Consultation on Options to Increase Folate Intakes of Young Women

Background on NTDs, Folate and the SACN Report

1. The term “neural tube” describes the boney ring that surrounds and protects the nerves of the spinal cord. A NTD is caused when, in the early stages of pregnancy, the bones in the spinal column of the foetus fail to form properly, leaving a gap or a split in the neural tube and resulting in damage to the central nervous system.

2. There is strong evidence that an increased intake of the vitamin folate prior to conception and during the first twelve weeks of pregnancy can reduce the risk of a NTD developing. Since the 1990’s, Health Departments have advised women who could become pregnant to take folic acid (the synthetic form of folate) supplements before conception and for the first twelve weeks of pregnancy, and to increase their intake of naturally folate-rich foods. However, research suggests that only around a quarter of women follow this advice. This is due in part to around half of pregnancies being unplanned.

3. In 2000, SACN’s predecessor, the Committee on Medical Aspects of Food and Health (COMA) published a report on *Folic Acid and the Prevention of Disease,* concluding that the universal folic acid fortification of flour would significantly reduce the number of conceptions and births complicated by NTDs. Following a stakeholder consultation process, the Agency’s Board considered the issue at its May 2002 open meeting, at which it decided not to recommend fortification at that time primarily because of concerns about the potential risks to elderly with a vitamin B_{12} deficiency and also because of the limitations to consumer choice. UK Health Ministers agreed to this recommendation.

4. In 2004, SACN was asked to assess the evidence that had arisen since the previous COMA review, and advise on any gaps in the evidence base, with particular reference to potential risks to the elderly. SACN published their draft

report for consultation in November 2005. In response to comments raised in the consultation, and the emergence of preliminary reports suggesting that higher folate intakes may affect cancer risk, SACN requested further information and the opportunity to consider these issues. Following this further consideration, as well as input from the independent Committee on Carcinogenicity, SACN agreed the final report at its October 2006 meeting. SACN have recommended mandatory fortification of flour with folic acid, subject to action to reduce intakes from voluntarily fortified foods, advice on the use of supplements containing folic acid to consumers and a programme to monitor effects on folate intakes, status and health. Mandatory fortification would improve the folate status of the population, particularly young women, and so would reduce the risk of NTD-affected pregnancies.

5. The SACN report endorses COMA's earlier recommendation for mandatory fortification of flour, and also includes the recommendation that separate action is taken to address the incidence, prevalence and management of vitamin B_{12} deficiency in older people.

6. Further details of SACN's main conclusions and recommendations, can be found in the *Folate and the Prevention of Disease* report on SACN's website at: http://www.sacn.gov.uk/reports/

Appendix 1.

Disability Adjusted Life Years and Their Use in the Calculation of Benefits

1.1.1. Introduction

An initial attempt at valuing the benefits of fortification centred on the projected resource savings to the NHS through reduced lifetime treatment costs. This method, however, does not sufficiently reflect the true social benefit of the intervention; it does not quantify the gains associated with reduced pain, grief and suffering, nor does it consider the productivity gains associated with decreased morbidity or mortality.

The next step was to attempt a more comprehensive approach to determining the true social benefit (which includes the factors mentioned above) using, amongst other resources, the Department for Transport's transport-focused Value of Life study[1]. This is a useful starting point for determining the benefit of an intervention that is meant to prevent morbidity and mortality, but still further work was necessary in order to generate a more representative valuation for the policy under consideration.

Health Adjusted Life Year (HALY) models have been used by a variety of organisations, ranging from the World Bank to the National Institute for Heath and Clinical Excellence (NICE). Although primarily a cost-effectiveness tool, they are of some use in cost benefit analysis. Primarily two types of HALY exist: the Quality Adjusted Life Year (QALY) and the Disability Adjusted Life Year (DALY).

The QALY is the traditional tool used by NICE in its analyses, and is based on a simple product of a health state weight (where 0 represents death, and 1 full health) and the number of years lived in that health state. Each QALY represents one life-year enjoyed. For example, an individual living three years of full health enjoys three QALYs, whereas another individual who lives one year of full health followed by two years of diminished health (e.g. with a health state weight of 0.5) enjoys only 1 + 0.5

[1] Department for Transport (2004), Highways Economics Note No. 1. Available online at http://www.dft.gov.uk/stellent/groups/dft_rdsafety/documents/page/dft_rdsafety_610642.hcsp

+ 0.5 = 2 QALYs. The health state is determined through analysis of patient and public surveys, and is adjusted to illustrate that as an individual gets older, the highest attainable health state will diminish gradually.

Whilst similar in appearance, and indeed likely similar in outcome, the DALY takes a different approach based on the view of health professionals (as opposed to patients and the public) about the disability weight of illness, in light of the evidence and experience available. Whereas QALYs signify life years enjoyed, DALYs illustrate life years lost due to ill health; disability weights are used to illustrate the severity of a health state, where 0 represents zero disability, and 1 represents death[2]. Since the disability weight is designed such that it does not degenerate over time (for example, an individual in perfect health at aged 80 still enjoys zero disability), an additional age weight is introduced.

Although QALY based analysis has been favoured by HM Government, the availability of evidence, in part due to the analysis (notably the disability weights) undertaken by Access Economics Pty Ltd[3]. on behalf of Food Standards Australia New Zealand (FSANZ), means a DALY centric approach will be pursued here. In order to ensure there are no issues regarding copyright or IP protection, FSANZ and Access Economics were contacted; they are happy for us to use their disability weights, which were themselves based on an earlier study.

1.1.2. The DALY Calculation

The number of DALYs that a person currently enjoys at a given age *x*, assuming that the onset age of the disease in question is zero (as is the case with NTDs), is determined by the following formula:

$$DALY_x = \frac{D_x w_x}{(1+r)^x}$$

Where D_x = disability weight at age x

w_x = age weight

[2] It has been suggested, as with QALY weights, that there may exist states that are "worse than death". This is part of a wider debate about the nature of health weights; we do not consider it here.

[3] Access Economics Pty Ltd. for Food Standards Australia New Zealand (2006), Cost-Benefit Analysis for Fortifying the Food Supply with Folic Acid. Available online at http://www.foodstandards.gov.au/_srcfiles/P295%20Folic%20Acid%20Fortification%20DAR%20Attach%2011.pdf

r = discount rate

x = age at period x

The Net Present Value (NPV) of the DALYs experienced by an individual sufferer is obtained by summing the discounted DALY value (as obtained from the above formula) for each year occurring between the present time and the end of the sufferer's life. This NPV can then be monetised by multiplying by a given amount per DALY, in order to give the total monetary amount of pain, grief and suffering averted for each individual (plus a productivity component). The economy-wide monetised gain is of course equal to the aforementioned monetised NPV per individual, multiplied by the number of individuals affected.

The following three subsections discuss the disability weight, the age weight and the discount rate in greater detail.

1.1.2.1. D_x, Disability Weight

As mentioned above, DALY disability weights represent the severity of an illness, and range from 0 (no disability) to 1 (full disability/death). The weights are determined by medical professionals and academics; examples include a weight of 0.463 for Appendicitis, and a weight of 0.110 for Epilepsy[4].

Although DALY disability weights are not based on an individual's own valuation of health (as with QALYs), and are therefore arguably less suitable than QALYs (due to the fact that they do not reflect the individual's preferences), there is likely to be a strong correlation between the two. Differences may further drop out when comparing the disability and health state weights for two particular illnesses. Here, we attach a disability weight on anencephaly, spina bifida and encephalocele of 0.52, following Mathers et. al (1999). Neo-natal deaths and stillbirths are by definition accorded a disability weight of one. A more detailed discussion can be found in Appendix 2.

[4] Mathers et. al (1999), The Burden of Disease and Injury in Australia. Available online at http://www.aihw.gov.au/publications/health/bdia/bdia.pdf

1.1.2.2. W_x, Age Weight

In line with the established DALY methodology[5], we have introduced an age weight using the formula $w_x = Cxe^{-\beta x}$

Where C = a constant equal to 0.16243

β = a constant equal to 0.04

e = the exponential constant 2.718282…

As explained earlier, the DALY methodology uses an age weight to correct for the fact that the disability weights, unlike the full health state in the QALY methodology, do not degenerate with age.

1.1.2.3. Discount Factor

In order to determine the value of future DALYs in today's terms, and in line with established economic theory and the Green Book guidance on social time preference, we must discount DALYs that occur in the future. In line with Green Book guidance, we use a discount rate of 3.5% from year 0 to year 30, 3.0% from year 31 to year 75, and 2.5% from year 76 onwards.

1.1.3. Applying the DALY Calculation

Our application of the DALY methodology takes as a starting point the number of NTD pregnancies averted in any given year (for a given level of fortification). The number of NTD pregnancies averted for each scenario have been taken from the final SACN report (chapter 8). Note that the lower-bound figures are used here; if the higher bound figures were used, the benefits would of course be substantially larger. Using a set of conditional probabilities derived from NTD incidence data, the number of pregnancies are split into three categories: (i) stillborn or neo-natal deaths prevented, (ii) individuals who would have lived a standard life expectancy under illness, prevented and (iii) terminations prevented. The first two are computed in DALY terms and then monetised, and the third element is monetised using resource savings to the NHS.

[5] World Bank (2000), The Disability-Adjusted Life Year (DALY) Definition, Measurement and Potential Use. Available online at http://www.worldbank.org/html/extdr/hnp/hddflash/workp/wp_00068.html

The subsequent three subsections discuss the derivation of the conditional probabilities, the DALY weights for the two categories outlined above, and the monetisation of the total number of DALYs gained.

1.1.3.1. Deriving conditional probabilities from NTD incidence data

Our conditional probabilities are derived from the NTD incidence data presented in a publication by the Office for National Statistics (2001)[6]. The data covers three types of Neural Tube Defect: anencephaly, spina bifida and encephalocele. For the years 1995-99[7], the number of cases of NTDs in England and Wales can be recorded as follows:

[6] National Statistics (2001), Health Statistics Quarterly: Trends in Neural Tube Defects. Available online at http://www.statistics.gov.uk/downloads/theme_health/HSQ10_v3.pdf

[7] This is the most recent period under observation. This has also been chosen, rather than an average over all the available periods, because by this time Department of Health advice on folic acid intake had become firmly established.

Table 1: NTD Incidence 1995-1999 for England and Wales

	NTD Pregnancies					
	Of which Live Births			Of which Still Births	Of which Terminations	Overall NTD Pregancy Total
	Live Births SLE	Live Births NND	[SLE + NND] Total **(1)**	Total **(2)**	Total **(3)**	**[=(1)+(2)+(3)]**
All NTD Types	210	160	370	132	1621	2123
Of which Anencephaly	0	**90**	90	**68**	**807**	965
Of which Spina Bifida	202	**48**	**250**	**55**	**676**	981
Of which Encephalocele	8	**22**	**30**	**9**	**138**	177

Note: NND denotes ‘neo-natal death’ and SLE denotes ‘standard life expectancy’.

Figures displayed in bold have been drawn directly from the source; the other figures have been derived as follows. Firstly, for each type of NTD, the number of individuals living a standard life expectancy has been calculated by subtracting the number of neo-natal deaths from the total number of live births[8]. Totals for the overall number of pregnancies for each NTD are then computed by summing the number of live births, the number of individuals living a standard life expectancy and the number of terminations associated with the NTD in question. Lastly, totals for all NTD types are calculated for the number of live births, the number of individuals experiencing a standard life expectancy and the number of terminations. Here, each total is computed by adding together the number of anencephaly, spina bifida and encephalocele pregnancies. The original data also contains these totals; we have chosen to compute them ourselves in order to eliminate the error[9] in the original data (the three NTD categories do not exactly add up to the stated total). This modification ensures that our conditional probabilities (detailed further below) sum to one. Despite this change, it is expected that the numbers above provide a good idea of the relative number of NTD cases within each category.

To compute the conditional probabilities from the data given above, we divide each cell in the above table by the overall NTD pregnancy total for all NTD types (i.e. 2123). The results are as follows:

[8] The total number of live births for anencephaly has been adjusted so that it equals the number of neo-natal deaths, thus reducing the number of individuals with anencephaly and a standard life expectancy to zero. This is because although the original data are empirically correct, it is an unfortunate truth that anencephaly results in the lack of a functioning cerebrum. This permanently rules out the possibility of gaining consciousness and often results in a very short life expectancy. For the purposes of this model, the writer has made the judgement that no conceivable “normal life” or standard life expectancy could ever be enjoyed in these unfortunate incidents.

[9] The errors are extensively discussed in the original paper under the heading ‘Data Quality’.

Table 2: Conditional Probabilities (Percentage) Relating to NTD Pregnancies, 1995-1999 Data for England and Wales.

	NTD Pregnancies					
	Of which Live Births			Of which Still Births	Of which Terminations	Overall NTD Pregancy Total
	Live Births SLE	Live Births NND	[SLE + NND] Total **(1)**	Total **(2)**	Total **(3)**	**[=(1)+(2)+(3)]**
All NTD Types	9.8917	7.5365	17.4282	6.2176	76.3542	100.0000
Of which Anencephaly	0.0000	4.2393	4.2393	3.2030	38.0122	45.4545
Of which Spina Bifida	9.5148	2.2610	11.7758	2.5907	31.8417	46.2082
Of which Encephalocele	0.3768	1.0363	1.4131	0.4239	6.5002	8.3373

So, for example, there is a 76% chance that a pregnancy will be terminated, given that it is affected by an NTD. Additionally there is a 10% chance that a given pregnancy will suffer from spina bifida but will enjoy a standard life expectancy (given that the pregnancy is affected by an NTD), and a 4% chance that a pregnancy will suffer anencephaly and die within 4 weeks of birth (again, given that the pregnancy is affected by an NTD). We appreciate that the above probabilities are nonetheless imperfect; they do not cover the whole of the UK (only England and Wales), and further changes in the (ongoing) termination debate may alter the probabilities stated.

As stated earlier, the above conditional probabilities have been used to determine the number of (i) stillborn or neo-natal deaths prevented, (ii) individuals who would have lived a standard life expectancy under illness, prevented and (iii) terminations prevented for a given number of NTD pregnancies. For (i), the number of pregnancies is multiplied by the sum of the highlighted cells in the 'Live Births NND' and 'Still Births' columns; for (ii), the number of pregnancies is multiplied by sum of the highlighted cells in the 'Live Births SLE' column, and for (iii) the number of pregnancies is multiplied by the sum of the highlighted cells in the 'Terminations' column. Because the highlighted cells sum to 100%, the number of pregnancies calculated in categories (i), (ii) and (iii) must sum to the total number of NTD pregnancies that we begin with.

1.1.3.2. Disease types, life expectancy and the age weight

As stated earlier, we quantify potential DALY benefits for (i) stillborn or neo-natal deaths prevented and (ii) individuals who would have lived a standard life expectancy under illness, prevented. Because we use the same disability weight of 0.52 for anencephaly, spina bifida and encephalocele (and a weight of 1 for each category in the event of death), the potential DALY benefits for each type of NTD in category (i) (and, separately, category (ii)) are the same. Further information on the two categories that we examine is presented below:

(i) We consider individuals who do not live a standard life expectancy because they are either still born or die within a few weeks of birth. As stated earlier, a disability weight of 1 is applied in this case. It is suggested

therefore that the potential DALY benefit directly measures the estimated number of years of life (with zero disability) that would have been enjoyed by the individual had they not suffered an NTD.

(ii) We also consider individuals that live a standard life expectancy with a disability; under this situation, individuals live a full life but suffer the conditions under discussion (spina bifida or encephalocele). As mentioned before, the disability weight used here equals 0.52. The welfare 'gap' between this condition and a condition of zero disability is represented by the potential DALY benefit.

We have not computed the DALY benefits to those that are terminated following identification of a neural tube defect. Instead, we add up the savings to the NHS through a reduced number of termination procedures (see the Monetisation section). We note that the methodology in category (i) could be (additionally) applied to these cases. However, as the policy option is anyway clearly demonstrated to be cost-beneficial the potential extension of the benefits calculations in this regard can remain moot. If it were to be added into the calculations, it would substantially increase the value of the monetised benefits of the policy.

Note also that we assume a combined average life expectancy of 79 years for men and women. In situation (i), the DALY formula computes a total (undiscounted) benefit of 83 DALYs. This is inconsistent with our life expectancy assumption; to resolve the problem, we have applied a proportional adjustment factor to the age weight so as to limit the (undiscounted) DALY benefit in this case to 79 years.

1.1.3.3. Monetisation

The value people place on a QALY is uncertain. A figure of £30,000 however seems appropriate in this context. This figure comes from different sources: the value NICE is widely believed to apply as a passmark in appraisal of health technologies; a

recent study of air pollution for DEFRA[10]; and a study for DoH of willingness to pay for a QALY, which takes as a starting point the DfT value of a statistical life[11].

Given this figure relating to a year of perfect health's intrinsic value, we here apply the same figure of £30,000 to each discounted DALY. Whilst noting that the QALY analyses that yield this figure essentially capture the value of averted pain, grief and suffering and the consumption of individuals, they also incorporate a productivity component, i.e. production over and above own consumption that an average person in full health can produce. To the extent that NTD sufferers may tend on average to gain less than the national average wage in the labour market and in some cases require family/friend-provided care there is scope for the productivity element of this QALY/DALY figure to be too low in the case of NTD analysis. In addition, this figure does not take into account the wider health care costs associated with NTDs. These include treatment and health professional costs as well as home/vehicle etc adaptation costs to aid the mobility and quality of life of an NTD sufferer. To this extent there is further scope for the QALY/DALY figure of £30,000 to be a significant underestimate of the true monetised benefits of prevented NTD-DALYs within the current analysis. But, as is noted, the policy options whose monetised benefits are based upon DALY analysis are able to be demonstrated as significantly cost-beneficial without the need to further consider these potentially significant additional beneficial impacts of productivity and health care costs.

It was stated earlier that we also compute the total resource savings to the NHS resulting from a reduced number of termination procedures. The NHS reference cost of a termination has been identified as £542[12]; to calculate the overall saving, this figure is multiplied by the number of terminations averted.

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[10] http://www.defra.gov.uk/environment/airquality/airpoll_health/index.htm

[11] Mason H, Marshall A, Jones-Lee M, Donaldson C for the Social Value of a QALY Project Team. Estimating a willingness to pay based value of a QALY from existing contingent valuation studies of prevented fatalities. 2004.

[12] The combined 2005 reference cost schedules for NHS Trusts and PCTs (see http://www.dh.gov.uk/assetRoot/04/13/32/28/04133228.xls) were used to compute this figure. The figure is an average (weighted by the number of Fixed Consultant Episodes) of 'Surgical Termination of Pregnancy' and 'Medical Termination of Pregnancy' for each of Elective In-Patient (TELIP), Non-Elective In-Patient (TNELIP) and Day Case (TDC) data.

1.1.4. Monetised results

Our results for the two categories (i) and (ii) are presented below.

(i) For the category (i) scenario regarding still births and neo-natal deaths, the benefit is equivalent to 79 years (i.e. a full life expectancy) of zero disability over each individual's lifetime. In present value terms, this is equivalent to 29 years of life with zero disability (i.e. 29 DALYs). Following monetisation which reflects the value of averted pain, grief and suffering (plus a productivity component), this is equivalent to around £882,000 per individual. This result is consistent with the idea that the stillborn baby or a baby who does not survive very long after birth will not have a chance of living anything close to their full life expectancy.

(ii) Based on the calculations, the benefit to an individual in category (ii), who would have lived a standard life expectancy and suffered spina bifida under the base case, but is no longer an NTD sufferer, is equivalent to gaining 44 years of life with zero disability over their lifetime (i.e. 44 DALYs). When discounted into present day terms, prior to monetisation and comparison with costs of the policy, this figure is equal to just over 16 years (i.e. 16 DALYs). Lastly, the monetised benefit (which reflects the value of averted pain, grief and suffering, alongside a productivity component) is equivalent to around £487,000 per individual. Already at this stage, we start to see that the benefits to fortification will significantly outweigh the costs.

The annual benefits per year are computed by multiplying the number of individuals in each of category (i) and category (ii) with the appropriate monetised DALY figure. The resource benefits to the NHS in terms of a reduced number of abortion procedures (calculated by the reduction in the number of procedures, multiplied by the cost per procedure) are then added to the sum of the annual benefits, in order to give a final annual total.

A full table of results is provided in Appendix 3.

Appendix 2. Disability Weights

The disability weights used in this analysis are taken from Mathers et al (1999)[13] and are themselves based on a Dutch study published by the Department for Public Health in the Netherlands.

Comparable British literature on both disease weights and their potential application to spina bifida in the UK was not available, hence the use of a foreign study. Given that Australia has similar levels of health and standard of living to the UK (pre-fortification), the Australian disability weights used are likely to be similar to their 'true' values for the UK.

The Mathers et. al (1999) disability weights are also used in the cost-benefit analysis performed for Food Standards Australia New Zealand (FSANZ) by Access Economics (2006)[14]. The weights are quoted as follows:

Condition	**Disability Weight**
Anencephaly: Liveborn cases	1.000
Spina Bifida Low Level	0.160
Spina Bifida Medium Level	0.500
Spina Bifida High Level	0.680
Encephalocele	0.520

We use the anencephaly and encephalocele disability weights as quoted above. Following the FSANZ study, we also use an average of the three levels of severity of spina bifida (weighted by prevalence) that are presented in the table above.

[13] Mathers et al. (1999), The Burden of Injury and Disease in Australia. Available online at http://www.aihw.gov.au/publications/health/bdia/bdia.pdf

[14] Access Economics Pty Ltd. for Food Standards Australia New Zealand (2006), Cost-Benefit Analysis for Fortifying the Food Supply with Folic Acid. Available online at http://www.foodstandards.gov.au/_srcfiles/P295%20Folic%20Acid%20Fortification%20DAR%20Attach%2011.pdf

Condition	Proportion	Weight
Low spina bifida	0.10	0.160
Medium spina bifida	0.60	0.500
High level spina bifida	0.30	0.680
Weighted average		0.52

Appendix 3.

Cost-benefit analysis results table

Presented overleaf.

Per Year Effects on the UK population of mandatory fortification of all flour with folic acid INCLUDING fortification of wholemeal flour

Fortification level of folic acid ug/100g flour (level in food after processing)	Estimated NTD pregnancies prevented per year Lower Bound Estimate	Stillborn or Neo Natal Deaths prevented		Individuals who would have lived SLE under illness, prevented		Individuals who would have been terminated, prevented		**Total** Monetised DALY Benefit, per year, £K	Fortification of White and Brown Bread Flour Cost	Fortification of Wholemeal Flour Cost	Fortification of Biscuit and Cake Flour Cost	Fortification of All Other Flour Cost	Monitoring Cost (Inspections)	Other costs (Label checking, Data monitoring, Labelling costs, admin costs)	Total Cost	Net Benefit (Annual)*, £K
		Number	DALY Benefit	Number	DALY Benefit	Number	NHS Expenditure averted									
Includes folate and folic acid from all sources (including estimates of overage)																
BASELINE - 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	47	6	190	5	75	36	19	7984	101	9	24	43	10	0	187	7796
200	91	13	368	9	146	69	38	15458	202	18	49	86	10	0	365	15093
300	126	17	509	12	202	96	52	21404	303	27	73	129	10	0	542	20861
450	175	24	708	17	281	134	72	29727	455	40	110	194	10	0	809	28919
Excluding folic acid from fortified breakfast cereals and fat spreads																
0	-70	-10	-283	-7	-112	-53	-29	-11891	0	0	0	0	0	0	0	-11891
100	-7	-1	-28	-1	-11	-5	-3	-1189	101	9	24	43	10	0	187	-1377
200	42	6	170	4	67	32	17	7135	202	18	49	86	10	0	365	6770
300	84	12	340	8	135	64	35	14269	303	27	73	129	10	0	542	13727
450	140	19	566	14	225	107	58	23782	455	40	110	194	10	0	809	22973
Excluding folic acid from fortified breakfast cereals, fat spreads and supplements																
0	-91	-13	-368	-9	-146	-69	-38	-15458	0	0	0	0	0	0	0	-15458
100	-28	-4	-113	-3	-45	-21	-12	-4756	101	9	24	43	10	0	187	-4944
200	28	4	113	3	45	21	12	4756	202	18	49	86	10	0	365	4391
300	70	10	283	7	112	53	29	11891	303	27	73	129	10	0	542	11349
450	126	17	509	12	202	96	52	21404	455	40	110	194	10	0	809	20595

Per Year Effects on the UK population* of mandatory fortification of flour with folic acid EXCLUDING fortification of wholemeal flour

Fortification level of folic acid ug/100g flour (level in food after processing)	Estimated NTD pregnancies prevented per year Lower Bound Estimate	Stillborn or Neo Natal Deaths prevented		Individuals who would have lived SLE under illness, prevented		Individuals who would have been terminated, prevented		**Total** Monetised DALY Benefit, per year, £K	Fortification of White and Brown Bread Flour Cost	Fortification of Wholemeal Flour Cost	Fortification of Biscuit and Cake Flour Cost	Fortification of All Other Flour Cost	Monitoring Cost	Other costs (Label checking, Data monitoring, Labelling costs, admin costs)	Total Cost	Net Benefit (All other years)*, £K
		Number	DALY Benefit	Number	DALY Benefit	Number	NHS Expenditure averted									
Includes folate and folic acid from all sources (including estimates of overage)																
BASELINE - 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	42	6	170	4	67	32	17	7135	101	0	24	43	10	0	179	6956
200	82	11	332	8	132	63	34	13929	202	0	49	86	10	0	347	13582
300	114	16	461	11	183	87	47	19365	303	0	73	129	10	0	516	18850
450	163	22	659	16	262	124	67	27689	455	0	110	194	10	0	768	26921
Excluding folic acid from fortified breakfast cereals and fat spreads																
0	-70	-10	-283	-7	-112	-53	-29	-11891	0	0	0	0	0	0	0	-11891
100	-14	-2	-57	-1	-22	-11	-6	-2378	101	0	24	43	10	0	179	-2557
200	35	5	142	3	56	27	14	5945	202	0	49	86	10	0	347	5598
300	77	11	311	8	124	59	32	13080	303	0	73	129	10	0	516	12565
450	126	17	509	12	202	96	52	21404	455	0	110	194	10	0	768	20635
Excluding folic acid from fortified breakfast cereals, fat spreads and supplements																
0	-91	-13	-368	-9	-146	-69	-38	-15458	0	0	0	0	0	0	0	-15458
100	-35	-5	-142	-3	-56	-27	-14	-5945	101	0	24	43	10	0	179	-6124
200	21	3	85	2	34	16	9	3567	202	0	49	86	10	0	347	3220
300	63	9	255	6	101	48	26	10702	303	0	73	129	10	0	516	10186
450	112	15	453	11	180	86	46	19026	455	0	110	194	10	0	768	18257

ANNEX G

Further questions on which we would welcome your views

Views on a public health campaign to encourage supplement uptake.

2.A. What should this public health campaign look like? In particular, how would it be different from previous campaigns that have had limited success?

2.B. How can the Agency and Government ensure that the campaign messages reach those women most at risk of NTD-affected pregnancy?

2.C. What recommendations should the Agency make to Health Departments about campaigns which make use of existing networks and resources (such as local health services, local food initiatives, schools etc.) to deliver messages?

2.D. What could the Agency and Government do to ensure that the immediate impact of any campaign is maintained in the longer term?

If your recommendation is for option 3 – Encourage voluntary but structured fortification of foods.

3.A. How should the Agency determine the food categories in which fortification is to be encouraged, and the appropriate levels?

3.B. Are there any categories of foods in which fortification with folic acid should be specifically discouraged?

3.C. What incentives should be considered to encourage the uptake of fortification amongst industry?

3.D. How might consumers be encouraged to choose fortified products? Should a logo such as the folate flash[15] be used?

3.E. How could consumers, particularly those most at risk (such as young women with poor diets), be encouraged to choose fortified products?

3.F. Unrestricted voluntary fortification could lead potentially to uncontrolled high intakes of folic acid for some individuals. How could this issue be addressed?

If your recommendation is for option 4 – Mandatory fortification of flour or bread.

4.A. Should the fortification requirements apply to: bread, all flour, flour for bread use; or flour to which the current fortification requirements of the Bread and Flour Regulations (1996) apply?

4.B. What should the required fortification level be?

4.C. Do you have any comments on the Agency's assessments of the technical difficulties and likely costs for industry and enforcers provided in the Regulatory Impact Assessment produced by the Agency?[16]

4.D. What steps might be taken to prevent excessive amounts of overage being used – for instance by the agreement of an enforcement concordat?

4.E. What transitional arrangement should be made for the coming into force of any requirements – what should be the length of any transitional period?

4.F. What issues might there be for the export of UK produced flour and foods containing flour – and how might these be overcome?

[15] Former UK Health Education Authority (HEA)

[16] This can be downloaded from www.food.gov.uk/consultations/

4.G. What provision should be made for consumers wishing to avoid fortified products – how might food labelling be used to enable them to do so?

4.H. Should the Agency issue advice to industry to limit the voluntary fortification of other foods, such as breakfast cereals and low fat spreads, with folic acid?

4.I. The availability of fortified products may detract from the health message on supplementation. What steps could the Agency take to prevent this?

4.J. What provision might be made for ceoliac[17] sufferers and others who do not eat wheat based flour and bread products?

4.K. What advice should be issued to industry and consumers about consumption of supplements containing folic acid, by those at risk of high folic acid intakes?

4.L. What actions should be considered to address the prevalence of vitamin B_{12} deficiency among older people?

4.M. What cost implications might there be for businesses?

[17] Coeliac disease is an auto-immune disease, where gluten causes the body to produce antibodies which attack the gut.

ANNEX H

Executive Summary and conclusions of Consumer Research on Folate[18]

Background

1. Current Government advice is that women who may become pregnant should take a folic acid supplement to reduce the risk that their baby will develop a Neural Tube Defect (NTD) such as spina bifida. However, the policy of advice has not achieved a reduction in NTD rates in recent years.

2. In November 2005, the independent Scientific Advisory Committee on Nutrition (SACN) agreed its draft report *Folate and Health*, in which it recommends that flour should be fortified with folic acid in order to achieve the desired reduction in NTD-affected pregnancies[19]. The Board of the Food Standards Agency discussed the draft SACN report at its April 2006 open meeting[20], and agreed to hold a public consultation on options to increase population folate intake (including mandatory fortification as recommended by SACN). In order to inform subsequent discussions, the Board also agreed that qualitative research should be undertaken to gather consumers' views on these options:

Option 1: To continue with current Government advice

Option 2: To run a public education campaign to encourage women to take folic acid supplements

Option 3: To encourage food companies to fortify more foods with folic acid on a voluntary basis.

Option 4: To introduce mandatory fortification of flour with folic acid.

The Research

[18] Draft – once finalised, the full report will be available on the Agency website

[19] The report is published on the SACN website and can be downloaded from www.sacn.gov.uk

[20] The Paper discussed by the Board can be viewed at www.food.gov.uk/multimedia/pdfs/fsa060405.pdf

3. The main challenge identified in the planning of this research was the high degree of technical detail necessary to enable an informed discussion among participants. A two-stage deliberative process was therefore developed, and was successful, in allowing participants to be carefully briefed, and providing sufficient time for them to explore the issues in detail. Participants' views on the options were also tracked throughout the process which provided an insight into how participants' views evolved as they received further information and had the opportunity to reflect on what they had heard.

4. Five pairs of consumer workshops were held across the UK. Twelve adults of all ages took part in each workshop. Participants from all social economic backgrounds, were included, with an even male/female ratio. In addition to the workshops, four paired depth interviews with women from black and minority ethnic groups (BME's) were conducted.

Research outcomes

5. Participants' initial response was to view NTDs seriously, and there was a majority view that some action from Government was warranted. Throughout the deliberative process however, a small but consistent part of the sample favoured the status quo because they felt that this was a proportionate response given the number of people affected.

6. Participants were first introduced to the options towards the end of the first deliberative session, at which point they had been briefed on the benefits of folate in reducing NTD-affected pregnancies, and on the possible risks associated with increased folate intake. At this stage, the option of a renewed public education campaign (option 2), had the most support, with less than 2 people per group on average, favouring any kind of additional fortification, and only three people among the five groups favouring a mandatory approach.

7. Participants' preferences were check again at the beginning of the second session with self completion questionnaires that had been completed at home.

By this stage, they had had the opportunity to read more detailed information provided in their briefing packs, discuss the issue with friends and family, and to reflect on the earlier session. There was a significant swing away from the education campaign (option 2) and towards fortification. It appears that the reason for this was that participants came to doubt that other options i.e. educational and / or voluntary options, would be successful in reducing NTD rates rather than because their anxieties about fortification were completely resolved.

8. At the end of the second session, participant's final preferences were checked. There had been a further shift towards mandatory fortification (option 4), with more support for this than any other option, and with around two thirds of participants now favouring some kind of fortification. However, the strong opposition towards option 4 persisted among some participants throughout the process.

9. Discussions were extremely wide ranging, however three themes were frequent in the discussions, and impacted on participants' final preferences.

10. Participants spent a good deal of time attempting to gain a clear understanding of the nature and extent of the potential risks attendant on higher folate intake; and reaching a judgement on where (if at all) a balance could be struck between these and the more obvious benefits. There was a clear expectation among participants that these issues would be adequately considered by 'Government'. These discussions suggest that it will be important to communicate to consumers not just the risk factors, but also that a rigorous and balanced risk assessment process had been conducted. It is clear that consumers would also expect the eventual policy to include active measures to manage these possible risks. This might include, for example, a programme of B12 and bowel cancer screening, coupled with adequate monitoring of population folate intakes.

11. The high proportion of unplanned pregnancies was consistently seen as an obstacle to the success of any policy reliant on behaviour change, and therefore instrumental in persuading the supporters of mandatory fortification. Many saw this as a compelling argument for a targeted, vigorous education campaign – aimed as much at reducing unplanned pregnancies *per se* as NTD rates.

12. Issues of consumer choice were discussed in two broad themes – that of the personal and practical; and in more broad ethical terms. There was an almost unanimous view that full labelling of folic acid added to food was essential to enable those consumers who wished to avoid additional folate intake to do so. For many participants this labelling was seen as answering any ethical concerns inherent in mandatory fortification. It must be recognised however that in the event of mandatory fortification being taken forward, a small but significant minority would oppose it strongly on the grounds that it reduced consumer choice, whether or not they perceived there to be additional risks.

13. The view expressed in interviews with black and ethnic minority participants mirrored the wide range of views voiced by the main sample. These results suggest that ethnicity or faith grouping is not associated with a particular view on this issue.

Implications of the research outcomes

14. The study showed that this is a complex issue and opinions of participants changed as time was spent considering the different options for improving the folate status of young women. The results suggest that the initial response of consumers may be overwhelmingly against fortification of foods, especially on a mandatory basis (option 4). However, access to further information and the opportunity to deliberate may persuade more consumers of the merits of further fortification. However, even among consumers who have had the opportunity to reach an in depth understanding of the issues involved, more than half opted

not to support mandatory fortification (option 4). Around a third of participants did not support any type of fortification (option 3 or option 4).

Summary

15. The research was successful in stimulating a highly informed discussion by participants with little or no previous knowledge of this complex and technical issue.

16. The majority of participants saw NTDs as a serious and significant problem, and supported (at least in principle) action by the Government to address the issue.

17. By the end of the deliberative process, no single option was supported by the majority of participants. However, more participants supported mandatory fortification (option 4) than any other option, with the remaining support split fairly evenly among the other options.

18. There was a shift towards Option 4 as the research progressed. This was usually because participants came to believe that this was the option most likely to achieve the desired outcome i.e. (an improvement in NTD rates) rather than because their anxiety about the risks involved was satisfied.

19. Some participants retained a strong opposition to Option 4. In most cases this was because they considered the potential risks involved to be unacceptable or because they felt strongly that consumer choice should be maintained.

20. Option 1 - maintaining the status quo - was supported by a number of participants, either because it brought no additional risks or because it was a low cost option. However, a large number came to reject this option as the research progressed, because they did not believe it would be effective in reducing the rate of NTD-affected pregnancies.

21. Option 2 – an education campaign – received strong initial support. Support declined as the research progressed, and as participants became less convinced of its likely effectiveness. This option was also considered by many to be an important supporting element to option 3 or 4.

22. Option 3 – encouraging voluntary fortification - was favoured by some as a less risky and less radical option than mandatory fortification. Those who did not support this option were either opposed to fortification *per se*, or preferred the more structured approach of option 4.

23. Participants did not feel that lack of consensus should prevent the Agency from moving forward on this issue. Participants recognised that, in a complex area such as this, consensus was not always possible.

24. It was clear that participants would wish and expect to be informed of any significant change of strategy in this area, especially if mandatory fortification was chosen.

25. There was a clear expectation that any increase in fortification (whether on a voluntary or mandatory basis) would be monitored and regulated by an official body to prevent high folate intake by those consumers to whom potential risks may apply.

26. In the event of further fortification, whether on a voluntary of mandatory basis, there is a strong demand for the fortificants to be clearly labelled.

27. Views expressed in black and ethnic minority interviews were wide ranging, yet similar to participants in the main sample.

ANNEX J

Executive summary of literature review on approaches to increasing uptake of folic acid by women of reproductive age

Background

1. Current government advice is that in order to reduce the risk that their baby will develop a neural tube defect (NTD), like spina bifida, "All women who could become pregnant are advised to take 400 micrograms a day of folic acid as a medicinal or food supplement prior to conception and until the twelfth week of pregnancy".

2. In 1996 the National Health Promotion Agency in England, the Health Education Authority, launched a three year integrated programme to increase the consumption of folic acid in women of childbearing age. Although the original campaign was developed for England, it was adapted and work implemented in the other three countries of the UK. This work succeeded in raising awareness and increasing use of folic acid supplements to some extent. However, it was less successful for younger women, those in lower socio-economic groups, and women from some minority ethnic groups.

3. Data from recent national surveys indicates that around 55% of women planning their pregnancy take supplements or change their diet in increase folate intake prior to pregnancy. Around half of pregnancies in the UK are unplanned, therefore this suggests that only about 25% of women take folic acid as recommended before becoming pregnant.[21]

The purpose of this work

[21] Blake M, Herrick K & Kelly Y (2003) Health Survey for England 2002:Maternal and Infant Health. The Stationery Office, London.

4. The aim was to carry out three complementary reviews, to provide a research basis for improving the use of folic acid supplements in the UK, particularly in low-income and younger groups of women.

- *The purpose of the first review was to gain a picture of the types of initiatives which are successful in encouraging women to take a positive action in order to reduce a possible future risk, for example behaviour such as attending screening, eating fruits and vegetables, or practising contraception.*

- *The second review examined the effectiveness of various approaches to preconception care.*

- *The third review looked at research that aimed at encouraging women, particularly those who are younger or from low-income groups, to take folic acid in the periconceptual period.*

The key findings

5. Very few relevant research studies have been undertaken in the UK, or elsewhere. This means that many of the findings are from other countries, and may not be applicable in the UK context. In addition many studies only collected results for a short time after the intervention, so it is difficult to say how sustained any effects were.

6. Work has previously been carried out on the characteristics of effective health promotion interventions, and these include using a 'package' of complementary components using different communication channels, locations, and health promotion approaches, and also sustaining the intervention over a long period of time. The importance of these characteristics for effective interventions was re-enforced by the findings of all three of the reviews.

7. The first review covered several diverse topics. Generally the most effective approaches: targeted high risk groups; worked with families, peers, and organisations/places which provided access to the target groups; and included practical steps to make the 'positive action' easier.

8. The second review found little research based evidence on approaches to effective preconception care, although increasingly policies and guidance for preconception care have been developed in countries around the world. The health and social care structures in those countries with most research and/or preconceptual polices or guidance are very different to those in the UK, e.g. in terms of the availability, setting and timing of preconception care contact with women, which limits the applicability of much of the work that was identified. Nevertheless, there is some evidence from the USA that preconception care can have a positive impact on health behaviours, including folic acid uptake. For this to happen in the UK would need changes to structures within the health care system, and to training and ongoing support for health professionals.

9. The third review covered awareness and knowledge of folic acid, as well as sources of folic acid information, descriptions and results of integrated national or regional campaigns, and the results of research trials. The main findings were: -

- Uptake (as recommended) reported by pregnant women and new mothers, ranged from 7% to 53%. There are some factors that are particularly associated with lower awareness and rates of uptake. One of the most important of these is the link with unintended pregnancy. The UK has about 50% unplanned pregnancies.

- Other factors which were identified as being associated with lower awareness and uptake include: lower household income; lower educational attainment; being a lone parent or unemployed or from a lower socio–economic group or younger or from other racial/ethnic groups; lacking awareness/knowledge of

the potential benefits, not being convinced of efficacy; and having a less healthy lifestyle.

- The most common sources of information about folic acid tend to be mass-media advertising, magazines, newspaper articles and family and friends. Although health professionals are usually cited less frequently, their advice is regarded as more credible. Generally, family doctors seem to be a more frequent source of advice than other health professionals, including midwives. In the UK practice nurses appear to be the group who are asked most frequently about folic acid.

- Four integrated campaigns were identified which appear to have been successful in increasing uptake of folic acid supplements to some extent. These four campaigns were carried out in South Australia, Canada, the Netherlands, and in England. In Australia, there was no evidence that the effects would be sustained. In Canada, it was noted that even at the end of the study there was 'considerable room for improvement' (in uptake of folic acid supplements). In the Netherlands, there was particular concern about reaching women in lower socio-economic groups. Two other campaigns were reported, from Germany and from South West Virginia, where the effects of the interventions were limited. In Germany, awareness of the need to take folic acid supplements before pregnancy was significantly higher after the campaign than before but this did not result in a significant increase in supplement use. In South West Virginia, awareness of the benefits of folic acid was significantly higher after the campaign than before but knowledge about the need to take folic acid before and during pregnancy did not increase.

- The English campaign (1996-1999) was also adapted for and implemented in the rest of the UK. Evaluation of the campaign in England showed (amongst other things) that between 1995 and 1998, spontaneous awareness of folic acid among women of child-bearing age increased from 9% to 49%, with prompted awareness increasing from 51% to 89%, whilst the percentage of

pregnant women and new mothers claiming to have taken folic acid when trying for a baby, rose from 24% to 38%.

- Research trials indicate that: a) printed resources and the mass media used in isolation are not effective in the longer term, particularly for vulnerable groups; b) the health care system is well placed to provide advice on preconceptual folic acid, and it also appears to have potential to be effective. However, the preliminary conclusions from the limited number of trials which have been carried out, is that advice needs to be embedded in a structure (e.g. preconceptual counselling) and delivered in a committed and relevant way; c) using a health claim may also make it easier for women to identify relevant foods and supplements.

- There are important gaps in the research literature, which are described in detail in the report.

Conclusions

10. From these reviews it seems likely that efforts to increase supplement intake will have a limited effect. At the end of the UK campaigns, only 38% of pregnant women, asked retrospectively, said they had taken folic acid supplements. This, together with data from the other national and regional campaigns, indicates that even high quality and intensive national campaigns apparently result in under half of women in the target group taking supplements. Based on the information available, it also seems that campaigns have the potential to exacerbate inequalities in folic acid use between women in lower and higher socio-economic groups. If campaigns or programmes are undertaken, they should include elements that specifically target women in vulnerable groups. To achieve and maintain an effect, they need to be based on good health promotion practice, and to be sustained over a long period of time.

DRAFT PARTIAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1. This Regulatory Impact Assessment considers the potential impact of a proposal for the mandatory fortification of flour or bread with folic acid in the UK.

2. Purpose and intended effect of the measure

(i) Objective

2.1. The primary objective of the proposed measure is to increase the folate intake and improve the folate status of women of childbearing age in the UK in order to reduce the incidence of neural tube defect (NTD) affected pregnancies.

(ii) Background

Folic acid and folate

2.2. Folic acid is the synthetic form of the B vitamin folate. Folate is found naturally in green leafy vegetables, such as brussel sprouts and spinach. Folic acid is not found naturally but is used in the voluntary fortification of food, primarily breakfast cereals and reduced/low fat spreads, and in supplements in the UK.

2.3. Folate is important for the production of healthy cells, particularly during periods of rapid cell division and growth, such as in very early pregnancy (particularly the first 28 days), foetal development and infancy. Folate deficiency can slow growth rate in infants and children and can cause anaemia in adults. Poor folate status in early pregnancy has been associated with greater risk of NTDs.

2.4. Although current dietary intakes of folate are generally sufficient to meet recommended daily requirements, they are not optimal for protecting against the risk of NTD-affected pregnancies. National nutrition surveys show that folate status can be marginal, particularly among young women and adults aged 65 years and over. Therefore these groups would particularly benefit from any policy that succeeds in improving the folate status of the general population.

Folate and neural tube defects

2.5. NTDs are a family of birth defects caused by failure of the neural tube to close properly very early in foetal development, resulting in damage to the central nervous system. This can cause a range of conditions, from anencephaly, where the brain does not develop at all, to spina bifida, where the spinal cord does not develop properly. Anencephaly is fatal, but most infants with spina bifida survive, in some cases with major lifelong physical disabilities, requiring corrective surgery in addition to intellectual impairment on occasion. NTDs are usually diagnosed at pre-natal screening, following which women are offered elective termination.

2.6. There are about 700-900 NTD-affected pregnancies in the UK per year (live births, still births and therapeutic abortions)[22], with many more affected foetuses being lost as spontaneous miscarriages. In addition to the trauma and distress this can cause to both parents and relatives, it can also impose significant costs on the public health system.

2.7. There is now strong evidence that the risk of a woman having a baby with an NTD is related to her folate status at conception and during the very early part of the pregnancy[23,24] and that a low folate status is associated with an

[22] Folate and disease prevention, SACN 2006

[23] Hibbard, BM (1964). The role of folic acid in pregnancy; with particular reference to anaemia, abruption and abortion. J Obstet Gynaecol Br Commonw. 1964 Aug;71:529-42

increased risk of having an NTD[25]. A number of studies have shown that taking folic acid supplements prior to conception and for the first 12 weeks of pregnancy reduces the risk of NTDs[26,27, 28]. The magnitude of the reduction depended on the background folate status, and women with the lowest initial folate status, had the most reduction in risk[29].

2.8. All women in the UK planning a pregnancy are advised to take a folic acid supplement from the time contraception use is stopped until the 12th week of pregnancy[17]. Only about a quarter of women follow this advice. It is least likely to be followed by young women and those living in the most socio-economically deprived communities[30].

2.9. This suggests that a policy of mandatory fortification in the UK would particularly benefit women from the lower socio-economic grouping who tend to have the poorest folate status.

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[24] Laurence KM, James N, Miller M, Campbell H (1980), Increased risk of recurrence of pregnancies complicated by fetal neural tube defects in mothers receiving poor diets, and possible benefit of dietary counselling. Br Med J. 281:1592-4

[25] Daly LE et al (1995) Folate levels and neural tube defects. Implications for prevention. JAMA. 274:1698-702.

[26] Smithells RW et al (1981). Apparent prevention of neural tube defects by periconceptional vitamin supplementation. Arch. Dis Child. 56: 911-918.

[27] MRC vitamin Research Study Group: Prevention of neural tube detects: results of the MRC vitamin study (1991). Lancet. 338: 131-137

[28] Czeizel AE and Dudas I (1992). Prevention of the first occurrence of neural tube defects by periconceptional vitamin supplementation. N Engl J Med. 327: 1832-1835

[29] Daly S, Mills J L, Molloy A M, Conley M, Lee Y L, Kirke, P N Weir D G Scott J M. *Minimum effective dose of folic acid for food fortification to prevent neural-tube defects*. *The Lancet*. 1997.350: 1666-1669.

[30] Department of Health. *Folic acid and the prevention of neural tube defects.* Report from an Expert Advisory Group. 1992. (Available from DH, PO Box 410, Wetherby LS23 7LN).

Risk factors for NTDs

2.10. As well as folate status, other factors which can affect the tendency to develop NTDs, include genetic predisposition (including ethnicity, with those of Northern European descent having the highest prevalence and Black Africans and South Asian descent having the lowest prevalence), diabetes and obesity[31].

2.11. The rates of NTDs vary widely across the UK, with Scotland, Wales and Northern Ireland having higher rates than England. The reasons for this are unclear, but it is likely that at least some of the differences could be due to reporting inconsistencies. That said, as it appears that northern and western parts of the UK tend to suffer both a high risk of NTD and high levels of socio-economic deprivation, increased fortification might be expected to be particularly beneficial in these areas, including Scotland.

Folic acid and vitamin B12 deficiency

2.12. Vitamin B12 (cobalamin) is part of the vitamin B complex, and is found in meat, eggs and dairy products. It is involved in the production of red blood cells and the maintenance of a healthy nervous system. A deficiency results in anaemia and a progressive nerve damage (neuropathy), which can be irreversible if not treated early. The metabolism of vitamin B12 and folate are linked and intake of folate can resolve the anaemia of B12 deficiency, although it does not resolve the neuropathy.

2.13. Although folic acid is safe for most people, there has been concern that high intakes may mask vitamin B12 deficiency, thereby delaying diagnosis and treatment and potentially leading to irreversible nerve damage and consequential disability in extreme cases. SACN has noted that low vitamin

[31] Folate and Disease Prevention, SACN 2006

B12 status is seen in 5-10% of older people and has recommended action by UK Health Departments to address this.

2.14. On the basis of expert opinion, SACN has advised that folic acid intakes of 1mg/day would not be expected to 'mask' vitamin B12 deficiency and observed that most adverse effects in relation to B12 deficiency have been reported at doses at or above 5mg/day.[32,33 ,34]

2.15. SACN has also noted that whilst low vitamin B12 status is common among adults aged 65 years and older (5-10%), cases of irreversible neurological condition associated with severe vitamin B12 deficiency are rare in the UK. There were 28 cases in 2002[20], not all of which would have manifested as anaemia. Initial data from the United States[35] and Canada[36], suggests that there has not been masking of the anaemia of vitamin B12 deficiency post mandatory fortification of food by these countries.

2.16. Information obtained from the USA indicates that the number of cases of irreversible neurological disease has remained constant at less than 30 cases per year, post fortification.

Folate and colorectal cancer

2.17. Colorectal or bowel cancer is common in the western world and a major public health concern. There has been much discussion in recent years about the role of folate in colorectal carcinogenesis, with speculation of a possible dual modulatory role, depending on the timing and dosage of folate intervention. Some studies suggest that if pre-cancerous growths are

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

[33] Opinion of the Scientific Committee on Food on the tolerable upper intake level of folate, 2000.

[34] Institute of Medicine. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline (1998).

[35] Mills et al (2003). Am J Clin Nutr. 77(6):1474-7. Low vitamin B-12 concentrations in patients without anaemia: the effect of folic acid fortification of grain.

already present, folic acid supplementation promotes progression to tumour development. Other studies suggest that if pre-cancerous growths are not present, folate deficiency appears to predispose their formation, while folic acid supplementation has an inhibitory effect[37]. The independent Committee on Carcinogenicity discussed the evidence at their meeting on 13 July 2006, and concluded that a precautionary approach to fortification should be adopted. SACN noted that the evidence for a relationship between folic acid and increased or reduced cancer risk is unclear and agreed that there should not be a substantial increase in the average folic acid intake of the population or the numbers consuming more than the upper limit (UL)[38] per day.

Strategies for increasing folate intakes and improving folate status

2.18. Folate status may be improved by increasing intake of foods naturally rich in folate, foods fortified with folic acid and/or supplements containing folic acid. However, this improvement needs to be achieved before conception and very early in pregnancy (i.e. in the first 28 days) to be effective.

2.19. The experience is that advising women to take folic acid supplements has not been effective in significantly improving folate status and reducing the NTDs anywhere in the world including in the UK, despite active health promotion campaigns[39,40] in some countries. A recent literature review[41] concluded that efforts to increase folic acid supplement intake were likely to

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[36] Liu et al (2004). A comprehensive evaluation of food fortification with folic acid for the primary prevention of neural tube defects BMC Pregnancy Childbirth. 27;4(1):20

[37] Young-In Kim (2003). J. Nutr. 133:3731S-3739S. Role of folate in colon cancer development and progression

[38] The Tolerable Upper Level (UL) represents the highest level of daily nutrient that is likely to pose no risk of adverse health effects for almost all individuals in the general population. UL for folic acid is 1mg/day for adults aged 18 years and above; 300μg/day, 400μg/day, 600μg/day and 800μg for children aged 4-6 years, 7-10 years, 11-14 years and 15-17 years respectively (European Scientific Committee on Food, 2000).

[39] Botto et al (2005). International retrospective cohort study of neural tube defects in relation to folic acid recommendations: are the recommendations working? *BMJ*, 330:571.

[40] Busby et al (2005). Preventing neural tube defects in Europe: population-based study. *BMJ*. 330:574-575

[41] Stockley (2006) Folic acid: influencing low-income groups. Report for the Food Standards Agency.

be of limited effect. This is because half of all pregnancies are unplanned in the UK[42], and of those who do plan their pregnancy, less than half complied with the advice appropriately (i.e. very early in pregnancy[43]).

2.20. A number of countries have therefore implemented mandatory fortification of staple foods, of which the United States, Canada and Chile have reported consequent significant improvement in the population folate status and a corresponding reduction from 27% to over 50% in NTD-affected pregnancies.

Mandatory fortification of food in the EU

2.21. No EU country has implemented a mandatory folic acid fortification of food policy, although the Republic of Ireland has now recommended the mandatory fortification of main breads[44] and is currently working on legislation to implement this recommendation. This is expected to be in place by July 2007. There is currently no specific EU legislation governing the mandatory addition of folic acid to food, and where Member States choose to implement such a fortification policy, they will need to notify the draft measure to the European Commission.

2.22. Manufacturers in the UK have to fortify white and brown wheat flour with calcium, thiamine, niacin and iron under the Bread and Flour Regulations 1998 (or the Bread and Flour (Northern Ireland) 1998 Statutory Rule Number 24 in Northern Ireland). The Food Labelling Regulations 1996 as amended (Food Labelling Regulations (Northern Ireland) 1996 as amended Statutory Rule Number 383) currently provide exemption from the requirement to label these ingredients. These Regulations are currently being reviewed by the European Commission who is expected to publish a proposal in 2007.

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[42] Department of Health. Folic acid and the prevention of disease. Report on health and social subjects 50. London: The Stationery Office, 2000.

[43] The Health Education Authority folic acid campaign-UK: 1995-1998

[44] Food Safety Authority of Ireland. Report of the National Committee of Folic Acid Food Fortification (2006)

2.23. If a mandatory approach to the fortification of flour is adopted, consideration will need to be given to how this would be implemented. One possibility would be to bring in the new provision by amending the Bread and Flour Regulations 1998.

Voluntary fortification of food in the EU

2.24. A new European Regulation on the addition of vitamins and minerals and certain other substances to food was adopted in 2006, although publication and application is unlikely until 2007. This is concerned with voluntary fortification and authorises which vitamins and minerals or sources thereof can safely be used, allows the prohibition of other substances on safety grounds and establishes labelling rules. The Regulation also requires the European Food Safety Authority to agree upper safe limits for a number of vitamins and minerals, and this is likely to include folic acid.

2.25. Meanwhile, voluntary fortification is widespread in the EU, but is dealt with in a variety of ways. Some Member States require notification, whilst others require a nutritional need to be demonstrated before they will give authorisation. The situation is further complicated by the fact that some Member States limit the number of fortificants, while others control the foods that can be fortified. In future, food fortified voluntarily, provided it conforms to the conditions set out in the Regulation, will be able to freely circulate in the EU. This will benefit consumers across Europe by increasing access to safe, fortified food.

2.26. In the UK voluntary fortification of food is permitted subject to the provisions of the Food Safety Act 1990. A number of foods are fortified with folic acid on a voluntary basis with breakfast cereals and low fat spreads making notable contributions to dietary intakes. There is little voluntary fortification of flour or bread with folic acid at present in the UK, and manufacturers'

experience in the past is that the limited lines of fortified breads that were available were poorly taken up by consumers.

UK strategy to increase folate intake

2.27. The current UK policy is to advise women of childbearing age to take 400μg/day folic acid supplement prior to conception and until the 12th week of pregnancy and to eat folate-rich foods. In addition, voluntary fortification of some foods has been practised in the UK since the late 1980s, in particular of breakfast cereals and some low-fat spreads. However, this has not resulted in a significant reduction in NTD prevalence, which has changed little since the 1990s.

2.28. In 2003 SACN revisited the issue in order to assess the evidence that had arisen since the Committee on Medical Aspects of Nutrition Policy (COMA) considered this matter in 2000[45]. The SACN report, which is published alongside this consultation, endorses the earlier COMA recommendation for all women who could become pregnant to take an extra 400μg/d folic acid. It also recommends, amongst other things, the mandatory fortification of flour with folic acid in the UK, accompanied by action to reduce intakes from voluntarily fortified foods, and that action is taken to assess the incidence, prevalence and management strategy for vitamin B_{12}-deficiency in older people.

2.29. Health Departments will be considering options to manage any potential risks arising from increased folic acid intakes that would occur as a result of mandatory fortification, including masking of vitamin B12 deficiency.

[45] Department of Health. Folic acid and the prevention of disease. Report on Health and Social Subjects 50. London: The Stationary Office, 2000

(iii) Rationale for Government intervention

2.30. The absence of Government action would amount to the 'do nothing' option in the consultation, relying on the current policy of voluntary fortification and advice to women of childbearing age about taking folic acid supplements. The risk is that due to poor compliance with Government advice as noted above, the current rate of NTD-affected pregnancies would remain unchanged, with the attendant impact on the individuals affected and health care costs.

3. Consultation

(i) Within Government

3.1. The Agency has consulted closely with Health Departments in developing the risk management options described in this impact assessment. Other Government departments including the Department for Environment, Food and Rural Affairs, the Department for Trade and Industry, and the Cabinet Office have been kept informed of developments in relation to the proposal.

(ii) Previous consultations

Public comment on the science of the draft SACN 2005 report

3.2. Over 500 interested parties were invited to comment on the risk assessment carried out by SACN in its draft report for an 8-week period in November 2005. There were 32 responses, 39% of which were from professional/academic/research organisations, while the rest were from health bodies (28%), trade associations (18%), consumers and consumer representatives (9%) and general practitioners (6%). The detail of the formal responses can be found at http://www.sacn.gov.uk/meetings/subgroups/folic/2006_02_10_responses.html.

3.3. The majority of respondents welcomed the report as a comprehensive and significant review of information available on folic acid and disease prevention, and agreed broadly with its conclusions and recommendations for mandatory fortification.

3.4. Respondents raised the following additional issues. Some respondents felt that the issue of vitamin B12 deficiency and its management had not been comprehensively addressed, while others felt that the risk of vitamin B12 masking had been given undue weighting. A number of respondents felt that co-fortification of vitamin B12 with folic acid would be a valid management option to mitigate against the potential risk of vitamin B12 masking. Two respondents raised concerns about the potential impact of free circulating folic acid intakes in children. A number of respondents noted that the literature review, whilst, significant, had omitted some important areas where data had been published.

Stakeholder engagement

3.5. Trade associations noted their preference for a mandatory approach to the fortification of flour with folic acid, and suggested that the simplest means of implementing this would be by amending the Bread and Flour Regulations 1998. They also noted potential difficulties with labelling and trade barriers.

3.6. The Agency also consulted informally through meetings with various stakeholder groups, including the Association for Spina Bifida and Hydrocephalus, millers, bakers and related industries and consumer representatives.

Previous consultation on the COMA 2000 report

3.7. A consultation was held in October 2000 by Health Departments and the Agency following publication of the COMA report, during which over 1000

interested parties, including academics, professional bodies, consumer groups and industry trade organisations were invited to comment.

3.8. Fifty-nine percent of respondents agreed with the proposal to fortify wheat flour with folic acid, while 30% opposed this and 11% expressed reservations. Academics and professional bodies were the most likely to agree. Consumer groups and many individuals opposed fortification on the grounds of lack of consumer choice and potential risk to certain population groups. It was considered important to establish the prevalence of vitamin B12 deficiency in older adults and hence the potential risk for vitamin B12 deficiency masking, as well as the impact of higher intakes in children and learn from the experience of countries that had already introduced mandatory fortification. In general, those who agreed with the proposal that fortification is desirable and acceptable were in favour of it being compulsory. Those who disagreed with fortification, and stated a preference, said they would favour a voluntary approach.

3.9. In March 2002, the Agency, together with the UK Health Departments, held a public stakeholder meeting to discuss the proposal to fortify with flour, a report of which was published on the Agency's website. Ninety people attended from the fields of science, medicine, consumers' rights and food production. The meeting was welcomed by all as a good opportunity to be better informed and be part of the debate on folic acid.

4. Options

4.1. There are 4 options being considered for increasing folate intake and improving folate status, two of which could be taken up by Scotland, Wales and Northern Ireland independently of England (Options 1 and 2). The other two of which (Options 3 and 4) would be difficult to apply independently as food manufacturers tend not to be separate for each country.

4.2. However, regardless of which of the four options is chosen, the advice for women of childbearing age to take folic acid supplements of 400μg/day will need to continue to afford maximum protection against NTDs. Therefore it is not envisaged that there will be any major impact of mandatory fortification of bread or flour on the supplements sector.

4.3. The four options are as follows.

Option 1 Do nothing (maintain status quo)
Option 2 Actively promote increased intake of folate via food and supplements through health education promotion campaign.
Option 3 Encourage voluntary fortification of appropriate food vehicles.
Option 4 Implement mandatory fortification of the most appropriate food vehicle.

Option 1

4.4. This option would maintain the current policy of advising women of childbearing age to take 400μg/d folic acid supplement and the current general encouragement of voluntary fortification of food with folic acid.

4.5. The advantage here is that no legislative action would be required, there would be no additional costs to Government or industry and consumer choice would be maintained. The disadvantage is that this approach on its own would be unlikely to have a significant impact on folate intakes or status, and the prevalence of NTDs would remain unchanged. Potential risks to the elderly from high intakes of folic acid would be unchanged.

Option 2

4.6. This option would involve more active promotion of current advice by Government, targeting women of childbearing age, particularly those from deprived communities. No legislative action would be required. There would be cost implications for the Government. Consumer choice would be

maintained. This option requires the target population (i.e. women of childbearing age) to have knowledge of folate-rich foods and to comply with the health promotion advice to take more of these foods and folic acid supplement. Those at most risk from NTDs are those least likely to take up voluntarily fortified foods or comply with the folic acid advice, namely, women who are young, do not plan their pregnancies and are from low socio-economic classes.

Option 3

4.7. This option would involve further encouragement of voluntary fortification. As a result of informal consultation, it was noted that manufacturers considered that this approach would not be successful, i.e. the current levels of voluntary cereal and bread fortification are unlikely to increase.

4.8. The advantages of this approach are that no legislation is required. The disadvantages are that this is unlikely to lead to further fortification of foods and any such voluntary fortification if progressed, its level and the foods to be fortified, would be uncontrolled. The benefits sought might not be accrued by the target population and the potential risks of consuming levels above the upper limit, might increase.

4.9. If this option was taken up by industry it is likely to be taken up on a product by product basis. Given the large number of food products on the market and the rapid rate of product development, this option would have the disadvantage of being very hard to monitor effectively. In order to ensure safety (intake of folic acid does not exceed guidance levels – see 9raph 2.17), there would be a need to know how many products are fortified, at what level and how much each product contributes to individual and population folate intake.

4.10. Modelling work carried out by SACN suggests that some older adults for example, already have relatively high exposures to folic acid through fortified low fat spreads and supplements.

4.11. Two manufacturers have already indicated their intention to reduce the level of fortification in their spreads, thus reducing the number of people exceeding 1mg/day folic acid (see paragraph 4.15).

Option 4

4.12. This would involve the implementation of mandatory fortification of the most appropriate food vehicle at a level to be determined, and may be sub-divided into further options as discussed below. Bread has been considered the most appropriate fortification vehicle, as it has a relatively uniform consumption across subgroups of the population. Therefore fortification will increase folic acid consumption in a predictable way and increase the intake of the target group.

4.13. The sub-options are as follows:

- The fortification of all wheat flour, except those exempt from the Bread and Flour Regulations 1998, namely wholemeal flour, self-raising flour with a calcium content of 0.2% and wheat malt flour. Initial consultation with industry stakeholders suggests that most consider this to be the most economically and technically viable approach. For this reason, this is the option that has been considered in the cost/benefit analysis that follows. Other options have also been included below for consideration. If one of these options is preferred following the public consultation, then the cost/benefit analysis may be altered as appropriate.
- The fortification of all wheat flour.
- The fortification of flour for use in bread making only.
- Fortification at the bread making stage only.

4.14. A decision will need to be made about the most appropriate level of fortification. This will need to be high enough to achieve the desired level of reduction in NTD risk, whilst keeping the risk of vitamin B12-masking in older and lower risk adults to a minimum. SACN has carried out modelling work looking at potential benefits in terms of NTD risk reduction and theoretical risk in terms of numbers of older people with low vitamin B12 status exceeding 1mg folic acid/day and numbers of individuals achieving intakes above the recommended UL[46] for folic acid. This is set out in Table 1[47].

4.15. SACN also recommended that voluntary fortification of foods with folic acid should be reduced and clear guidance given on the use of supplements containing folic acid in order to limit the number of individuals exceeding the UL for folic acid (see Table 1).

4.16. A combination of mandatory fortification of bread and reduced voluntary fortification of breakfast cereals and low fat spreads as recommended by SACN would redistribute the folic acid intake of the population.

[46] UL for folic acid is 1mg/day for adults aged 18 years and above; 300μg/day, 400μg/day, 600μg/day and 800μg for children aged 4-6 years, 7-10 years, 11-14 years and 15-17 years respectively (European Scientific Committee on Food, 2000).

[47] The potential impact of folic acid fortification of flour on folate intakes, Annex 5, Folate and Disease, SACN, 2006

Table 1: Summary of risks and benefits to the UK population of fortifying flour with folic acid**

Fortification level μg folic acid/100g flour	Number of NTD pregnancies prevented per year (Excluding fortification of wholemeal flour)	Estimated No of people aged ≥65 with low vitamin B12 status exceeding 1mg folic acid/day* (Excluding fortification of wholemeal flour)	Estimated No of people exceeding UL of folic acid* (Excluding fortification of wholemeal flour)
Includes natural folate and folic acid from all sources			
0	-	900	127,000
100	47-99 (42-93)	1700	241,000 (225,000)
200	91-198 (82-180)	2800 (2000)	460,000 (404,000)
300	126-285 (114-261)	3300 (2500)	907,000 (773,000)
450	175-378 (163-369)	9000 (6300)	2,535,000 (2,200,000)
Excludes folic acid from voluntary fortification (but includes supplements)			
0	-70	800	18,000
100	-7 (-14)	800	38,000
200	42-90 (35-63)	900	52,000
300	84-189 (77-162)	900	119,000 (115,000)
450	140-315 (126-279)	1400 (900)	660,000 (559,000)

***These figures will reduce when low fat spread manufacturers implement plans for reformulation (see paragraph 4.11)**

**** Modelled from National Diet and Nutrition Survey data (1995, 1998, 2000, 2003, 2004). See SACN report on folate and disease prevention (www.sacn.gov.uk)**

4.17. The advantage of this approach is that it is likely to increase the folate intake of the population with poor intakes, including that of women of childbearing age, reducing the number of NTD-affected pregnancies each year.

4.18. It can be seen from table 1 that approximately 127,000 people in the UK are currently at risk of consuming levels of folic acid above the UL (see Table 1**). Excluding folic acid from voluntary fortified foods reduces this number to 18,000, therefore 109,000 people are at currently at risk of consuming levels of folic acid above the UL due to the consumption of voluntary fortified foods.

4.19. Taking into account the SACN recommendation to reduce voluntary fortification of foods, fortification of flour at a level of ≥200μg ≤ 300μg folic acid/100g flour, excluding folic acid from voluntary fortification, would reduce the number of NTD-affected pregnancies to below current levels (see Table 1). There would also be no increase in the number of older people at risk of vitamin B12 deficiency, exceeding 1mg folic acid/day and fewer people over all with folic acid intakes above the UL than is currently the case given the current level of voluntary fortification.

4.20. Two major manufacturers of fortified reduced fat spreads recently announced plans to reduce the level of folic acid in their spreads by 50%. Folate intakes were remodelled with the revised figures. Compared to current intakes the number of people aged 65 years and over with low vitamin B12 status exceeding 1mg/day folic acid was reduced by 10%, the total number of people exceeding the UL was reduced by half.

4.21. Comparison of the effect of mandatory fortification of flour with folic acid and the reduced levels in fat spreads with the effect of mandatory fortification of flour at current levels of folic acid fortification in fat spreads showed: the number of people aged 65 years and over with low vitamin B12 status exceeding 1mg folic acid/day was reduced by a range of 50% at 100μg folic acid/100g flour up to 75% at 450μg folic acid/100g flour. Furthermore the total number of people exceeding the UL was reduced by 50% at each level of flour fortification.

4.22. The disadvantages of this approach are that it would require legislative action, monitoring, enforcement and additional costs for industry. Consumer choice would also be limited, and there might be consumer concerns about mass medication.

Mandatory fortification of flour and coeliac disease

4.23. If the policy to fortify wheat flour on a mandatory basis is adopted, consideration will need to be given to options for improving the folate status of women of childbearing age who have coeliac disease. As strict avoidance of wheat and all gluten-based products is currently the only treatment for this relatively common condition (UK prevalence, 1%[48]), these individuals would not benefit from the fortification of wheat flour. However, this is a generic matter, as gluten-free products are not covered by the Bread and Flour Regulations 1998, under which wheat flour has to be fortified with calcium, thiamine, niacin and iron. In order to ensure that gluten-free foods can benefit from a policy of mandatory folic acid fortification, manufacturers in this sector will be invited to take part in the Agency's discussions with stakeholders.

Mandatory fortification, legal and international issues

4.24. If the mandatory approach were adopted, it would be important to ensure that the regulatory framework is adequate and that the new measure is proportionate and does not create unnecessary trade barriers. The new measure may be brought in by amending the Bread and Flour Regulations 1998. The measure would be notifiable in draft to the European Commission under the Technical Standards Directive 98/34/EC and, if there were a specific labelling requirement, under Article 19 of the General Food Labelling Directive 2000/13/EC. The justification for the measure would be protection of public health. The requirements of the Bread and Flour Regulations 1998 do not apply to products from other EU or EEA member States. Consideration would need to be given as to whether it was appropriate for this exemption to apply in the case of folic acid. It would also be necessary to comply with any appropriate notification requirements under World Trade

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

Organisation agreements on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

5 Costs and benefits

Initial Public Sector Cost Calculation

5.1. The impact on the public sector was estimated with reference to Cabinet Office guidance and in consultation with the Local Authorities Co-ordinators of Regulatory Services (LACORS). An initial public sector RIA is not required because the proposal affects both public services and the private sector, with the additional costs to public services relating to Option 4 only being around £10,000 per annum. This estimate covers the cost of monitoring and analysing 100-200 samples a year.

Option 1:

5.2. As this option would maintain the status quo, there would be no additional cost/benefit implications.

Option 2:

(i) Business sectors affected

5.3. Government could disseminate information to the public through a range of health promotion approaches. These could range from localised activity targeting specific group to a full scale national population campaign, similar to the Agency's Salt campaign. Alternatively an increased education campaign through already established prenatal care methods, for example through family planning and general practice services, including classes, could be employed. In addition, targeted leafleting, advice through the education system or campaigns through retail outlets could be used.

(ii) Costs

5.4. Dissemination by the press keeps costs relatively low, though effectiveness is not guaranteed. Even then, taking into account ONS data relating to the total number of pregnant women (births, stillbirths and abortions)[49], given the previous experience it is estimated that the cost of an effective campaign would be substantially upwards of £1.5m[50] for England and Wales alone. A more direct approach will make use of existing resources such as those in the health industry, but as previous experience with the previous campaign shows, raised awareness but did not change consumption patterns or generate any significant benefits. A Scottish campaign (consisting of a press and radio campaign, plus leaflets and posters in doctors' surgeries) to promote folic acid to women of child bearing age was estimated at around £460K for a 6 month campaign and £660K spread over a year.

(iii) Benefits

5.5. Whilst the press-based method is not particularly effective at reaching the target groups, it may still be useful if employed in conjunction with the final option chosen. The benefits associated with a campaign similar to the Salt Campaign would be dependent upon the message being communicated effectively to the salient audience. For example, the group of women who will conceive within the next month (that is, those who stand to benefit significantly) is particularly difficult to identify and thus target. A pilot study into such effective targeting would further inform whether this approach is possible. Any intervention that utilised existing health service resources (such as GPs) would also suffer from a targeting issue, given that benefits of folic acid start to occur before conception, that is, in many cases before doctors are consulted.

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[49] ONS, Abortion Statistics 2001, and ONS Birth Statistics 2004

[50] Assuming a cost of getting across a message to the UK population of £1m.

Option 3:

i) Business sectors affected

5.6. Self-regulation (through voluntary codes of practice) and co-regulation (through statutory or Government-backed codes of practice) are gaining increased prominence in the literature, FSA consultations and the Strategic Plan. Under a voluntary set of guidelines any manufacturer of food or food ingredients that decided to fortify would be likely to be influenced by such guidelines. The national coverage of many manufacturers, retailers and brands make it likely that any benefits of such voluntary fortification would be felt throughout the UK.

ii) Costs

5.7. Only those companies that choose to comply with this option will need to reformulate and label their goods. Formulation and label changes tend to constitute periodic and cyclical business activities. Therefore, if the firms involved seek to implement fortification and label changes during already planned cyclical commercial activity, then the incremental cost to industry of the policy should be minimal if not zero. Even to the extent that an *ad* hoc reformulation/labelling is undertaken it is once more a decision of the firm concerned and thus the costs involved are incurred voluntarily. Nonetheless, costs may be incurred in complying with any requirements surrounding voluntary fortification (for example, providing information or sample analysis to authorities). Costs to Government may include assistance to the industry in developing their scheme and the monitoring of those that choose to voluntarily fortify and label.

5.8. Currently, there is insufficient evidence to hypothesise about costs to reflect the potential impact of over-consumption of folic acid such as the theoretical masking of vitamin B12 deficiency and carcinogenic effects and costs to Health Departments to prevent, diagnose or treat.

Benefits

5.9. As we cannot identify in advance the choices that food companies may make, it is difficult to determine the salient costs and benefits, as well as the likely outcome on the health of the population at large. Discussions with bakeries and associated industries have highlighted the issue that uptake by consumers of fortified cereals and spreads has not been mirrored in the market for bread, making any fortification as a commercial decision not currently viable. Consequently such an option would also require an informal campaign and possibly an incentive structure from Government to provide the desired universal health benefits.

Option 4: Mandatory fortification: Millers

i) Business sectors affected

5.10. This is a UK-wide policy, and the effect of this option will be of interest to all industries in the supply chain for flour products. We consider that millers would be likely to opt to add folic acid to their pre-mix, alongside other current fortificants, such as iron and thiamine. Therefore, the input industry costs are in the first instance likely to be incurred by the pre-mix companies; it is then expected that proportions of these costs will be passed on to millers, in the form of higher prices, with further price transmission towards bakeries and then consumers.

5.11. The main benefit will be the projected reduction in NTD rates, which will vary depending on the chosen level of fortification. Benefits have been calculated using a Disability Adjusted Life Year (DALY) approach, which is explained in Appendix 1. The full results table is presented in Appendix 3.

5.12. If the advice on the taking of folic acid supplements is still followed, the demand for these supplements should be unaffected. Of course, there may still be people that mistakenly stop taking supplements; there may be others

that start to take supplements following the publicity surrounding folate fortification. These effects are of course difficult to predict; it is unclear which one would dominate.

ii) Costs

5.13. In light of the findings of SACN, the following cost/benefit analysis assumes UK fortification at 300μg folic acid/100g required flour, in the absence of voluntary industry fortification.

The potential for increased anaemia health costs

5.14. In their report, SACN note "evidence suggests that folic acid intakes up to 1 mg/day are not associated with delayed diagnosis of vitamin B12 deficiency in older people" (Page 53). Given this, SACN recommend mandatory fortification of flour on the basis that, "voluntary fortification is controlled" (Page 'ii'), and state that, "If no foods were voluntarily fortified, the option that appears to provide the optimum balance between benefits and possible risks is mandatory fortification at a level of 300μg of folic acid per 100g flour (excluding wholemeal flour)" at which level, "it is unlikely that there would be an increase in the number of adults aged 65 years and over, with low vitamin B12 status, exceeding intakes of 1mg/day." (Page 109).

5.15. Whilst SACN do not provide ranges for the reduction in voluntary fortification rates in fat spreads and cereals, only their inclusion or exclusion, assuming voluntary fortification controls are set at levels that take average daily intakes close to those levels that exclude voluntary fortification, there will thus be little, if any, increase in the number of those aged over 65, with low vitamin B12 status, exceeding a 1mg/day intake.

5.16. SACN further estimate that mandatory fortification with folic acid at doses between 300-450μg/100g flour would be required to achieve an increase in folic acid intakes equivalent to those in the USA following their introduction of

mandatory fortification there (Page 111). SACN explain that US "data indicate that the number of diagnoses of sub acute combined degeneration of the spinal cord have not increased post-fortification". They further state, "this suggests that mandatory fortification has not led to a delay in the detection of vitamin B12 deficiency by masking the diagnosis of pernicious anaemia" (Page 113). Given this evidence, on the basis that UK fortification does not exceed these levels, it does not appear appropriate to speculate about any potential negative health effects regarding anaemia in the UK post-fortification. Given this it does not appear appropriate to consider any costs of anaemia screening undertaken by the NHS to be incrementally attributable to this policy option.

The potential for cancer health costs

5.17 SACN notes that the evidence for an association between folic acid intake and increased or reduced cancer risk in humans is equivocal. No randomised controlled trials (RCTs) designed to investigate the relationship between folic acid and cancer incidence have yet reported (Page 85).

5.18. SACN concludes that, "Although the trend data do not prove an association, they raise concerns about a possible relationship between folic acid fortification and increased colorectal cancer (CRC) progression. Further RCTs would be required to determine if folic acid is associated with increased risk of cancer in susceptible populations" (Page 85).

5.19. Given this uncertainty, it is not possible to estimate any potential associated health effects concerned with cancer and folic acid fortification in the current analysis. In addition, provided voluntary fortification is controlled, the number of adults exposed to high levels of folic acid may be less than current levels.

Non-healthcare costs

5.20. The main non-healthcare cost identified concerns the cost of purchasing the folic acid that would be added to flour (probably in the form of pre-mix). We assume a cost of £40 per kilogram of folic acid; at a fortification rate of 100µg/100g, 1Kg of folic acid is needed to fortify 1,000 tonnes of flour[51]. Flour production levels (in thousand tonnes) have been identified from 2000-2005 average annual data from the Flour Millers Survey[52]; the number of kilograms required was computed from this figure. The annual cost is thus £532,000 if all flour is fortified to a level of 300µg/100g, and £505,000 if wholemeal flour is excluded from fortification[53]. Secondly, a monitoring cost (to check that manufacturers are fortifying flour correctly) of £10,000 is assumed, following discussion with the Local Authorities Coordinators of Regulatory Services (LACORS) as noted earlier.

5.21. As noted under Option 3, the updating of labels tends to constitute a periodic and cyclical business activity. Thus, given sufficient lead times it is likely that any required label changes to indicate the fortification of flour, and those products containing it, can be undertaken during already planned or cyclical commercial activities. To this extent the incremental cost to industry of any labelling requirements of this policy option should be minimal if not zero. That said, as noted in the Small Firms Impacts Test to follow, the National Association of Master Bakers (NAMB) have been consulted and consider that labelling requirements for pre-packed products (costed at £1,000 per line) could total a one-off cost of £1 million. Whilst the Agency still considers that given sufficient lead times the proportion of this labelling cost attributable to this potential policy would be much less than this figure it is noted in the

[51] For higher fortification rates, the costs increase linearly; for example, at a 300µg/100g fortification rate, the total amount of folic acid needed will be 3 times greater than for a fortification rate of 100µg/100g.

[52] Wheat Milled and Flour Production (5th October 2006), Flour Millers Survey, Department for Environment, Food and Rural Affairs. Available online at http://statistics.defra.gov.uk/esg/index/list.asp?i_id=062

[53] In the short term, there is the potential for these costs to be higher, as increased demand for folic acid may force up its price. This is unlikely to be an issue if folic acid supply can be easily increased, or if folic acid manufacturers increase supply in expectation of an increase in demand.

net benefits presented below. In addition, to the extent that any labelling requirements would need to be monitored by the public authorities for compliance, it is expected that these public costs would again be minimal given existing monitoring activities.

5.22. In terms of public monitoring of folic acid intake across the UK post-fortification, the National Diet and Nutrition Survey (NDNS) already possesses an established mechanism for collecting these data. There would however be a small administrative burden facing pre-mixers/millers in terms of reading and understanding any new regulations under this option and in terms of record keeping to show that they are fortifying appropriately. Whilst being difficult to estimate at this pre-policy decision stage, any such administrative burden would be small for individual undertakings of which there are currently 59 mills in the UK (National Association of British and Irish Millers).

Benefits

5.23. As noted, the main benefit will be the projected reduction in NTD rates, which will vary depending on the level of fortification. The lower bound of the number of NTD pregnancies averted is taken from the SACN report[54]. The cost benefit analysis uses data on the various probabilities of (i) stillborn or neo-natal deaths prevented, (ii) individuals who would have lived a standard life expectancy under illness, prevented and (iii) terminations prevented, via splitting the total number of NTD pregnancies into these respective categories. Using SACN's lower bound NTD pregnancy estimates and the 300µg/100g fortification scenario, a Disability Adjusted Life Year (DALY) methodology has been used to attach a monetary value to the first two categories. This methodology captures willingness to pay to avoid the pain, grief and suffering that results from NTD pregnancies, and also an element of the possible increased productivity to society that would result from fewer

[54] The fortification rates (of existing products) were recorded in November 2005.

such pregnancies. It does not however capture the reduced treatment costs experienced by the NHS, although we do not quantify the savings to the NHS that result from carrying out fewer termination procedures. The DALY and wider monetisation methodology is described in detail in Appendix 1.

5.24. The cost-benefit analysis given here shows a UK net benefit (deducting the currently measurable costs; the folic acid input; and LACORS monitoring costs) of £13.7 million per annum for the 300µg/100g mandatory fortification rate in the absence of voluntary fortification and of £12.6 million per annum when the fortification of wholemeal flour is excluded. Indeed, even with the deduction of a one-off pre-packed product labelling cost of £1 million in the first year of this proposed policy, the net benefits would be £12.7 million and £11.6 million respectively in the first year and as previously stated for year thereafter. These benefits after cost deductions are clearly very substantial and we consider potentially conservative based as they are on SACN's lower bound estimates of prevented NTDs and with the potential to be bolstered by further productivity and health care savings.

Trade issues

5.25 Trade in flour[55]

(All figures source: www.uktradeinfo.com)

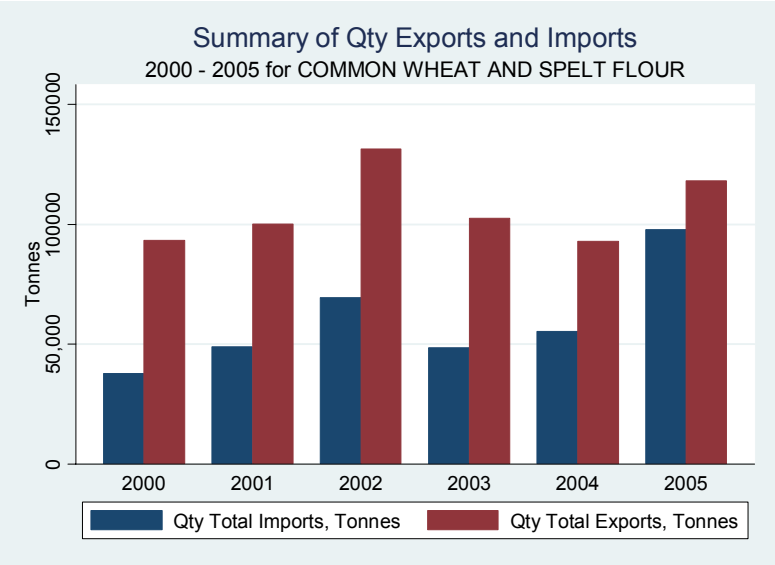
5.25.1. It is assumed here that the flour of importance is 'common wheat and spelt flour'. Two other (far more marginal) types exist: 'durum wheat flour' and 'meslin flour', neither of which are considered here.

5.25.2. For the past five years, the UK has been a net exporter of flour. The gap between exports and imports has closed in the past couple of years, especially in 2005, although it is unclear whether this is the start of a systematic change.

[55] Source for all trade figures: HM Revenue and Customs, http://www.uktradeinfo.com

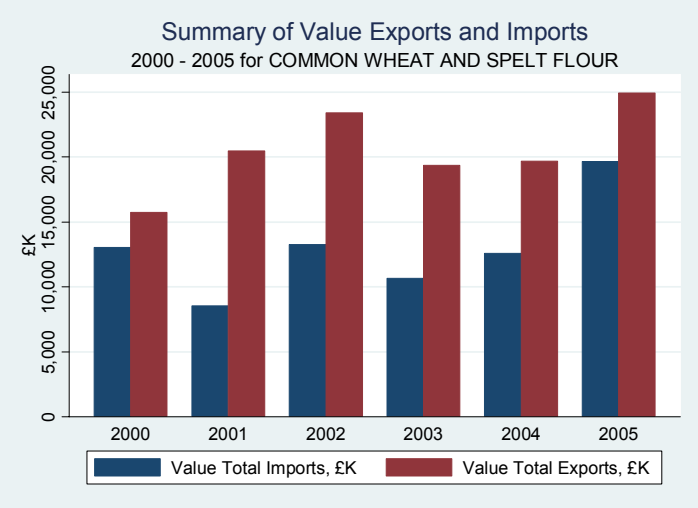
5.25.3. Total Production of flour in the UK has averaged 4.3 million tonnes over the past 5 years, with very little variation[56]. Putting the figures into perspective, in 2005, 2.7% of UK flour production was exported, and a similar amount was imported. Approximately 98% of this trade was with the EU15.

5.25.4. In value terms, the export market for flour is worth around £20-25 million. The impact of folic acid fortification on export values and volumes is uncertain; it would clearly depend on any reactions of our key trading partners and on underlying attribute preferences and price elasticity's.



[56] Source: Flour Millers Survey, Department for Environment, Food and Rural Affairs (DEFRA); available online at http://statistics.defra.gov.uk/esg/index/list.asp?i_id=062

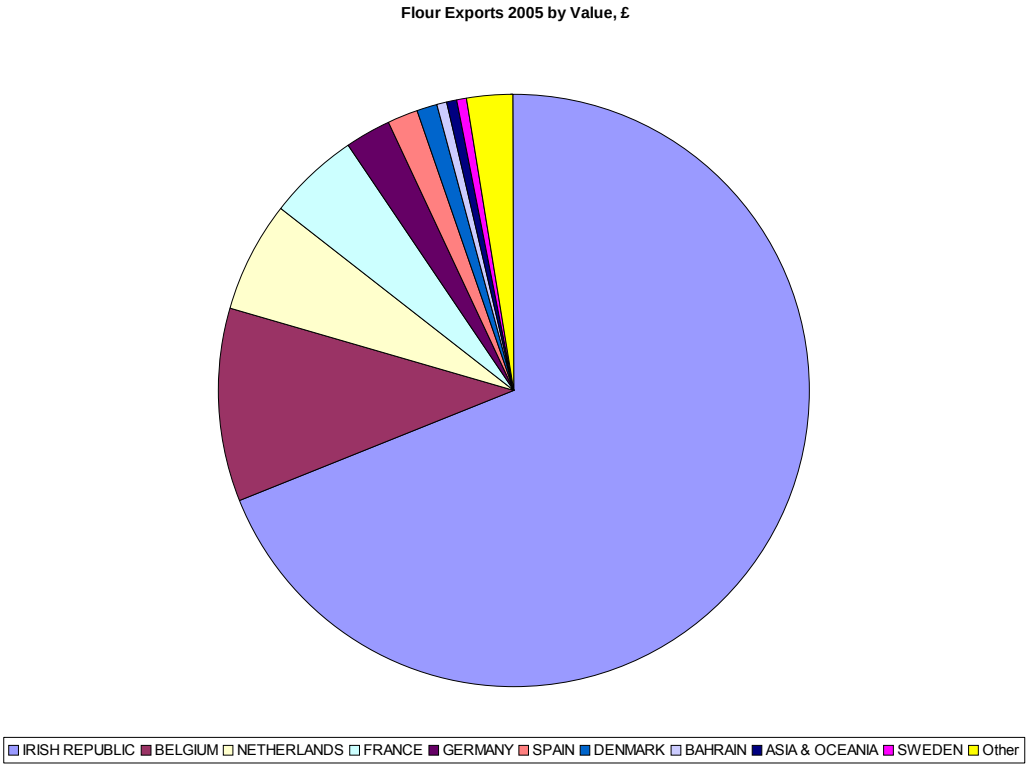

160
140
120
100
2000 = 100
2000
2001
2002
2003
2004
2005
£K
Index of Export Values
Index of Qty Exports


Summary of Value Exports and Imports
2000 - 2005 for COMMON WHEAT AND SPELT FLOUR
25,000
20,000
15,000
10,000
5,000
0
£K
2000
2001
2002
2003
2004
2005
Value Total Imports, £K
Value Total Exports, £K

5.25 Republic of Ireland and Folic Acid Fortification

Introduction

5.25.5. In 2005, 65% of all UK exports of flour went to the Republic of Ireland and they are thus a key trading partner with the UK. The Food Safety Authority of Ireland (FSAI) recently presented a report from the National Committee on Folic Acid Food Fortification to the ROI's Minister for Health and Children today. She has subsequently accepted the recommendation for mandatory fortification of bread in the Republic of Ireland. It is expected that legislation will be ready for implementation there by July 2007.



Observations

5.25.6. The aim of the policy is to reduce NTD births in the Republic of Ireland. After consultation, it was recommended that fortification takes place at the bakery stage of all main breads. There are a number of reasons cited for this, but one of the most critical concerns is that a large proportion of ROI flour, perhaps the majority, comes from outside the Republic; in particular from NI and GB. With this in mind, it is more practical to implement the policy at the next stage in the supply chain (i.e. the bakery stage). In the UK, by contrast, most flour is milled domestically, making it probably easier to follow a fortification programme at the milling stage.

5.25.7. Another justification for this approach was the fact choice would be restricted under an alternative option. The policy allows for certain minor products and retail flour to be exempt, and bread that is imported (mainly from the UK) may also be folate free. It could therefore be argued that consumer choice in the ROI may be limited if the UK chooses to fortify as well.

5.25.8. It is further noted that a cost/benefit analysis was not published with ROI's work, although relevant discussions on costs took place. It is therefore implicitly assumed in the document that fortification will yield a net social benefit. This is consistent with the analysis in the UK.

5.25.9. B12 anaemia masking was not discussed to a large extent in the ROI. However, it too concluded that the level of fortification was not significant enough to put any individuals at greater risk of B12 anaemia masking.

Potential issues

5.25.10. Under the new legislation unfortified flour will be imported and folic acid will be added at the bread stage. Should the UK choose to fortify, decisions may need to be made over the optimal way of achieving both countries' goals. Such issues include whether UK flour can be exported unfortified, whether Irish bakers would need to change their fortification

practices (and/or even potentially source their inputs from non-UK suppliers), and, even if the UK does not fortify, whether special consideration is needed for communities in Northern Ireland, due to their potentially increased exposure to folic acid via imported bread from the ROI.

Option 4: Mandatory fortification (Bakeries)

i) Business sectors affected

5.26. If the onus is on bread manufacturers and bakeries to fortify their products with folic acid, it will be these companies that will be affected by the regulation. As explained above, the Republic of Ireland has chosen to fortify with folic acid at the bakery stage.

ii) Costs

5.27. This variant of the policy option is likely to be more costly than fortifying at the milling stage. This is partly due to the fact that the number of businesses that will be affected by the legislation would be significantly larger and more difficult to identify. ONS data suggests that there are at least 2,700 manufacturers of bread, fresh pastry goods and cakes, and 400 manufacturers of rusks and biscuits, preserved pastry goods and cakes (all with a turnover in excess of £60,000) in the UK[57]. As noted previously there are currently 59 UK flour mills. As such the administrative burden facing industry would be much higher for bakery level fortification in terms of the number of undertakings required to fully understand the legislation and keep records demonstrating compliance.

[57] Because this data (which is drawn from the Interdepartmental Business Register (IDBR)) only covers businesses with a turnover exceeding £60,000 or that have a PAYE payroll tax system, it will under-represent the overall number of manufacturers, many of whom are likely to be smaller businesses.

5.28. In addition to the administrative cost, the increased number of firms directly affected by the legislation at the bakery level would also likely impose greater total costs upon industry due to lost scale economies when purchasing folic acid. Thousands of small firms will be less able to negotiate best prices when buying folic acid compared to larger purchasers such as millers/pre-mixers. Also the search costs (whereby bakeries must invest time in identifying a suitable supplier of folic acid) will be greater in aggregate, given that these costs will be imposed in a larger number of firms. Potentially even more saliently extra resource costs may be incurred in terms of bakeries needing to invest in specialist equipment, storage, training and increased labour costs in order to fortify. With these costs in mind, the impact on SME bakers is likely to be even more significant. Finally, because breads are made using a variety of recipes, it is likely that bakeries would have to take this into account across their range when folic acid is added to ensure accuracy of dose – thus again adding to costs.

5.29. Any public monitoring regime would be substantially more costly (and potentially more complex and less effective, due to the fact that a less homogeneous product, bread instead of flour, needs to be monitored) due to the larger number of businesses that would need to be covered.

iii) Benefits

5.30. This policy may not fully capture as many consumers in terms of folic acid intakes as effectively as the flour fortification method, on which the SACN report is based. This is important to note for the cost-benefit analysis of the options, to allow them to be compared with the best information and evidence available.

5.31. Although largely the same benefits as before can be identified, the potential for this method to be less efficient and more difficult to enforce means that possibly fewer NTD pregnancies may be averted. This situation would

reduce the monetised value of the benefits (via the DALY methodology) accordingly.

5.32. Because the benefits may possibly be smaller and the costs are likely to be much larger than the milling option, it might be concluded that this sub-option within Option 4 is less cost-beneficial. Although we note that the potential trade issues are yet to be bottomed-out.

Sensitivity analysis

5.33. With all the options, but in particular with Option 4, there are a number of potential sources of risk that may affect the overall effectiveness of the policy, or the costs incurred. These risks include:

- The possibility of some firms not complying with fortification requirements. This would result in lower folate consumption, and would incur addition enforcement costs;
- The possibility that a reduction in NTD affected pregnancies will lead to a reduced NTD-affected birth rate i.e., because a greater proportion of pregnancies would result in healthy births. This may make underlying assumptions less reliable,
- The possibility that consumption of flour will decrease over time. This is perhaps the most significant issue since the modern diet may alter to result in less consumption of fortified products. This could be as a result of conscious choice or social changes, but it may affect the success of the fortifying regime, and can draw parallels with those problems suffered by people with coeliac disease.
- The possibility that the commodity price of folic acid will increase significantly. This would lead to greater compliance costs to industry, which may act as a disincentive for firms to comply, or which may be passed on to consumers.

5.34. The proposed provisions would apply to businesses of all sizes, should they be adopted on a mandatory basis.

Racial Equality

5.35. The proposed measure will not have any racial equality impacts. Mandatory fortification (option 4) will provide the greatest benefit to those currently most at risk of NTD-affected pregnancy. Some black and minority ethnic groups (BMEs) have a greater prevalence of NTDs (this may be due to genetic factors or socio-economic factors including diet) and could therefore be expected to gain an increased benefit.

6. Small Firms Impacts Test

6.1. Trade representatives, including the National Association of Master Bakers (NAMB) and the National Association of British and Irish Millers (NABIM) were consulted via stakeholder events and factory visits.

6.2. NABIM had no particular concern with fortification but was interested in the practical detail around implementation and monitoring of any fortification policy.

6.3. NAMB was additionally contacted directly in order to identify the likely impact of a mandatory approach to folic acid fortification on their members, the majority of whom are small and medium sized enterprises (SMEs). The Small Business Service (SBS) was contacted to advise on the implementation of a small firms impact test.

6.4. NAMB noted that their members operate 6,000 shops and had 8% of the flour market and 6% of the bread market. They indicated a preference for fortification at the milling stage, and estimate that the extra cost of flour fortified with folic acid would be in the region of £80-104k per year for the industry. As noted in the above cost-benefit analysis, this estimate is likely to

be conservative if the option of fortifying all flour to a level of 300µg/100g were taken.

6.5. If there were a requirement to indicate folic acid on the labelling, one-off labelling changes would cost around £1k per product or £1m in total for pre-packed products. For non-prepacked products, costs for the whole sector would vary depending on the manner of labelling as follows:

a. £0 where labelling is not required,
b. £6k where a general notice is used in the store to indicate the presence of folic acid in for example all products except those made of wholemeal and
c. £300-600K one-off cost where products are individually labelled, plus an additional staff cost of £0.93m-£1.86m for daily label display.

6.6. NAMB noted a preference for a) and b), were labelling to be required, as the continuing staff costs associated with option c) would be an unjustifiable burden on the craft baking industry, which is primarily made up of SMEs.

6.7. NAMB noted that fortification at the bread-making stage would be more costly, although they could not estimate by how much more at this stage. This would include additional costs for example for the bread improver and changes in recipes. Labelling costs would be the same as for fortification at the milling stage, but there would be additional costs for enforcement, as individual bakeries (around 2,700) would have to be checked for compliance.

7. Competition assessment

Option 1

7.1. As this option would maintain the status quo, there would be no implications for competition.

Option 2

7.2. This will be a government initiative, most of the preparation for which can be done within the public sector. Consumer choices may change, but this will likely be met by changes in the practices of firms in a competitive environment.

Option 3

7.3. Many food producers already have considered fortification, and certain cereal producers and low-fat spread manufacturers are already fortifying voluntarily. A government backed voluntary regulation of this nature will be taken on by firms who chose to fortify out of a perceived benefit to competition. The result of this policy, if firms chose to take it on, would probably be increased differentiation of food products, maintaining consumer choice and the competitive environment.

Option 4 (Millers)

7.4. The sector most likely to be affected would be the premix manufacturers, although any increased costs to them would be likely to be transmitted further down the supply chain. There are a small number of large companies in this UK sector. Technical barriers to entry to this sector are already high due to the nature of the product, but changes in the constituents of the premix is unlikely to lead to significant increases in these barriers, with folic acid being generally available. Innovation will not suffer since folic acid can already be offered as an option by premixers. Indeed, there may be increased incentives to fortify flour increasingly cheaply.

Option 4 (Bakeries)

7.5. The bread manufacturing industry is diverse, and there are over 2,700 firms with baking as their main function, with 90% of these being listed as micro or

small businesses. This doesn't include those producers who list selling as their primary function, but who still also produce bread from scratch. Fortifying flour with folic acid at the bakery stage may incur extra cost, due to labour or capital costs required to establish suitable practices in this larger number of businesses. It is also important to take account of the distribution of that cost and how it affects companies of different size. If fortification were to take place at the bakery stage, then the costs associated with purchase of folic acid, maintaining consistency and adding it to the process is likely to represent a larger proportion of the total cost to a small bakery than a large one.

7.6. In the event that the proposed provisions are adopted on a mandatory requirement basis, the UK will have to notify the measure in draft to the European Commission and other Member States, who will then have the opportunity to comment. As such should these potential provisions be thought to possibly have any disadvantageous effects on the competitiveness of UK businesses in other Member States, these can be addressed. It would also be necessary to comply with any appropriate notification requirements under WTO rules.

8. Enforcement and sanctions and monitoring

8.1. If the decision is made to adopt the mandatory fortification of flour, manufacturers would be expected to comply by adding folic acid to flour at the milling stage, possibly in the pre-mix of nutrients that is currently used to fortify flour in the UK. The same enforcement, sanctions and monitoring can be applied as is currently the case for fortification of flour under the Bread and Flour Regulations 1998. If this was extended to imported foods, Port Health Authorities and local authorities and Local Authority Trading Standards and Environmental Health Departments will be responsible for enforcement of any new mandatory provisions. UK enforcement authorities' representatives have been consulted and have indicated that there would be minimal additional costs.

8.2. Additional costs relate to the costs of analysis by Public Analysts of food samples taken by enforcement officers to check the actual levels of folic acid against the declared levels. Such costs (based on 200 samples per year) are not expected to exceed £10,000 per year.

9. Implementation and delivery plan

9.1. If the option is adopted to go for mandatory fortification, it will be necessary to have an implementation team to oversee future stages of the implementation programme. This will include for example, drafting the statutory instrument in light of comments from the public consultation, ensuring that effective procedures are in place for monitoring industry and consumer uptake of the new provision, and that the folate and vitamin B12 status of population groups are monitored. Full guidance notes will be drawn up in full consultation with stakeholders and published on the Agency's website, and the impact of the new requirements will be kept under regular review.

9.2. The Agency has also prepared guidance notes on the issues around the Agency's current consideration of folic acid. These are primarily for the general public but may also be useful to industry and enforcers. These too will be published on the FSA website.

10. Post implementation review

10.1 The effectiveness of the policy will be reviewed in 5 years' time.

11. Sustainable development

11.1. All the impacts identified in the costs and benefits sections under each of the four options are in relation to the economic and social (including health) pillars of sustainability. There are no identified environmental impacts arising

from any of the options. The sustainability of options 1 and 2 are similar. In both cases, there will be little if any health benefit, economic costs will remain high and these options are therefore the least sustainable of the four. Option 3 off-sets a likely slight increase in economic costs against some minor health benefits. Option 4 is the most sustainable of the four options as it offers by far the greatest potential health benefits, which far outweigh the estimated associated costs.

12. Summary

12.1. This assessment has explored the policy options available for increasing folate intakes among women of childbearing age in the UK as a way of reducing the incidence of NTDs. Four options were identified, and the advantages and disadvantages of each are summarised in Table 2.

Table 2: Summary of advantages and disadvantages of each policy option

Advantages	**Disadvantages**
Option 1 Do nothing • No legislative action required • Consumer choice is maintained • No cost impact for Government or industry • Risks to the elderly from high folic acid intakes would be unchanged	• Would rely on consumer compliance with folic acid advice • Unlikely to achieve folate status needed to reduce NTDs • High NTD rates and related public health costs remain

<u>Options 2: Actively promote increased intake of folate via food and supplements through health education promotion campaign</u> • No legislative action required • Consumer choice is maintained • Some cost implication for Government • No effect on risk to mask vitamin B12 deficiency or increase risk of colon cancer	• Would rely on consumer knowledge and compliance with folic acid advice • High unplanned pregnancy rate reduces the potential impact • Unlikely to achieve folate levels needed to reduce NTDs • Current NTD rates and related public health costs remain but based on previous campaigns for England and Wales, an effective campaign would cost in excess of £1.5m per annum
<u>Option 3: Encourage more voluntary but structured fortification of food</u> • Consumer choice is maintained • More likely than option 2 to result in increased folate intake in target and general population • May result in some reduction in NTD rates and related public health costs	• Would rely on consumer knowledge and uptake of fortified foods • Industry has indicated it is unlikely to increase voluntary fortification • Would require monitoring and enforcement with associated costs. • Potential for trade barriers in relation to the marketing of fortified foods • Unlikely to achieve folate levels needed to reduce NTDs significantly • Some increase in risks to the elderly and those at risk of bowel cancer from high folic acid intakes which would depend on the products fortified and level of fortification
<u>Option 4: Mandatory fortification of flour</u> • More likely to achieve folate levels needed to reduce NTD risk significantly	• Cost to industry • Would require legislative action, with associated costs for Government • Would require monitoring and enforcement, with associated costs

[58] These costs are assuming a mandatory fortification rate of 300µg/100g in the absence of voluntary fortification and excluding fortification of wholemeal flour

• Does not rely on voluntary action by the food industry • Does not rely on consumer knowledge and deliberate uptake of fortified foods • The cost-benefit analysis suggests a net benefit of £12.7 mn and £11.6 mn for the first year and second year respectively if SACN recommendations are implemented[58]	• Potential for trade barriers in relation to the marketing of fortified foods • Unlikely to achieve folate levels needed to reduce NTD risk optimally. Target population will still need to continue to follow advice about folic acid • Potential increased risk of B12 masking and bowel cancer unless voluntary fortification is reduced • Consumer choice will be restricted

13. Recommendations

This document is a Partial RIA and therefore no recommendation is included at this stage. Recommendations will be included in the Final RIA document, once agreed by the Agency's Board following the current process of consultation.

Declaration

I have read the regulatory impact assessment and am satisfied that the benefits justify the costs.

Signed……

Date:

Minister's name, title and department.

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List of interested parties

ADAS Wales
Adrian C Symonds
Advisory Committee on Animal Feedingstuffs
Age Concern
Alison Davidson
Alison's Celebration Cakes
All Wales Dietetic Advisory Committee
Alltech UK Ltd
Alzheimer's Society
Anastasios Giamouridis
Anne Wilks
Arden Fine Foods UK Ltd
ASBAH Wales
Association of Bakery Ingredient Manufacturers (ABIM)
Association of Cereal Food Manufacturers (ACFM)
Association of Spina Bifida and Hydrocephalus
Avana Bakeries Ltd
AWDAC
B. A. Jenkins & Sons
Bakemark UK
Bara Panteg
Baron's Patisserie
Barry Davies
Berwyn Bakery Ltd
Birth Defect Foundation
Biscuit, Cake, Chocolate and Confectionery Association
Brace's Bakery Ltd
British Dietetic Association
British Heart Foundation
British Medical Association
British Nutrition Foundation
British Retail Consortium
Carmen Willcox
Carolin's Real Bread Co.
Cereal Ingredient Manufactures Association (CIMA)
Cerform
Chartered Institute of Environmental Health
Chef on the Run Foods
Chief Medical Officer for Wales
Chris Carter
Chrissie Sugden
Consumers' for Health Choice
Co-operative Group
Council for Responsible Nutrition
Dave Jones
David McDowall
Department of Food Science & Technology
Derek Burns
Diabetes UK
Diena Bench
Dr Andrew McCaddon
Dr Anne Scott (Kent)
Dr Anne Scott (Norwich)
Dr Iris Krass
Dr J. David Spence
Dr Joseph Vida-Alaball
Dr Mark Lucock
Dr Paul Haggarty
Dr Reynolds
Dr Soja John Thaikattil
DSM
Dyfed Powys Health Authority
Eddie Vos
Elisabeth Goodwin
Emma Nobel
Federation fir Bakers
Federation of Small Businesses (North Wales)
Federation of Small Businesses (South Wales)
Fedwen Bakers (Cardigan) Ltd

Flour Advisory Bureau
Folic Acid Action
Food Additives and Ingredients Association
Food and Drink Federation
Food Standards Australia
Food Standards Group NZ
Garth Bakeries Ltd
General Dietary Ltd
Gill Mason
Godfrey P. Oakley, Jr
Good Food Distributors
Greggs Wales
Gwent Health Authority
Gwent Health Care NHS Trust
Gwynle Bakery
Health & Social Services Committee
Health Food Manufacturers Association
Health Promotion Agency for Northern Ireland
Helene McNulty
Help the Aged
Henllan Bread
Hennock Industries Ltd
Holland & Barrett
Home-Grown Cereals Authority
Hospital Caterers Association
IGD
Institute of Food Research
J. D. Wilson
Jackie Ugoala
Jan Thrower
JM & A Hughes (Station Bakery)
Joan Beever
Joan Cope
John Nicholas
Joyce Darracott
Judith Jones
Kate Adamson
Kevin Lasbury
L.F.I. UK Ltd
Lenore Abramsky
Les Branchett
Lewis Fine Foods
Lucy P.
Lucy Pollock
Marcus Williamson
Mark Law
Memory Lane Cakes
Meredith's Bakery
Mick Goodman
Mike Bridway
Miss G. Poole
MJ Ray
Mr C. Ahern
Mr Edmund Holt
Mr S. Ellis
Mr Stephen Ponder
Mr T.J. Loldrick
Mr W.O. Harris
MRC Human Nutrition Research
Mrs B. North
Mrs Cynthia Wagstaff
Mrs Davis
Mrs Gosling
Mrs J. Ellis
Mrs Jennifer Berry
Mrs M.E. Mulady
Mrs Slade
National Association of British and Irish Millers
National Association of Master Bakers
National Childbirth Trust
National Consumer Council
National Farmers Union Cymru
National Federation of Women's Institutes
National Heart Forum
National Institute of Clinical Excellence (NICE)
National Public Health Service for Wales
NHS Wales
Nice Bites Bakery Ltd

Nutrition Society
Ogmore Vale Bakery Ltd
Omya UK ltd
Pembrokeshire & Derwen NHS Trust
Peter Hunt
Professor Hilary J. Powers
Professor Hoffbrand
Professor Nicholas Wald
RHM
Robert Clarke
Robert Fraser
Robert Nock
Royal College of General Practitioners
Royal College of Paediatrics and Child Health
Royal College of Physicians
Scottish Association of Master Bakers (SAMB)
Simon Lovelock
Slater's Bakery
Smiths Flour Mills
Snowdrop Baker
Society for Research into Hydrocephalus and Spina Bifida
Soil Association
St Patrick's Centre for Community Health
Sue Smithson
Swansea Bakeries Ltd
Swansea NHS Trust
Tan y Castell
Teresa Owen
Tesco
The Society for the Protection of Ancient Buildings, Mills Section
The Village Bakery (Coedpoeth) Ltd
Tim Fairhead
Tommy's (baby charity)
Tony Osbourne
Tony Wilkinson
Trevor Stronach
Unilever
UWIC
Vicky Stanley
Vitrion UK Ltd
Wades Bakery
Wales Council for Voluntary Action
Welsh Assembly Government
Welsh Consumer Council
Welsh Food Alliance
Welsh Hills Bakery
Welsh Local Government Association
Whei Chan
Which? / Consumers Association
White's Golden Crust Bakery
Williams of Panarth Ltd
Women's Food and Farming Union
Y. Felin