

Folate and Health Consultation

December 2006

Summary of Key Points

- FSA has launched a consultation on what actions should be taken to improve the intake of the vitamin folate for young women in order to reduce the number of pregnancies affected by Neural Tube Defects (NTD), such as Spina Bifida
- The four options are:
 1. continue with the current policy of advice to women to take folic acid supplements and increase consumption of folate-rich foods; and/or
 2. actively promote increased intake of folate among young women through a health education campaign
 3. encourage industry to fortify more foods with folic acid on a voluntary basis; and/or
 4. recommend the mandatory fortification of flour or bread with folic acid
- The Scientific Advisory Committee on Nutrition (SACN) is recommending mandatory fortification of flour, with additional measures, including controls on voluntary fortification of other foods
- FSA recognises that this a complex issue where strong evidence of potential public health gains must be balanced against weaker evidence of possible risks, alongside consumer choice, ethical, legal, technical and financial considerations
- The FSA's consumer research indicates that no option receives majority support, but that support for mandatory fortification increases as levels of knowledge increase, while a significant minority opposes mandatory fortification
- The FSA Board will meet in May 2007 to agree its recommendation to Health Ministers, who make the final decision.

Background

- Folate is a B vitamin that is important for the production of healthy cells, particularly during periods of rapid cell division and growth, such as in very early pregnancy. Folate deficiency can also slow growth rate in infants and children and cause anaemia in adults.
- There is now conclusive evidence that an increased intake of folate prior to conception and during the very early part of the pregnancy can reduce the risk of a woman having a child with a Neural Tube Defect (NTD) and that a low folate status is associated with an increased risk of having an NTD.
- There are about 700-900 NTD-affected pregnancies in the UK each year causing trauma and distress to families as well as imposing significant costs on the public health system. The majority of NTD pregnancies result in terminations.
- Since the 1990s the Department of Health has advised women who could become pregnant to take folic acid (the synthetic form of folate) supplements, and to increase their intake of folate-rich foods. However, research suggests that only around a quarter of women follow this advice, owing in part to around half of pregnancies being unplanned.

FOOD STANDARDS AGENCY: PARLIAMENTARY BRIEFING

In May 2002, the FSA Board considered how to improve levels of folate among the population. It decided not to recommend fortification at that time primarily because of concerns that high folic acid intake might mask vitamin B₁₂ deficiency, particularly in the elderly, and lead to delays in its diagnosis and treatment, and also because of the limitations to consumer choice. Health Ministers agreed to this recommendation.

SCIENTIFIC ADVISORY COMMITTEE ON NUTRITION'S REPORT: "FOLATE AND DISEASE PREVENTION"

In 2004, SACN was asked to carry out a new scientific risk assessment on folate and health. SACN's finalised report is published alongside the FSA consultation. The report notes that while scientific evidence of the benefits of folic acid supplementation in reducing the risk of pregnancies affected by NTDs is clear and strong, the evidence on the potential harm of increased folate intake (such as in relation to a delay in the diagnosis of vitamin B₁₂ deficiency) is unclear and inconclusive.

Taking into account the impact of fortification on the rest of the population, SACN recommends.

- the mandatory fortification of flour with folic acid, providing voluntary fortification is controlled to limit the number of individuals exceeding upper safety limits for folic acid
- advice to consumers on the appropriate use of folic acid supplements (including continued advice to women to take folic acid supplements to achieve the optimal level of protection from the risk of NTD-affected pregnancy)
- a programme to monitor the effects on folate intakes, status and health

SACN carried out modelling to test the impact of different levels of fortification. They advise that if no foods are voluntarily fortified, the level that would be high enough to achieve reductions in NTD risk, whilst keeping the risk of vitamin B₁₂ masking in older adults to a minimum is 300 micrograms per 100g of flour (excluding wholemeal flour). Between 77 and 162 NTD pregnancies a year could be prevented (11-18% reduction).

Further details of SACN's main conclusions and recommendations can be found in "Folate and the Prevention of Disease" on SACN's website at: www.sacn.gov.uk

FSA RISK MANAGEMENT CONSULTATION

The FSA Board considered SACN's draft report at its meeting in May 2006 and agreed to consult on four possible options, designed to increase intakes of folate in young women and achieve a reduction in the incidence of NTD pregnancies. These need not be mutually exclusive and could be developed in combination. These are:

Option 1: continue with the current policy of advice to women; and/or

Option 2: actively promote increased intake of folate among young women through a health education campaign

Option 3: encourage industry to fortify more foods with folic acid on a voluntary basis; and/or

Option 4: recommend the mandatory fortification of flour or bread with folic acid

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SUMMARY OF ADVANTAGES AND DISADVANTAGES OF EACH OPTION

<u>Advantages of each policy action</u>	<u>Disadvantages of each policy action</u>
Option 1: Continue with current advice	
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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
Option 2: Actively promote increased intake of folate via food and supplements through health education promotion campaign	
<ul style="list-style-type: none"> No legislative action required Consumer choice is maintained Some cost implication for Government No effect on risk to mask vitamin B12 deficiency 	<ul style="list-style-type: none"> 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.
Option 3: Encourage more voluntary but structured fortification of food	
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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.
Option 4: Mandatory fortification of flour	
<ul style="list-style-type: none"> More likely to achieve folate levels needed to reduce NTD risk significantly 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. 	<ul style="list-style-type: none"> Cost to industry Would require legislative action, with associated costs for Government 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 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

FOOD STANDARDS AGENCY: PARLIAMENTARY BRIEFING

FSA'S CONSUMER RESEARCH

The FSA has carried out research with a range of consumers to explore public attitudes around some of the issues. This research is published along with the consultation. Since a high degree of technical detail was necessary to enable an informed discussion among participants, a two-stage process was developed which allowed participants to be carefully briefed and time given for discussion. Participants' views were tracked throughout the process.

- **Option 1** - initially supported by a number of participants but rejected by a large number as research progressed, because they did not believe it would be effective in reducing the rate of NTD affected pregnancies.
- **Option 2** – initially received strong support but this declined as the research progressed, and as participants became less convinced of its likely effectiveness. The high proportion of unplanned pregnancies was consistently seen as an obstacle to the success of any policy reliant on behaviour change.
- **Option 3** – 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**.
- **Option 4** – There was a shift towards Option 4 as the research progressed and participants knowledge increased, with more people supporting this option at the end than the others, although no single option overall was supported by the majority.

Around a third of the sample remains opposed to further fortification, with some opposing it on ethical grounds.

Other findings from the consumer research:

- 'Government' should communicate the risk factors and actively manage possible risks if mandatory fortification is the agreed way forward
- There should be full labelling of fortified food for those consumers who want to avoid additional folate intake
- It was recognised that consensus was not always possible with such a complex issue but that the lack of consensus should not prevent the FSA from moving forward.

Further research with young mothers from socially deprived areas is currently underway.

NEXT STEPS

- The FSA's consultation will close on the 13th March 2007.
- To reach a decision, the FSA Board will consider the results of the consultation, scientific research, a Regulatory Impact Assessment, and the results of the FSA's qualitative consumer research.
- The FSA Board will meet in May 2007 to agree recommendations to Health Ministers on the most viable option for improving the folate status of young women in the UK to reduce the number of NTD-affected pregnancies.
- The final decision on whether to recommend mandatory folate fortification will be made by the Health Ministers.

Links and Further Information:

A copy of the FSA's consultation pack is available at: www.food.gov.uk
Responses to the consultation should be sent to folicacid@foodstandards.gsi.gov.uk
For further information, contact the FSA's public affairs team on 020 7276 8823/8843 or email veronica.martell@foodstandards.gsi.gov.uk