

FOOD STANDARDS AGENCY PARLIAMENTARY BRIEFING

November 2005

FOLATE AND DISEASE PREVENTION

The Scientific Advisory Committee on Nutrition (SACN), which advises the Food Standards Agency and the Department of Health on diet, nutrition and health matters, has published a draft report reviewing and assessing the evidence on the health benefits and risks of dietary folate.

Key points

- **SACN's draft report, "Folate and Disease Prevention", reviews the evidence on the health benefits and risks of dietary folate and makes recommendations on how to increase the folate intake of the UK population.**
- **SACN's recommendations include:**
 - **the mandatory fortification of flour with folic acid in the UK to reduce the risk of neural tube defects (NTDs) such as spina bifida in unborn babies,**
 - **action to address the current problem of vitamin B12 deficiency, particularly in older people, the diagnosis of which could be delayed if folic acid intakes were increased**
- **There will be an eight-week period when comments on the *scientific* content of the draft report to SACN are invited.**
- **The final report by SACN on folate and disease prevention is expected to be published and presented to the Government by Easter 2006.**
- **The Food Standards Agency Board will consider the risk management issues that arise from the final SACN report, including whether to recommend the mandatory fortification of flour with folic acid, and will take into account dose, legal, technical, trade, costs and consumer choice issues.**
- **The FSA is expected to submit advice by Autumn 2006 to UK Health Ministers, who will make a final decision.**

FOLATE AND FOLIC ACID

Folate is a B vitamin that helps the body produce healthy cells and that adults and children need to make normal red blood cells and prevent anaemia. Folate is particularly important during periods of rapid cell division and growth, such during development of the foetus. It is found naturally in foods such as broccoli and Brussels sprouts, peas, chickpeas, yeast extract, brown rice and some fruit. Folic acid is a synthetic form of folate, and is used in food fortification and supplements.

Folate helps reduce the risk of neural tube defects (NTDs), such as spina bifida, in unborn babies. Fortification of flour with folic acid could significantly reduce the number of pregnancies affected by NTDs in the UK.

However, the mandatory fortification of flour with folic acid might mask early symptoms and could delay the diagnosis and treatment of vitamin B12 deficiency, potentially leading to irreversible neurological damage. In the UK, vitamin B12 deficiency is relatively common in people over 65.

BACKGROUND TO THE DRAFT SACN REPORT

This is the second time that the evidence on folate and disease prevention has been reviewed. The Committee on Medical Aspects of Nutrition Policy (COMA), the predecessor committee of SACN, published its report on Folate and Disease Prevention in 2000.

Following the publication of the COMA report and consultation with stakeholders, the FSA Board in 2002 considered the case for the mandatory fortification of flour with folic acid. The FSA Board advised the Government that at that stage it could not recommend mandatory fortification due to concerns over the risk to people over 65 with vitamin B12 deficiency. It said further evidence on the wider impact of folic acid fortification was needed, particularly the benefits and risks to older people.

Health Ministers responded in June 2004 and agreed with the Agency's advice and also called for a further review and an assessment of emerging evidence.

In 2004, SACN set up a sub-group to consider evidence on the health benefits and risks of dietary folate that has arisen since the 2000 COMA report.

SACN'S DRAFT REPORT SUMMARY FINDINGS

SACN has reviewed and assessed the evidence on health benefits and risks of dietary folate under five headings. Its draft report published on 23 November reaches the following conclusions

1 Intake and status of folate and other B vitamins in the UK population

There are significant percentages of women of childbearing age and people aged 65 years and over (groups at most risk of complications arising from folate deficiency) who currently have poor folate intake and/or status.

2 Uptake of folic acid supplements by women planning a pregnancy and pregnant women in the UK

Current advice for women who are pregnant or planning a pregnancy to take folic acid supplements to reduce the risk of neural tube defects (NTDs) is not being followed by large numbers of women

- About half of all pregnancies are unplanned
- Only half of women who report planning their pregnancy take folic acid supplements or modify their diet to increase folate intake

3 Fortification policies in other countries and emerging evidence relating to NTDs

There are over 600 NTD-affected pregnancies in the UK each year

In countries where the mandatory fortification of flour with folic acid has been introduced there have been reductions in the rates of NTD-affected pregnancies of between 27% to over 50%

COMA (Department of Health, 2000) estimated that if flour was fortified with folic acid at 280 micrograms per 100g then there would be a 41% reduction in the numbers of NTD-affected pregnancies in the UK

4 Risks associated with increasing folate intake

By masking early symptoms, high folic acid intakes could delay the diagnosis of vitamin B12 deficiency and therefore delay treatment, which could potentially lead to irreversible neurological damage. In the UK, vitamin B12 deficiency is relatively common in people aged 65 years and over.

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It is estimated that approximately 3000-6000 people aged over 65 in the UK could be put at risk of the masking of B12 deficiency if flour were fortified at the level proposed by COMA. The proportion of those who could in theory develop neurological damage is unknown.

There is no systematic data on the incidence of B12 deficiency nor for any related neurological damage from countries that have introduced mandatory fortification of flour with folic acid (countries include the USA, Canada and Chile).

5 The relationship between folate and other diseases (e.g. cardiovascular disease, neurodegenerative diseases and cancers)

There is currently insufficient evidence to draw conclusions on whether increasing folate intake would reduce the risk of chronic diseases such as cardiovascular disease, certain cancers and bone disease

SACN's overall conclusions:

The potential benefit to the health of the UK population of mandatory fortification of flour with folic acid is substantial; whereas there is difficulty in ascertaining the extent of potential risk due to a lack of data.

To minimise potential risks, fortification must be accompanied by measures to address the widespread vitamin B12 deficiency in people aged 65 years and over.

SACN'S DRAFT RECOMMENDATIONS

In its draft report published on 23 November, SACN has on balance concluded that the potential benefits from mandatory fortification of flour with folic acid outweigh the potential risks. Among its recommendations are:

- all women who could become pregnant should take a daily supplement of 400 micrograms of folic acid;
- There should be mandatory fortification of flour with folate in the UK;
- Action should be taken to assess the incidence, prevalence and management strategy for vitamin B12 deficiency in older people.

NEXT STEPS

Comments are invited on the *scientific* content of the report until the eight-week consultation period ends on **18 January 2006**. Following this, SACN will review submissions and then revise and agree the final report before submitting it to the Government (expected by spring 2006).

On receipt of the final SACN report, the Food Standards Agency will develop risk management options. The FSA will take into account dose, legal, technical, trade, costs and consumer choice issues.

The FSA recognises that this is a complex and sensitive issue and will consult widely when it produces risk management options. Following public consultation, the FSA Board will consider at one of its open meetings (expected to take place in the Autumn of 2006) what advice to give to Ministers. Health Ministers are responsible for making the final decision on mandatory folic acid fortification.

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LINKS AND FURTHER INFORMATION

A full copy of the SACN draft report, "Folate and Disease Prevention" can be found at www.sacn.gov.uk and via the FSA's website: www.food.gov.uk

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

FSA's advice to Health Ministers, July 2002:

http://www.food.gov.uk/multimedia/pdfs/folicacid_disease_annexa.pdf

Health Minister's response to FSA, June 2004:

<http://www.dh.gov.uk/assetRoot/04/08/55/47/04085547.pdf>

Further information about SACN can be found at www.sacn.gov.uk

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