

**EXTRACT FROM THE MINUTES OF THE FOOD STANDARDS AGENCY BOARD
MEETING OF 9 MAY 2002**

Item 4 Folic Acid and the Prevention of Disease

(Paper FSA 02/05/02)

[Prior to discussion of this item, Vernon Sankey declared an interest as Deputy Chair of Beltpacker plc, a company that manufactures and supplies health care products (including folic acid supplements). Vernon Sankey did not participate in the discussion or determination of this issue.]

1. The paper presented the background and conclusion of the Committee on Medical Aspects of Food and Nutrition Policy (COMA) discussions on folic acid and the prevention of disease, and the Board was asked to agree the terms of the Agency's advice to Health Ministers. In doing so, it was important to position the Board's advice in the general context of taking this work forward. Health Ministers would be receiving advice on this issue not only from the Agency, but also from a number of other advisers, including the Chief Medical Officers, on the wider public health implications of fortification.
2. The Board was familiar – through a formal written public consultation exercise and an open stakeholder meeting held in March 2002 – with the various issues that could arise through folic acid fortification. Whilst available information suggested that fortification of flour with folic acid could contribute to reducing the incidence of neural tube defects (NTDs), it could also mask vitamin B12 deficiency in the older population. It was possible that there were other benefits and negative effects on public health, but the level of evidence needed to consider these other benefits and form a view was currently lacking. The Agency had also engaged in detailed discussions with the industry, who had confirmed that a voluntary approach would not deliver fortification in products sufficient to achieve folate increases in the target group. This had been based on the practical problems for industry in fortifying all flours and the cost of folic acid which could not be passed down the food chain (industry would want Government to meet these costs). A mandatory approach to fortification would therefore be needed to achieve increased folate intake. Fortification was a practical possibility, but there would be technical difficulties should the fortification of wholemeal flour be attempted, and questions about the public acceptability of a

mandatory approach. It would be important for the Agency to provide Ministers with a clear view on the overall acceptability of folic acid fortification and the impact on consumer choice.

3. The Board had available the views of the Advisory Committees in Scotland, Wales and Northern Ireland. The Scottish Food Advisory Committee (SFAC) had taken the view that, whilst recognising the health benefits that could be obtained in relation to NTD reduction, more scientific evidence was needed on the masking effects of fortification before proceeding with a universal fortification of flour with folic acid. The Northern Ireland Advisory Committee (NIAC) tended to favour an option that promoted individual uptake of supplements rather than mandatory fortification. The Advisory Committee for Wales (ACW), whilst accepting that an element of consumer choice would be excluded, broadly supported mandatory fortification of flour with folic acid.
4. The Board recognised the difficult ethical decision it would have to make in forming a view on folic acid fortification, in particular in balancing beneficial effects against potentially harmful effects. There was also a dichotomy between the clear evidence of the beneficial effects on NTDs and the lack of evidence on the potential for harm to the elderly. The Board recognised the tensions with the basic principles: the Agency was an evidence based organisation, but there were some large gaps in the data; and it put the consumer first, but consumer organisations had indicated that they were opposed to mandatory fortification. For previous issues, the Board had been able to look at the evidence and make an assessment by balancing the risks. However, the lack of data and uncertainty in the science on folic acid fortification made this approach difficult.
5. The paper had given a clear estimate of the numbers of NTDs that could have been prevented through increased folate intake. However, there was little information provided to estimate the possible risk of harm arising from high levels of folic acid among people with vitamin B12 deficiency. The prevalence of vitamin B12 deficiency in older people had been estimated (around 3-4% among those aged between 65 and 74, and 5% among people over 75 years), but Board members asked for a clearer idea of the proportion of these that could suffer harmful effects through mandatory folic acid fortification. The diagnosis of B12 deficiency was not always clear cut, and clinical symptoms of the disease could vary considerably between individuals. It was also known from the Agency's dietary survey work that the level of bread consumption in these groups, and

consequently the level of folic acid intake, could vary. It was therefore very difficult to estimate the proportion of elderly people suffering from B12 deficiency that could be seriously affected by fortification. It was noted, however, that masking was only an issue for people with consistently high levels of folic acid intake (around 1mg per day). Board members were concerned that a general estimate could not be provided for the proportion of elderly people that could suffer harm to enable a direct comparison with the benefits. It was unfortunate that data from the United States or other countries where mandatory folic acid fortification had been introduced were not available to shed some light on this area of uncertainty.

6. Board members questioned the evidence for the suggested 19% decrease in NTDs in the USA, and asked whether data had also been collected on the incidence and extent of neuropathy in the elderly population. The seriousness of neuropathy could not be underestimated, and Board members were concerned that some of the elderly population who consumed white or brown bread could be considered at risk if that bread was fortified. It was not known what impact folic acid fortification could have on the elderly population, but there was a possibility of beneficial effects as well as harmful. For example, ongoing research into Alzheimer's Disease could show that increased intakes of folic acid in the elderly had a beneficial or protective effect. The dose-response relationship of folic acid intakes in the elderly was, however, a significant area of uncertainty.
7. The Executive had spoken at length to Government officials (at a senior level) in a number of countries to obtain background information on their decision to introduce mandatory folic acid fortification, and data on the impact this had had. Unfortunately, however, information on the reductions in NTD births on masking B12 deficiency in the elderly was not available from these countries. Professor Sir John Grimley-Evans (Chairman of COMA during its consideration of folic acid fortification) had been very helpful in providing the most up to date scientific information on folic acid and its effects on various groups of the population. The Executive was not aware of any research that could shed further light on the issue in the very near future.
8. Folate occurred naturally in a number of foods (including, for example, liver, asparagus, spinach), but was highly unstable and destroyed by the cooking process. It was difficult, therefore, to attain a high level of folate intake through the diet alone, particularly for those on a low income who tended to eat more of

staple foods (such as bread). These groups were also least likely to take folic acid supplements, and also had the highest incidence of unplanned pregnancies. It was known that overall 50% of pregnancies were unplanned and it was too late to gain advantage from folic acid supplementation when the pregnancy was known. It was thought, therefore, that folic acid fortification of flour could bring real benefits to these target groups possibly by reducing the number of NTD births. It was important to remember that the UK had undertaken a formal consultation exercise and a major stakeholder meeting on folic acid fortification and, whilst a range of views had been expressed, the majority had recommended mandatory fortification of flour with folic acid. Other countries, including the USA, Canada and Chile, had also opted for mandatory fortification and, although scientific information had not been collected to assess the benefits against the disbenefits, there did not appear to be a problem with fortification in these countries. In addition, flour was already fortified with iron, calcium and other elements and to add folic acid to the mixture would not be technically difficult. Moreover, it was possible to preserve consumer choice by fortifying only white and brown flour, and leaving wholemeal bread untouched. The Agency had always emphasised the importance of a balanced diet to obtain sufficient vitamins and minerals for a healthy lifestyle, and some Board members, therefore, favoured the fortification of flour with folic acid over the use of folic acid supplements.

9. Notwithstanding the arguments in support of folic acid fortification, some Board members felt that there were still doubts over achieving the desired outcome of reduced NTD affected births, and this needed to be balanced against the potential risk of harm caused by the masking of B12 deficiency in the elderly. The Northern Ireland Advisory Committee had taken the view that the level of NTD births in the UK may have already reached a minimum and folic acid fortification would not make an impact on this. It was also important to remember that the level of fortification recommended meant that dietary supplementation would still be required to prevent NTDs. However, this issue had been considered very carefully by COMA, as well as by a number of organisations as part of the DH consultation exercise, and the expert view had been that real benefits in reducing NTD births could be obtained through folic acid fortification. Against a background of concerns over genetically-modified foods, additives and residues in foods, folic acid fortification could be perceived by some members of the public as yet another 'chemical' being added to food. Careful consideration would need to be given to the communication of this issue so that consumers,

and in particular the target group, continued to eat bread. The Agency had a duty to promote consumer choice, and some Board members felt that it should assist and protect the (possibly small but important) group of people that did not want to eat fortified bread. This view was shared by the consumer organisations, who felt that consumers still needed to have a choice over whether or not to consume high levels of folic acid. Board members also raised concerns about the costs to GPs of an enhanced surveillance programme for vitamin B12 deficiency amongst the elderly, and the costs and impact on small flour millers. Some Board members felt, therefore, that the wider evidence was not strong enough to support mandatory folic acid fortification and that the Agency should instead focus its efforts on working with the Health Departments on a programme of education for vulnerable groups or those most in need (for example, teenage mothers). It was also suggested that an alternative approach could be developed to target the groups most vulnerable, instead of prescribing “mass medication” through fortification to the entire population.

10. COMA had highlighted the need for heightened clinical vigilance to detect masking of vitamin B12 deficiency resulting from fortification of flour with folic acid. The importance of this had been highlighted again in the recent work by Professor Sir John Grimley-Evans who had proposed that, amongst other things, the current yearly GP checks for those aged 75 and over could be used to test blood homocysteine levels (which would be raised in both folate and B12 deficiency). Some Board members felt that this proposal offered a good solution to managing the uncertainty in the evidence, whilst at the same time delivering concrete benefits in terms of reduced NTD births following folic acid fortification. However, concern was expressed about the limited number of over 75s that attended their annual health checks, and Board members felt that a greater understanding and reassurance from the Health Departments regarding their intention to undertake surveillance of the elderly was needed. Some Board members indicated that they would be happy to recommend the mandatory fortification of flour with folic acid, provided there was a commitment from the Health Departments and systems were in place to undertake surveillance of the elderly for vitamin B12 deficiency. As the harmful effects of fortification on the elderly could not be qualified, surveillance could help provide a safety net. However, it was for the Health Departments to determine whether expenditure was better spent on surveillance programmes for the elderly or other areas where other public health benefits could be drawn. The Health Departments would also

need to consider the public acceptability of fortification, based primarily on the advice given by the Agency.

11. Board members asked whether advice was provided to the elderly population at large concerning folic acid supplementation. The Government had put in place a number of precautionary measures to protect the elderly. Elderly people would be advised of potential dangers if they tried to purchase folic acid supplements from a pharmacist, and would not be prescribed a high dose of folic acid without having first undertaken a B12 blood test.

12. A number of Board members felt that, based on the current state of knowledge, they could not currently recommend mandatory fortification of flour with folic acid. A proper cost benefit analysis was not presently available, and therefore some Board members felt that it was premature to press ahead with mandatory fortification until further information was available regarding the costs of imposing fortification, including those related to B12 surveillance in the elderly, versus the savings from reduced NTDs. These members also agreed that the Board should return to the issue when further evidence came to light. Other Board members, however, felt that the major public health concern of neural tube defects needed to be addressed and the benefits that could be brought about by folic acid fortification outweighed the uncertainties concerning the impact on the elderly.

13. The Chairman summarised the opinions that had emerged during the Board discussion:
 - (i) recommending to Health Ministers mandatory fortification of flour with folic acid (supported by no Board members);
 - (ii) recommending mandatory fortification, conditional upon public health surveillance for the elderly (supported by four Board members); and
 - (iii) not recommending mandatory fortification at the present time, but to revisit the issue in due course as the evidence base developed (supported by six Board members). In the meantime, other work should be taken forward, such as developing education programmes to convey messages on supplements to vulnerable groups, and the broader issue of nutrition and diet in the elderly should be considered in the wider work of the Agency.

14. The Board thanked Tom Murray and his colleagues for their hard work. Summarising the Chairman noted that:

- by a majority, the Board had **not currently recommended** the mandatory fortification of flour with folic acid, and **agreed** to review the evidence base as soon as further information had been obtained. This should address the experience of other countries and also evidence from work on Alzheimer's Disease and cardiovascular disease.. Four members of the Board, however, had supported mandatory fortification, with the proviso that it should be linked to greater surveillance of the elderly;
- the Board **agreed** to support an education/information campaign for vulnerable groups; and
- the advice to Health Ministers on folic acid and the prevention of disease (attached at Annex 7 of the paper) would be **amended** as follows:
 - Bullet 2 – should emphasise the limitations of the available information, and should stress the importance the Agency attached to finding alternatives to fortification;
 - Bullet 5 – should highlight the absence of evidence to consider;
 - Bullet 6 – should make clear the efforts made by the Agency to obtain information from other countries;
 - Bullet 8 – should be based on the proposal put forward by some members of the Board that fortification of flour with folic acid should be conditional upon the implementation of a surveillance programme for the elderly;
 - Bullet 9 – the overall conclusion should explain that, by a majority, the Board did not recommend folic acid fortification, but would revisit the issue as evidence became available.

Action: Tom Murray (ND)