntary folic acid fortification would need to be notified, and there might be objections from manufacturers of voluntarily fortified products in other Member States if they were wishing to export such products into the UK.

2. The BFR, which do not apply to imported flour, currently require four nutrients to be added to white and brown wheat flour, but these do not need to be labelled because of a specific national provision in the Food Labelling Regulations 1996 (as amended). This provision is currently being reviewed as part of the EU review of food labelling legislation, and may as a consequence be removed (the timescale for adoption of the new EU food labelling legislation is 2010). The addition of folic acid would, it is suggested in this paper, needs to be accompanied by mandatory labelling. In this case folic acid would need to be declared in flour and flour products in all cases. This would mean that some flour products, such as sauces and fish fingers, where the level of folic acid is so low as to be nutritionally insignificant, would have to indicate folic acid on the label. This raises the issue of whether such labelling would be misleading or appropriate. A possible solution would be to explore the possibility of a *threshold* below which labelling the indication of folic acid would not be required. Again, this would be subject to the notification to the Commission.

3. A starting point for discussions for a *threshold* would be 5% of the RNI per 100g product (10 micrograms folic acid/100g product; 15% of the RDA[1]/100g is need for a content claim (see Board paper FSA 07/05/04)) which would mean that products that were less 3.3% flour would not require labelling if a fortification dose of 300 micrograms/100g went ahead. This does not take into account issues such as process losses that would need to be considered.

[1] RDA is the Recommended Daily Amount which is 200 micrograms for folate. This is equal to the Reference Nutrient Intake (RNI).

4. The Agency is currently preparing to consult publicly on a number of domestic pieces of legislation that do not fully implement EU in preparation for the EU review of food labelling that is underway. It is possible the current exemption for micronutrients added under the BFRs (1998) will not continue. Industry is aware of this. They are keen that if they are required to label folic acid then the implementation of this coincides with a removal of the current national provisions and hence any requirement to label the four micronutrients already added to flour. This could be considered. With regard to timescales, it is expected that a draft proposal will be published by the Commission by the end of this year and new EU legislation by 2010. In theory, industry would have until the new legislation comes into force to bring in labelling changes with regard to the nutrients currently added to flour, although there is nothing to stop them bringing in labelling changes sooner than this if they choose to, for example, together with the labelling of folic acid in the event that this requirement comes in sooner.

Trade

5. From a legal point of view mandatory fortification of flour should not constitute a trade barrier (see Board paper FSA 07/05/04) once the new EU rules are fully in place (2009). However industry is concerned that consumers may choose not to buy fortified products in other countries and this will effect trade. This is a particular concern if they are required to label folic acid.

6. The BCCCA confirmed that they currently do not label fortificants already added to flour and raised concerns about trade effects due to national rules or, should labelling be required, because of consumer resistance in other EU countries (about half of their exports are to the EU). Although BCCCA are uncertain about the impact on trade they feel it would be a huge risk. They thought that it would be unlikely that their Members would switch to imported flour as this would require increases in storage capacity.

7. Foods fortified with folic acid are marketed in most countries in the EU.

ANNEX 5

PRODUCTION AND TRADE: FACTS AND FIGURES

Flour, Bread and Biscuit/Cake Industry

Flour

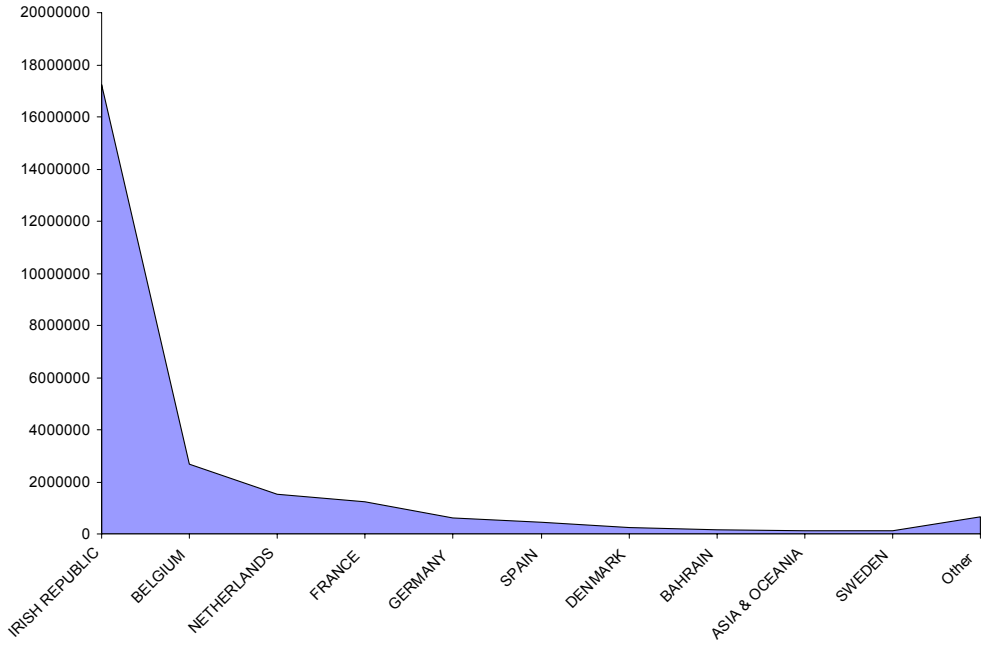
- About 4.4 million tonnes of flour is produced in the UK (at a value of just under £1 billion / year), about 3% of which is exported; an amount equal to about 1% of domestic production is imported.

- In 2006 value of imports was £14.7 million, the value of total exports was £22.8 million.

Item	**Production (Tonnes, 2006)**	**Amount Imported (Tonnes, 2006)** ***[% of Production]***	**Amount Exported (Tonnes, 2006)** ***[% of Production]***
Flour	4,430,000	65,683 [*1.48%]*	114,737 *[2.59%]*

- In 2005, 65% of all UK exports of flour went to the Republic of Ireland.

UK Flour Exports 2005 by Value (£)



Biscuits/Cakes

- BCCCA estimate that cakes and biscuits account for approximately 90% of their members' output.

Item	Production (£, 2006)	Amount Imported (£, 2006) *[% of Production]*	Amount Exported (£, 2006) *[% of Production]*
Sweet biscuits	1,453,697,039	147,757,041 *[10.16%]*	170,454,080 *[11.73%]*
Cakes and cake bars	1,233,317,150	371,616,472 *[30.13%]*	130,933,622 *[10.62%]*

- Exports of cakes and biscuits equal roughly 10% of production.

- BCCCA states half of biscuits (not including retailer branded biscuits) are exported to the EU and the other half to the rest of the world. Of the half exported outside the EU, 20% goes to the US.

- UK export of sweet biscuits: 64% to the EU; 12% to North America; 9% to Asia and Oceania and 6% to the Middle East and North Africa.

- UK export of cakes and cake bars: 90% to the EU; 1.5% to North America; 3.7% to Asia and Oceania and 2.1% to the Middle East and North Africa.

- There is industry concern that in addition to the situation within the EU, trade to the Middle East and North Africa may be adversely affected by folic acid fortification.

- Protein levels in biscuits and pastry ranges from 8.5 to 10%, Fruit cakes contain 11% protein.

Bread

- The estimated value of UK bread sales is £1.96 billion.

- UK bread export market represents approximately 2.9% of this figure at £56 million whilst imports of £87 million are recorded (4.4%).

- HMRC trade data shows that over 98% of UK bread imports (by value) come from the EU and 94% of our bread exports are currently bound for the EU. The next largest trading block to import UK bread is the Middle East and North Africa, these account for less than 2% of UK bread exports.

- Federation of Bakers stated 15 million loaves are exported a year (other doughs etc are extra), 100,000 tonnes of bread. Most of the bread exported is used for food service and sandwiches.

ANNEX 6

MANDATORY FORTIFICATION WITH FOLIC ACID: COSTS & BENEFITS OF THE VARIOUS POLICY OPTIONS

1. This document aims to set out the costs and benefits of various approaches to mandatory fortification of food with folic acid. Specifically, the following policy options are considered:

    - (1) Mandatory fortification of all flour (excluding wholemeal flour) with folic acid

    - (2) Mandatory fortification of only white and brown 'bread-making flour' with folic acid

    - (3) Mandatory fortification of bread with folic acid

2. We aim to set out which of the above policy options is most cost-beneficial, balancing policy benefits (in terms of a reduced number of Neural Tube Defects) against policy costs (such as costs to industry and potential health downsides). It should be noted that all cost-benefit analyses in this document assume that (i) wholemeal flour is not fortified and (ii) voluntary fortification of breakfast cereals and fat spreads is restricted.

(1) Mandatory fortification of all flour (excluding wholemeal) with folic acid

3. This policy option was modelled in the Partial Regulatory Impact Assessment (Partial RIA). All flour (excluding wholemeal flour, so as to preserve an element of consumer choice) would be fortified with folic acid in the flour mill. Specifically, folic acid would be added to the existing mix of fortificants (niacin, thiamine, iron and calcium) that is currently legally required to be added to all non-wholemeal flour.

The following analysis assumes a fortification rate of 300 micrograms folic acid per 100 grams flour.

Benefits

4. As with all of the policy options, the benefits of this option are in terms of a reduced annual total of Neural Tube Defects (NTDs). The goal of our analysis is to identify a monetary value for this policy benefit. Using the Scientific Advisory Committee on Nutrition (SACN) report issued in December 2006, we take as a

starting point the estimated lower bound of the annual reduction in NTD pregnancies[1].

5. The full methodology for identifying the monetary value of the benefits is stated in the Partial RIA; a summary is presented here. The first step of the analysis is to decompose the estimated reduction in NTD pregnancies into three categories:

   (i) Still births and neo-natal deaths averted,

   (ii) Cases of spina bifida with a standard life expectancy, averted and

   (iii) Terminations averted.

6. The second step is to identify a monetary value for each case of (i) to (iii) averted. A Disability Adjusted Life Year (DALY) methodology is used to find a monetary value for (i) and (ii); this methodology identifies a discounted value for the number of life-years saved, and places a monetary amount of £30,000 on each life-year to capture averted pain grief and suffering, saved productivity and (to an extent) saved NHS costs. Each case of (i) averted is judged to equal 29.4 DALYs (after discounting), giving a monetary value of £881,940 per case, whereas each case of (ii) averted is judged to equal 16.2 DALYs (again, after discounting), giving a monetary value of £486,816 per case[2]. Lastly, the NHS reference cost for a termination is used to identify a benefit of £542 for each termination ((iii) above) averted.

7. The analysis results in a monetary benefit of **£13.1 million per annum**. The table in Appendix A gives greater detail on how this result was calculated, including the number of cases of (i) to (iii) averted. Summary results for other fortification rates are also presented.

8. It should be noted that because milling firms are already required to fortify flour with niacin, thiamine, calcium and iron, UK millers already have the capital equipment and expertise to carry out folic acid fortification. They are therefore in a position to carry out fortification reliably, which adds certainty to the above monetary benefit figure.

Costs

9. *Costs to the UK flour milling industry:* Because of the existing requirement for millers to fortify their flour with four nutrients (as discussed in the previous

[1] This number varies depending on the fortification rate being modelled; higher fortification rates yield a higher reduction in NTD prevalence. Here, as stated, we consider a fortification rate of 300 micrograms folic acid per 100 grams flour.

[2] The monetary value for (ii) is lower than for (i) because the individual now has a fully healthy life (as opposed to a life of disability); the methodology judges this to be a lesser benefit than in scenario (i), where the individual now has a fully healthy life (instead of no life at all).

paragraph), the only cost to the milling industry of folic acid fortification is that of purchasing sufficient folic acid to add to the existing nutrient mix. This enhanced mix would be added to the existing hopper (and feeder)[3] in the existing manner, with fortification occurring (as is currently the case) at the end of the milling process.

10. It is not legally required for the aforementioned four fortificants to be added to wholemeal flour. Therefore, if wholemeal flour is also exempted from folic acid fortification, no change would be needed to current business practices for wholemeal flour; no cost will be imposed here.

11. We note (as in the Partial RIA) that certain small additional costs will be faced by each firm. These include familiarisation with what is required of them under the policy and then a potential administrative burden in terms of keeping records demonstrating compliance. There is also a search cost for each firm to identify a suitable folic acid supplier. However, we do not currently quantify these costs; they are likely to be very small, especially at the economy-wide level due to the small number of firms affected (59 mills[4]; the UK flour milling industry is relatively concentrated).

12. We can therefore conclude that the cost to the flour milling industry will largely equal the cost of purchasing the folic acid itself. Using production data from the Defra Flour Millers Survey[5], we compute that 12,650 kilograms of folic acid would be required to fortify all UK flour production (excluding wholemeal flour) to the required level. At a price of £40 per kilogram, the total cost to the UK milling industry would be **£506,000 per annum**.

13. *Enforcement costs to HM Government:* The Local Authorities Coordinators of Regulatory Services (LACoRS) have stated that 100-200 samples per annum would be required, and that this would cost in the region of **£10,000 per annum (total)**.

14. *Trade:* In 2006 the UK exported approximately £23million's worth of flour (65% of which was to Ireland). This represented just over 2.5% of UK flour production. In terms of biscuits and cakes the UK exported just over £301million's worth of products in 2006 (11% of production) and in 2005 it exported £56million's worth of bread (2.9% of production).

15. To the extent that the UK's trading partners would be less likely to import its flour and flour-based products post folic acid fortification then these are the magnitudes of the main markets obviously at stake. It is not possible to

[3] 'Hopper' is used to refer to the device that stores the fortificant mix and gradually releases it into the flour.
[4] National Association of British and Irish Millers (NABIM); see http://www.nabim.org.uk/nabimmembers.asp
[5] See http://statistics.defra.gov.uk/esg/index/list.asp?i_id=022

accurately estimate potential trade effects at this stage but we can note that countries already fortifying products (either voluntarily or by regulation) with folic acid (e.g. the USA) are less likely to take an adverse view than certain areas where such fortification may be less welcome, e.g. industry groups inform the Agency that Middle Eastern markets may be quite averse to fortification.

16. *Potential health downsides:* Because this is a reliable means of achieving folic acid fortification that covers a broad group of foods, this policy option is best able to control (i.e. minimise) the proportion of the population consuming more than 1 milligram of folic acid per day. This minimises the risk of health downsides (and associated monetised costs) including Vitamin B12 anaemia and colorectal cancer.

17. *Choice:* This policy provides one means through which consumers can avoid folic acid fortification: the exemption of wholemeal flour. To the extent that some consumers may be willing to pay for greater choice, the lack of any further choice could be regarded as a cost of this policy option.

18. *Labelling:* Because this policy option covers the widest range of products, it has the greatest potential labelling implications. A threshold approach could be adopted (such that products containing more than a certain threshold of folic acid must be labelled). The precise number of Stock Keeping Units (SKUs) potentially affected by such an approach is difficult to identify (although, of course, more SKUs will be affected if the threshold is higher); there are around 500,000 SKUs in the biscuit and cake industry alone[6]. It should be noted that labelling changes occur regularly for most products; if sufficient notice is given to manufacturers, there should be a minimal cost of adding folic acid to a label if that label were to be changed commercially in the near future anyway. However, we note that some products (for example, traditional products) do not experience regular (e.g. every 18 months) labelling changes; the British Retail Consortium (BRC) consider a cost of up to £1,000 per SKU for a label change that does not form part of the usual renewal cycle to be realistic. We also note that costs may be imposed on firms for testing whether or not their product meets any specified threshold. Lastly, labelling costs may be particularly significant for small businesses. It is further noted that industry would be keen to see any folic acid labelling requirements be made in unison with any labelling requirements of other nutrients as a result of possible modification of the bread and flour regulations. As such it is not currently possible to attribute any potential final labelling costs to this policy analysis in a stand-alone manner.

[6] This figure includes SKUs destined for export, but excludes SKUs of retailer-branded ('own-brand') products

(2) Mandatory fortification of only white and brown 'bread-making flour' with folic acid

19. This policy option is similar to the option modelled above (in that it occurs at the milling stage), but is different in that only 'bread-making' flour would be fortified.

20. In order to establish roughly the same population daily increase in folic acid as fortifying all white and brown flour at 300ug/100g (78ug folic acid per day) it would be necessary to fortify white and brown bread flour only at about 450ug/100g (resulting in 83ug folic acid per day). As such for illustrative purposes the following analysis considers fortification rates of both 300 and 450 micrograms folic acid per 100 grams flour.

Underlying practical problems

21. This approach assumes that it is simple to identify (at the mill) which flours are destined for bread-making, so that folic acid can be added to those flours only. Because certain flours are milled to order for bakery firms, these flours can be clearly identified as 'bread-making flour' (and fortified accordingly). However, the miller is not aware of the final use of all the flour that they produce (for example, even an indirect indicator such as the flour's protein strength[7] is not always a certain indicator of final use); this makes it difficult to target fortification only at 'bread-making flour'. Some flour that is eventually used to make bread may therefore escape fortification, whilst some 'bread-making flour' may be used to make non-bread products, resulting in those products being unintentionally fortified.

Benefits

22. The monetary benefits for Option 2 are calculated using the same methodology as in Option 1. However, because only bread-making flour (as opposed to all non-wholemeal flour) is fortified, the overall dose of folic acid under this policy option (at 300 micrograms) is reduced. At 300 micrograms this significantly reduces the number of averted NTD pregnancies per annum, and lowers the monetary value of the benefits accordingly. Whilst benefit figures for 450 micrograms folic acid per 100 grams flour are produced, as is explained at Appendix B it is unlikely to be possible in practice to fully achieve these average intake-based benefits by increasing the dose of folic acid in bread-making flour alone due to the likely distribution of population bread consumption. In addition, such dose increases in bread (making flour) further the risk that some segments of the population will consume excess folic acid (with the potential associated health downsides)[8].

[7] It might be argued that flour with higher protein strength is best suited to bread-making.
[8] As noted at Appendix B, 450ug bread/bread flour fortification is associated with over 900,000 more people possessing intakes below the RNI compared to 300ug fortification across all flour (excluding

23. The analysis results in a benefit of **£7.3 million per annum** for 300 micrograms folic acid per 100 grams flour and **£14.5 million per annum** for 450 micrograms, which represent respectively a 44% reduction and an 11% increase in the benefits figure for Option 1 (£13.1 million per annum); but again we must note the caveats relating to this second benefit estimate. The table in Appendix B gives greater detail on how these results were arrived at, including the number of cases of each type of NTD pregnancy averted. Summary results for different fortification rates are also presented in this annex.

Costs

24. *Costs to the UK flour milling industry:* The first element of the cost to the UK flour milling industry is, as with Option 1, the cost of purchasing the folic acid itself. Because a smaller sub-section of flour is being fortified, the cost will be lower as less folic acid will be required. Using Defra Flour Millers Survey data, we calculate that 7,280 kilograms of folic acid will be required to fortify white bread-making and brown bread-making flour (as defined in the data) at 300 micrograms. At a cost of £40 per kilogram of folic acid, this works out to be **£303,000 per annum**. The equivalent figure for 450 micrograms is **£455,000 per annum**.

25. Again, we note that the small administrative burdens and search costs mentioned in Option 1 will also apply here. As stated earlier, they should be minimal, especially at the economy-wide level due to the small number of UK flour milling firms.

26. However, unlike with Option 1, this policy option will require some significant capital expenditure. In consultation with the National Association of British and Irish Millers (NABIM), we have identified the process through which folic acid fortification of only bread-making flour might be carried out. Firstly, note that any given flour mill may be used to mill both bread-making and non-bread-making flour. The existing hopper (filled with the current four-nutrient mix) would remain in use when non-bread making flour is being processed. As it is not possible to empty this hopper without releasing its contents into the flour, a second hopper would be required to contain and introduce the separate (folic acid-including) fortificant mix for bread-making flour. This second hopper would be used instead of the original hopper when processing bread-making flour. The second hopper comes at a cost (estimated by NABIM) of at least £20,000 per mill. To the extent that some mills would not have easy access to space for these new hoppers there may be need for redesign, even if such space can be made available. These further considerations lead to the costs potentially increasing to up to £100,000 per mill if substantial changes are required to the mill's set-up. As there are 59 UK mills, this represents a **one-off capital cost of between**

---

wholemeal) and it also yields an approximately 80,000 person increase in those exceeding the daily UL of folic acid (compared to 300ug across all flour).

£1,180,000 and £5,900,000[9]. There may also be some expenditure or time lost for training staff to use the new dual-hopper system in addition to possible management difficulties in embedding the new system.

27. In addition any potential system whereby the same flour specification could be produced where the end use was known; (either for bread making and thus with folic acid added, or for other products and thus not fortified at the mill with folic acid), would not only create operational complexity but would involve very significant capital investment in both bulk and bagged flour storage.

28. *Enforcement costs to HM Government:* As with Option 1, the Local Authorities Coordinators of Regulatory Services (LACoRS) have stated that 100-200 samples per annum would be required, and that this would cost in the region of **£10,000 per annum**.

29. *Trade:* The UK exported just over £301million's worth of biscuit and cake products in 2006 (11% of production) and in 2005 it exported £56million's worth of bread (2.9% of production). By allowing flour destined for biscuit and cake manufacture to remain free of folic acid fortification there is the scope for any potential adverse trade effects to be negated in these markets. However the bread and a large proportion of the flour export markets still have the potential to be affected.

30. *Potential health downsides:* As with Option 1, because adding at the milling stage is a reliable means of achieving folic acid fortification, this policy option is able to control (i.e. minimise) the proportion of the population consuming more than 1 milligram of folic acid per day. This minimises the risk of health downsides (and associated monetised costs) including Vitamin B12 anaemia and colorectal cancer.

31. *Choice:* This policy option provides greater choice than Option 1 (which excludes fortification of wholemeal flour), as even fewer products are compulsorily fortified. This might be regarded as a lesser cost to choice than in Option 1 (to the extent that consumers are willing to pay for greater choice).

32. *Labelling:* This policy option has the potential to result in smaller labelling costs than Option 1, as it would only affect products containing white or brown bread-making flour (rather than all products containing non-wholemeal flour). It would need to be decided whether only bread (and bread-like products) should be labelled, or whether labelling should be extended to other products containing bread-making flour (potentially subject, as before, to some kind of threshold). As with the previous policy option, the impact of labelling costs can be reduced (or even removed) by giving industry sufficient notice; folic acid-related changes

[9] When allocating these "one-off" costs in the cost-benefit tables to follow we will assume an effective five-year life of any capital investments.

can then be implemented alongside other commercially planned changes to the label. However, as before, some firms will face a cost at the margin, as not all product labels are changed regularly; the British Retail Consortium (BRC) consider a cost of up to £1,000 per SKU for a label change to be realistic.

(3) Mandatory fortification of bread with folic acid

33. This policy option assumes that bread itself (not the flour that is used to make it) would be fortified with folic acid. The fortificant would be added in the bakery.

The fortification rate for bread is assumed to be equivalent (in terms of overall intakes) to the fortification rate suggested for bread-making flour, i.e. rates of both 300 and 450 micrograms folic acid per 100 grams flour.

Underlying practical problems

34. The definition of 'bread' itself is unclear. For example, it is unclear whether products such as doughnuts, croissants and so on would be classified as 'bread'. The analysis below uses the National Diet and Nutrition Survey (NDNS) definition of bread[10].

Benefits

35. The monetised value of the benefits for this policy option is identified using the same methodology as before. As with Option 2, this option involves the fortification of a smaller group of foods (when compared with Option 1), so the overall dose of folic acid is significantly reduced at 300 micrograms. This again lowers the number of NTD pregnancies averted per annum (and the associated monetary benefit)[11].

36. Given that the fortification rate in bread would be set such that it is the same (in terms of overall intake) as the fortification rate for bread-making flour, the NTD reduction benefits are also the same. The results are shown in Appendix B. The analysis results in a benefit of **£7.3 million per annum** for 300 micrograms folic acid per 100 grams flour and **£14.5 million per annum** for 450 micrograms, which represent respectively a 44% reduction and an 11% increase in the benefits figure for Option 1 (£13.1 million per annum); but again we must note the caveats at Appendix B relating to this second benefit estimate.

37. Furthermore, we note that the process of fortifying bread with folic acid is complex, as it involves adding a very small quantity of folic acid to the product.

[10] The NDNS definition is a statistical one, and is not necessarily appropriate for identifying which bread-like products should be fortified.

[11] As with Option 2, offsetting the reduced NTD benefits (by increasing the dose in bread) is not possible without increasing the number of people that may be exposed to more than one milligram of folic acid per day. This may lead to negative health impacts.

Unlike in the UK milling industry, many bakers do not already have the capital equipment or skills to fortify bread with folic acid. Although expenditure on capital equipment and training will help to mitigate this, there remains the possibility that some bakeries will fail to fortify at the specified level due to the difficulty of the task. The likelihood of a certain number of failures is further increased by the fact that there are many more bakeries than millers[12], with many bakeries being small businesses. If these failures result in bread being fortified (on average) at a rate lower than stated above, or if fortification is forgotten or ignored entirely, the possible NTD benefits (and their associated monetary value) will be reduced accordingly.

Costs

38. *Costs to the UK baking industry*: As stated above, the bakery industry do not already have the capital equipment or skills to carry out folic acid fortification. Consultation with the Federation of Bakers (FoB) suggests that the cost of measuring equipment and suitable training for staff could exceed £1,000 per bakery. As the industry has around 4,000 firms, this represents a **one-off cost of at least £4 million[13]**.

39. The larger number of baking firms creates other problems in that the previously mentioned costs of familiarising firms with the legislation and the administrative burdens - i.e. of keeping records demonstrating compliance – are likely to be significantly larger (in total) than for millers. This also holds true for the aforementioned search costs. This is because there is less potential to exploit scale economies – 4,000 firms needing to familiarise with new legislation is likely to impose a significantly larger cost than 59 firms needing to familiarise, for example.

40. To calculate the overall costs to the UK baking industry, the costs of purchasing the folic acid needed to fortify bread needs to be added to the figures given above. These costs would be at least as large as those of fortifying bread-making flour as noted in Option 2 and would probably be in reality larger given the lack of scope and scale economies in buying open to 4000 bakeries compared to the more concentrated mixing and milling industries. To be conservative we use the Option 2 figures.

41. *Enforcement costs to HM Government:* The cost of £10,000 per annum stated in Option 1 was based on 100-200 samples per year. If folic acid were added at

[12] The UK milling industry consists of 59 firms, whereas the ONS publication 'UK Business: Activity, Size and Location' (2006) states that there are around 3,100 bakery firms in the UK. The latter number is known to be an underestimate as the ONS publication relies on VAT and PAYE data, which are not available for the smallest firms. A more accurate estimate of 4,000 bakery firms in the UK is given by the National Association of Master Bakers (NAMB); see http://www.masterbakers.co.uk/wiki/doku.php?id=careers

[13] As noted, when allocating these "one-off" costs in the cost-benefit tables to follow we will assume an effective five-year life of any capital investments.

the bakery stage, a larger number of samples would need to be taken due to the larger number of firms (4000 firms versus 59 mills). If we scale up by a factor of 68 to adjust for the higher number of firms in the baking industry, total costs to HM Government would be **approximately £680,000 per annum.**

42. *Trade:* The UK exported £56million's worth of bread (2.9% of production) in 2005. By not fortifying either flour or biscuit and cake manufacture with folic acid there is the scope for any potential adverse trade effects to be negated in these markets. However the bread export markets still have the potential to be affected.

43. *Potential health downsides:* It was noted earlier that fortification at the bakery stage is likely to be less reliable than fortification at the milling stage. This may result in excess folic acid being added in some cases, potentially increasing the number of people consuming more than one milligram of folic acid per day (and increasing the potential risk of Vitamin B12 anaemia and colorectal cancer). Although we do not quantify this potential health downside here (due to insufficient information), we note that the **pain, grief and suffering (and the equivalent monetary value) are likely to be significant should such events come about**.

44. *Choice:* This option offers a similar level of choice to Option 2, as only bread is intended to be fortified. It might be argued that this option facilitates greater choice, as folic acid will be more precisely targeted at bread[14]; there is less chance of folic acid being added to non-bread products.

45. *Labelling:* This policy option would result in similar labelling costs to the previous policy option (fortification of bread-making flour). As before, given sufficient notice, some labelling costs will be marginal given that the label would have been changed in commercial cycles anyway. For label changes that are not part of the usual cycle, the British Retail Consortium (BRC) consider a cost of up to £1,000 per SKU for a label change to be realistic.

Issues surrounding fortification of organic flour

46. NABIM state that around 40,000 tonnes of UK flour production (1% of total UK production) is organic. There are around six mills dealing with organic flour in the UK, many of which are smaller plants; some are pure specialists in organic flour, whereas for others organic flour represents a significant (although not complete) share of their business.

47. *Potential impact on benefits:* Exempting organic flour may slightly reduce the projected reductions in NTD pregnancies (and the associated monetary benefit). Given that organic flour only represents around 1% of UK production,

[14] It is noted above that it is difficult to identify exactly which flours constitute 'bread-making flour'.

this effect will be small. We note that this may not remain the case if organic flour grows in popularity over time.

48. *Feasibility of exempting organic flour:* Because the rules surrounding organic certification require that organic produce is kept separate from other produce, it would be feasible to exempt the fortification of organic flour.

49. *Potential cost to industry of exempting organic flour:* Organic flour is not exempted from the current legal requirement to add niacin, thiamine, calcium and iron. In an organic-producing mill, the existing hopper would therefore be used (along with the existing fortificant mix) in order to produce organic flour without added folic acid. However, plants that also process non-organic flour would nonetheless be required to add folic acid to that flour. This would require an extra hopper (containing the new fortificant mix, including folic acid) for use when producing non-organic flour. As mentioned above, such hoppers have a cost of £20,000 to £100,000 per mill, depending on the ease of adding the extra hopper into the existing factory set-up.

Summary tables (Appendices A and B) of measurable costs and benefits

50. The annexed tables below summarise the measurable costs and benefits that have been set out in this document. In addition a summary discussion of those not quantifiable follows in the conclusion regarding the most likely net beneficial option for fortification with folic acid.

Conclusion

51 As can be seen in the Annexes, the annual net benefits associated with Options 2 and 3 at the 300 micrograms per 100g flour fortification level only reach about a half of those gleaned by Option 1.

52 In order for the Options 2 and 3 to marginally exceed the modelled net benefits of Option 1 (see the shaded rows of Appendix B) they require fortification of folic acid in bread to reach 450 micrograms. As is explained these modelled increased positive benefits at this much higher bread fortification rate are anyway likely to be illusionary due to their average intake-based modelling nature.

53 In addition the 450ug fortification rate for bread (and bread flour) also yields two further negative characteristics. Firstly 450ug bread/bread flour fortification is associated with more people possessing intakes below the RNI compared to 300ug fortification across all flour (excluding wholemeal) and it also gives an increase in those exceeding the daily UL of folic acid (compared to 300ug across all flour).

54. **Given these arguments it is likely that on balance (and in reality) the fortification of all flour (excluding wholemeal) at 300 micrograms per 100g flour is the most demonstrably cost-beneficial policy option (Option 1) for folic acid fortification. It attains understood monetised net benefits at a level not achieved by Options 2 or 3 without introducing further potential health concerns by significantly increasing the concentration of fortification within one defined food, bread.**

55. Turning to the policy effects that are not currently quantifiable, we note that Option 3 would be likely to increase the potential scope for either too much or too little folic acid to be added to bread at the bakery stage compared to the more concentrated milling stage where nutrient addition is already part of the process.

56. Decisions still to be considered regarding threshold levels, timings of any changes and possible modifications of the bread and flour regulations all act to make it currently impossible to attribute any potential final labelling costs to this policy analysis.

57. In terms of providing consumers with increased choice to avoid fortification of products with folic acid should they so wish to, Options 2 and 3 focusing on bread only increases this choice over Option 1's wholemeal products choice provision. To the extent that some consumers may be willing to pay for this greater choice, the relative lack of choice under Option 1 could be regarded as a cost of this policy option. However quantifying this potential cost would be very difficult and time consuming.

58. In terms of both the familiarisation of firms with new regulations and any subsequent administrative burdens relating to demonstration of compliance it would be sensible to assume that the smaller the group of affected firms the less the overall costs to industry would be. As such Options 1 and 2 hold the advantage over number 3 here as there are only 59 UK millers compared to approximately 4000 bakers.

59. Finally turning to potential trade issues it is noted that to the extent that the UK's trading partners would be less likely to import its flour and flour-based products post folic acid fortification then there are some potentially significant UK export markets to be considered - including approximately £23million's worth of flour, just over £301million's worth of biscuit and cake products and £56million's worth of bread.

60. As explained it is not possible to accurately estimate potential trade effects at this stage but to the extent that Option 1 involves all UK flour being fortified (excluding wholemeal) then it has the potential to have the highest impact. Next ranked is Option 2 which excludes non-bread making flour and the least likely (negative) impact on trade is yielded by Option 3 – fortification of bread alone.

APPENDIX A OPTION 1

ANNUAL RESULTS TABLE ASSUMING FORTIFICATION OF ALL FLOUR (EXCLUDING WHOLEMEAL FLOUR)

Also assumes no voluntary fortification of breakfast cereals and fat spreads

Fortification rate (micrograms per 100g flour)	Category of life saved	Number of cases within this category	Monetary benefit per individual in this category	Total monetary benefit for all individuals of this category
300	Still birth / neo natal death	11	£881,940	£9,340,338
	Spina bifida with standard life expectancy	8	£486,816	£3,707,875
	Terminations	59	£542	£31,866
			Total benefit:	**£13,080,079**

Fortification rate (micrograms per 100g flour)	Total number of lives saved	Total monetary benefit associated with these lives saved	Total costs (folic acid addition and LA costs)	Net benefit after cost
0	-70	-£11,890,981	£0	-£11,890,981
100	-14	-£2,378,196	£178,520	-£2,556,716
200	35	£5,945,490	£347,040	£5,598,450
300	77	**£13,080,079**	**£515,560**	**£12,564,519**
450	126	£21,403,766	£768,340	£20,635,426

APPENDIX B OPTIONS 2 AND 3

ANNUAL RESULTS TABLE ASSUMING FORTIFICATION OF ALL BREAD-MAKING FLOUR (EXCLUDING WHOLEMEAL BREAD-MAKING FLOUR) - Option 2, *OR* **FORTIFICATION OF ALL BREAD (EXCLUDING WHOLEMEAL BREAD) – Option 3**
Also assumes no voluntary fortification of breakfast cereals and fat spreads

Fortification rate (micrograms per 100g flour)	Category of life saved	Number of cases within this category	Monetary benefit per individual in this category	Total monetary benefit for all individuals of this category
300 (450)	Still birth / neo natal death	6 (12)	£881,940	£5,291,640 (£10,583,280)
	Spina bifida with standard life expectancy	4 (8)	£486,816	£1,947,264 (£3,894,528)
	Terminations	31 (64)	£542	£16,802 (£34,688)
			Total benefit:	**£7,255,706 (£14,512,496)**

Fortification rate (micrograms per 100g flour)	Total number of lives saved	Total monetary benefit associated with these lives saved	Total costs (folic acid addition, minimum capital spend and LA costs)	Net benefit after cost
0	-70	-£11,890,981	£0	-£11,890,981
300 – Option 2	**41**	**£7,255,706**	**£549,000**	**£6,706,706**
450 – Option 2	**84**	**£14,512,496**	**£701,000**	**£13,811,496^***
300 – Option 3	**41**	**£7,255,706**	**£1,783,000**	**£5,472,706**
450 – Option 3	**84**	**£14,512,496**	**£1,935,000**	**£12,577,496^***

^ The NTD calculation is based on the average daily increase in folic acid for women of childbearing age across the population, therefore increasing fortification of white and brown BREAD flour from 300-450ug/100g might not reach any more women with poor intakes (those at risk of NTDs) particularly if they are not bread consumers, but simply "top up" those with sufficient intakes. As such this benefits figure has the distinct probability of being optimistic as to likely NTD reductions – the outturn figure may well be lower in terms of real health benefits.

*** Not only is this net benefit figure smaller than that pertaining to the 300ug fortification rate for all flour, but it also yields two further negative characteristics. Firstly 450ug bread/bread flour fortification is associated with over 900,000 more people possessing intakes below the RNI compared to 300ug fortification across all flour (excluding wholemeal) and it also yields an approximately 80,000 person increase in those exceeding the daily UL of folic acid (compared to 300ug across all flour).**