

**Response from the Scottish Spina Bifida Association
to the Food Standards Agency Consultation on
“Options for increasing folate intake of young women”**

The Scottish Spina Bifida Association welcomes the SACN report and acknowledges the extent to which the committee have attempted to ensure that this complex issue has been addressed extensively, fairly and objectively using the latest available research data.

The Association, however, would wish to ensure that decisions are reached on the basis of this fairness and objectivity and resist the temptation to make judgement on the basis of cost (albeit there is clearly a very significant cost benefit in reducing the incidence of NTD). It is a matter of concern that a significant section of the report has been focussed on such cost benefit analysis material.

Similarly, in an attempt to be as objective as possible and to trawl the literature for all relevant data, the report has the unfortunate potential in our view of being misinterpreted by the public and media as being a recommendation which could cause bowel cancer and mask B12 deficiency in the elderly simply because these 2 aspects are dealt with within the report.

It is our view that SEHD and Scottish Ministers should be clear about the public health benefit of the recommendations, as a matter of principle, taking into account a full risk assessment of the benefits of fortification of flour.

In our own risk assessment of the benefits of fortification we have taking into consideration all of the aspects as detailed in the SACN report, including the issues of B12 deficiency and risk of bowel cancer. We have done this to reflect our commitment to ensure our recommendations are evidence based rather than preference based.

We have examined the impact of Fortification of flour in other countries to help us in our assessment.

SUMMARY Recommendation

Option 4 Recommend the mandatory fortification of bread or flour with folic acid.

The Scottish Spina Bifida Association favours Option 4 (Amended) as it is the only option that will unquestionably significantly reduce NTD's in the UK.

It urges the FSA to ensure that the recommendation of the SACN Report of mandatory fortification of flour with folic acid **alongside** control of voluntary fortification **and advice about supplement use**, is put forward to the SEHD and ultimately to Scottish Ministers.

We would also urge the UK Government to support Option 4 as amended, as an appropriate strategy to reduce NTD's UK wide.

Background rationale behind our Recommendation

Over the past decade, two expert scientific committees have conducted detailed assessments of the evidence and on each occasion have concluded that mandatory fortification is the most appropriate route to achieve maximum safe benefit.

B12 Deficiency

The 2000 COMA report did highlight the issues of B12 deficiency and a decision to fortify was deferred to attempt to secure more research data. Our view of the B12 deficiency argument is that although there is a theoretical possibility of masking, there has been no evidence of this in reality. The suggestion which we would endorse of limiting voluntary fortification once mandatory fortification is in place would give sufficient safeguards for any minimal risk of increase Folic Acid intake above the recommended tolerable Upper Level and therefore would not impact on the elderly population who hitherto had been cited as at potential risk.

Consumer Choice. We accept that there will always be a body of opinion which, as a matter of principle, is opposed to any level of additive to the food chain, irrespective of the benefits. We have taken a reasoned view of this in our assessment and have to conclude that as the proposal allows for consumer choice (by allowing consumers to choose a range of products not made of white flour) then concerns of this sub group of the population are reasonably addressed.

Risk of Bowel Cancer: Since the 2000 COMA report, some studies have suggested a link between folic acid and bowel cancer. The evidence suggests that those who already have Cancer of the bowel may experience an acceleration of symptoms, whereas those where no cancer is present may find that folic acid supplementation may help reduce the likelihood of cancer developing. However SACN concluded that the evidence is unclear but as a precautionary measure there should not be a substantial increase in the average folic acid intake. The levels of suggested fortification of flour are well within the TUL (Tolerable Upper Level) and therefore any potential risk is adequately minimised.

Scotland Specific issues

Whilst there will be significant benefit to the UK as a whole it should be noted that there are variances in prevalence rate in all four countries. Scotland has indeed an even greater requirement for fortification, as there is strong historical evidence of an increased prevalence of Spina Bifida in Scotland per head of population. (based on one of the most robust data sources in the UK which regrettably only covers the Greater Glasgow Area (GRCA) There has also been a long association between diet and health generally and again it would be of significant benefit to the health of our Scottish nation to fortify white flour in this way.

Benefits, to the UK population in general and Scotland specifically, are two fold

1. In Scotland approx 65% of NTD pregnancies are terminated (E&W figures 90% terminated) Fortification of flour would have a significant impact on reduction of the number of NTD terminations.
2. Spina Bifida is the most common NTD. Spina Bifida often results in paralysis of the lower limbs, urological, neurological and orthopaedic problems that often become even more significant throughout life. Fortification would reduce the number of babies born with this lifelong disability.

Evidence from other countries who fortify flour with folic acid. By far the most significant data is available from the USA which has fortified flour for the past 8 years with no adverse effects within the population (all ages). We believe this is a very significant finding in a country which has a strong history of litigation claims.

In countries where mandatory fortification with folic acid has been introduced, there have been reductions of 27% to 50% in NTD affected pregnancies.

Folic Acid Fortification and Cleft Lip and Palate. A recent Study in Norway indicates that intake of folic acid also reduces risk of isolated cleft lip with or without cleft palate by about a third (BMJ: 3 March 2007: vol 334 p464-467)

Response to other options

Option 1 Continue with the current policy of advice to women.

We would not support this option because the evidence to date shows that the current policy has had little impact in reducing NTD pregnancies in the UK. (Mainly we suspect because 50% of pregnancies are unplanned) Part of the reason for this has been poor uptake.

Option 2 Increase the effort to encourage young women to take folic acid supplements (folic acid is a synthetic form of the vitamin folate, used in supplements and as a food fortificant) and changes to diet to increase the consumption of folate rich foods.

This recommendation would not be effective because it relies too heavily on consumer knowledge and awareness. We would however wish to ensure that women planning a pregnancy still need to take folic acid supplements.

Option 3 Encourage industry to fortify more foods with folic acid on a voluntary basis.

We would not recommend this option for the following reasons

- 1 Companies are likely to fortify premium products only, which would reduce the impact on high risk low socio economic groups
- 2 Voluntary measures, by their very nature, cannot offer sufficient safeguards to reduce risk in terms of dosage and would increase complexity of monitoring and evaluating impact of fortification.

How should the impact of the Scottish Spina Bifida Association's preferred option be monitored?

In Scotland NHS Information and Statistics Division provide a range of quality data on the Scottish population. We would expect the Scottish Executive Health Department to ensure that sufficient resources are made available to ensure that such data is robust and accurate. It would also be essential to ensure that comparative data is available for the UK and in other countries where fortification is mandatory.

The Scottish Spina Bifida Association has already indicated to NHS Information Statistics Division that they are compiling a Scotland wide database of NTD's and this may also be useful in verifying data.

Further Questions Annexe G

4a Should the fortification requirements apply to bread, all flour, flour for bread use or flour to which current fortification requirements of the Bread and Flour Regulations 1996 apply.

We would recommend the 1996 regulations

4b What should be the required fortification level.

We would concur with the SACN recommendation of 300 mcg

4c 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.

We would recommend that folic acid be included with other nutrients. It would also be important to ensure that no additional costs are passed on to consumers. Government, therefore, should meet all costs relating to mandatory fortification of flour on the basis of significant net gain in savings on health, education and social care.

4e What transitional arrangements should be made for the coming into force of any requirements - what should be the length of the transitional period?

We would recommend as swift and smooth a transition as possible, guided by the practicalities of the flour millers.

4h 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?

We would recommend that advice be given to industry to limit such fortification to ensure intake of folate does not exceed the Tolerable Upper Level (UL). If combined with mandatory fortification then adults exposed to high levels of folic acid may indeed be less than current levels

9th March 2007