

FSA BOARD BRIEFING SESSION ON FOLIC ACID:

Part 1: 18 APRIL 2007 (16:10-18:30)

Part 2: 19 APRIL 2007 (09:00-09:45)

Present:

Dame Deirdre Hutton, Chair
Ian Reynolds, Deputy Chair
Richard Ayre
Tim Bennett
Chrissie Dunn
Maureen Edmondson
Michael Parker
Chris Pomfret
Bill Reilly
Nancy Robson
John Spence
Sandra Walbran

FSA Officials attending:

John Harwood, Chief Executive (Part 1 only)
Andrew Wadge, Chief Scientist
Steve McGrath, Chief Executive, Meat Hygiene Service (MHS)
Vivienne Collett, Director of Legal Services
Terrence Collis, Director of Communications
Gill Fine, Director of Consumer Choice and Dietary Health
Morris McAllister, Director of FSA Northern Ireland
George Paterson, Director of FSA Scotland
Joy Whinney, Director of FSA Wales
Allan Hutton, Finance Director
Alick Simmons, Veterinary Director
Richard Calvert, Director Designate of Strategy and Resources
Alastair Cannon, Board Secretary
Keith Gregory, Board Secretariat
Claire Voller, Board Secretariat
Rosemary Hignett, Head of Nutrition Division
Alison Tedstone, Head of Nutritional Science Branch, Nutrition Division
Lynda Harrop, Nutritional Science Branch, Nutrition Division

External speakers:

Professor Alan Jackson, Chair of SACN ¹	}
Sue Davies, Chief Policy Adviser, Which?	} 18 April only
Professor Robert Dingwall, University of Nottingham	}
Alex Waugh, Director General of NABIM ²	19 April only

¹ Scientific Advisory Committee on Nutrition

² National Association of British and Irish Millers

Wednesday 18 April 2007 (16:10 – 18:30)

Briefing Session – Folic Acid (Part 1)

(Paper BRF 07/04/02)

1. The Chair invited the FSA's Director of Consumer Choice and Dietary Health, Gill Fine, to chair this briefing session.
2. Gill Fine welcomed Alison Tedstone (Head of the FSA's Nutritional Science Branch, Nutrition Division), Professor Alan Jackson, (Chair of SACN³), Sue Davies (Chief Policy Adviser, Which?) and Professor Robert Dingwall (Director of the University of Nottingham's Institute for Science and Society) to the meeting.
3. Gill Fine informed those present that this briefing session would consist of five presentations followed by question and answer sessions. The purpose was to provide background in advance of the Board's consideration of the issue of folic acid fortification at its May Board meeting. The presentations would cover:
 - Options for increasing the folate intake of women and preventing NTD⁴s (Alison Tedstone)
 - SACN recommendations (Professor Alan Jackson)
 - General consumer choice issues (Sue Davies)
 - Ethical research (Professor Robert Dingwall)
 - FSA consumer research (Alison Tedstone)

Options for increasing the folate intake of young women and preventing NTDs

4. Alison Tedstone gave a presentation setting out the background and options for increasing the folate intake of women and preventing neural tube defects (NTDs) (presentation slides are attached at Annex 1). Board members raised the following points:
 - The Department of Health (DH) advice from 1992 was queried as this stated that women 'planning a pregnancy' should take folic acid supplements. Was this advice not appropriate for all women of reproductive age? It was also not clear why the presentation had referred to young women, rather than all women of reproductive age. Alison Tedstone responded that DH had slightly different versions of the advice so that it was often interpreted as for women planning pregnancy, when it should be advice for all women of reproductive age;
 - Clarity was sought as to which products were fortified in the US and at what levels. Alison Tedstone confirmed that grain products and rice were currently fortified. The US aimed for an average fortification level of 140 micrograms folic acid/100g product but overage had been a problem. A comparison between SACN advice and doses of folic acid used in other countries would be provided.

³ Scientific Advisory Committee on Nutrition

⁴ Neural tube defects

SACN recommendations

5. Professor Alan Jackson gave a presentation on the SACN recommendations, including the risks and benefits (presentation slides are attached at Annex 2). Board members raised the following points and questions:

- **Q.** As folic acid/folates were vital for cell division, was there any evidence to suggest that folic acid fortification could cause an increased risk of cancer? **A.** Professor Jackson confirmed that there had been a significant amount of work in the cancer field in respect of folates, and folate-related metabolism. However it was unlikely that a clear-cut answer could be provided. A clinical trial to assess the associated risk of cancer from taking folic acid supplements would need to be very large, which would be probably unfeasible. It was therefore more important to ensure that effective monitoring and evaluation was in place to identify any risk from fortification at an early stage. The Chief Scientist added that evidence on the risk of cancer and its relationship with folic acid intake was very complex as there was also evidence to suggest that increasing folic acid protected against cancer;
- **Q.** In terms of the safe upper limit of consumption, which was currently advised as being 1 mg per day, was this not dependent on other factors such as age group and body weight? **A.** Professor Jackson noted that the evidence used to set guidance on safe levels of intake of folic acid was not strong; it mainly comprised case studies of older people taking folic acid supplements. These show that there is a risk of masking the diagnosis of vitamin B12 deficiency at a dose of 5mg per day of folic acid. The safe guidance level of 1mg folic acid per day therefore included a safety margin. There was no evidence to suggest that children are at any risk from folic acid fortification;
- **Q.** If the reference nutrient intake of folic acid was 200 micrograms, why was a supplement of 400 micrograms recommended for pregnant women? Was this a 'belt and braces' approach? **A.** Professor Jackson confirmed that 400 micrograms was the recommended supplement for pregnancy based on experiments from studies on NTDs, which had observed the effects of different dosages. Randomised trials had also been carried out on those who were likely to become pregnant, and those who were at risk of developing NTD-affected pregnancies;
- It was noted by a Board member from the graph on the effect of folic acid fortification of flour on number of people achieving the reference nutrient intake for folate of 200 micrograms, that even with folic acid fortification 5-6% of the population would still have folate intakes below this value; currently 23% have intakes below this value;
- **Q.** Was there any clear evidence from trials that NTDs were linked to particular socio-economic or ethnic categories of the population? **A.** Alison Tedstone responded that those from the lowest socio-economic groups were at the highest risk and that ethnicity does also affect risk. Asians and white

Europeans are at a higher risk than Afro-Caribbean's origin, but poverty confounds the data;

- It was recalled by a Board member that when this issue was previously discussed by the Board in 2002, the Board had been particularly concerned that folic acid fortification could result in a masking of Vitamin B12 deficiency. Professor Jackson confirmed that there was less concern about this interaction;
- It was known that B12 deficiency was a problem for elderly people, regardless of whether their intake of folic acid increased. **Q.** If mandatory folic acid fortification was introduced, would this increase the occurrence of B12 deficiency? Professor Jackson clarified that B12 deficiency was a problem for older people, whose ability to digest this vitamin had become impaired. If left untreated, this could result in neurological damage. There was currently no evidence to suggest that increasing the levels of folic acid would increase the prevalence of B12 deficiency. It was known that, at an intake of 5mg per day and above, older people had an increased risk of developing neurological conditions as a result of the masking of B12 deficiency. However it was unlikely that elderly people would consume such high levels;
- **Q.** It had been stated that taking a supplement of 400 micrograms of folic acid per day prevented 70% of all NTD pregnancies in women that were considered to be high risk. Had the Committee on Toxicity (COT) reviewed the cancer promoting aspects of folic acid? **A.** Professor Jackson confirmed that the Committee on Carcinogenicity (CoC) had been asked to examine the evidence, and its comments had been incorporated into the SACN position. It was not known why the remaining 30% of pregnancies still developed NTDs;
- **Q.** How would mandatory fortification impact across the whole population, and was there any reassurance that could be obtained regarding the cancer risks? **A.** Professor Jackson clarified that, currently with no mandatory fortification a small number of the population are estimated to have folic acid intakes above 1 mg per day; if voluntary fortification and supplement use continued at current levels and mandatory fortification was to go ahead at a dose of 300 micrograms per 100g white and brown flour then the number of the population exceeding 1mg per day would slightly increase.

General Consumer Issue

6. Sue Davies gave a presentation on general consumer issues (presentation slides are attached at Annex 3). Board members raised the following points:

- Clarification was sought as to whether Which? had changed its position since 2004 in the light of new evidence. Sue Davies confirmed that Which?'s position had been modified, but it still thought that more research was needed before a decision could be made to go ahead with mandatory fortification. More evidence was now available from other countries which supported mandatory fortification, and there was less concern in respect of the increased risk of masking of vitamin B12 deficiency. However, this was still an issue.

While cardiovascular benefits that had been proposed now seemed less likely, there was still uncertainty over the effect on the cancer risk, and there was concern that some people could be put at risk from mandatory fortification. Consumer choice issues also remained unaddressed;

- A Board member noted that further information was needed on the risk of neurological disease from vitamin B12 deficiency before the Board could make a decision on this issue in May. Alison Tedstone confirmed that the FSA was working with DH colleagues on this aspect. It has been advised by SACN that DH should develop a strategy to manage vitamin B12 deficiency irrespective of a decision on folic acid fortification. Further detail on this would be included in the May Board paper;
- **Q.** Were there treatment methods for diseases resulting from NTDs, colorectal cancer and B12 deficiency? **A.** Professor Jackson confirmed that NTDs resulted in life-long debilitating disabilities for which there was no treatment. Cancer of the colon could often be treated if it was caught early enough, otherwise it was fatal. B12 deficiency was treatable by administering muscular injections of the vitamin. However, if not detected and treated at an early enough stage, in extreme cases it could result in irreversible nerve damage.

Ethical Implications

7. Robert Dingwall gave a presentation on the ethical implication of the options (presentation slides are attached at Annex 4). Board member raised the following points and questions:
 - **Q.** Option 1 (no change) and option 4 (mandatory fortification) had been given as clear cut choices in terms of ethical considerations. What was the “killer punch” for rejecting option 2 (increased public education) and option 3 (voluntary industry fortification) on these grounds? Professor Dingwall responded that options 1, 2 and 3 gave the greatest weight to autonomy, which traditionally - in bioethics - had been the “killer punch”, but options 1, 2 and 3 were ineffective at delivering equality and justice. Option 4 (on mandatory fortification) delivered equality, protection of the vulnerable and social responsibility but at the cost of autonomy. Option 1 (no change) kept autonomy intact, and therefore allowed maximum individual choice. Although Options 2 and 3 provided autonomy they did not provide very much overall benefit above option 1. Options 1 and 4 therefore provided the most ethically coherent positions;
 - Clarity was sought on the basis of research used for this ethical report. Professor Dingwall confirmed that he had used the SACN report and recommendations, the FSA consumer research, and the literature review commissioned by the FSA;
 - Although option 4 on mandatory fortification was highly rated for protecting a vulnerable group (i.e. the unborn child), going down this route would create another possible vulnerable group who could be put at increased risk of

disease. Professor Dingwall confirmed that he had already captured this point in his full report, which would be made available for the May Board meeting;

- This was a very interesting framework and the Board looked forward to receiving the final version of the ethical report. Professor Dingwall confirmed his final report would be a full consideration of the current discussions in bioethics and what they implied in respect of considering the options for dealing with improved folic acid intake.

Presentation on Consumer Research

8. Alison Tedstone gave a presentation on the FSA's consumer research (presentation slides are attached at Annex 5). Board members raised the following points and questions:

- A Board Member noted that it was important to remember that small samples of people were included in the interviews and workshops in this consumer research, so their views could not be regarded as representative of a majority view. It was therefore important not to overstate the conclusions from this research. The literature review however provided more robust data on consumer research;
- A Board Member noted that the results from the consumer research indicated that people who were opposed to mandatory folic acid fortification might not feel strongly enough to campaign against it or write to their MPs about this in the event of it being introduced. This was an interesting position compared to the situation regarding the addition of fluoride to tap water. Before its introduction, there had appeared to be considerable public opposition to this. Alison Tedstone noted that the FSA would be considering the outcome of the consultation exercise which would include all responses including those from people who were strongly against mandatory folic acid fortification;
- It was noted that folic acid campaigns did not have any impact on unplanned pregnancies for young women;
- **Q.** Could the campaigns not be targeted at specific groups? **A.** Alison Tedstone confirmed that the evidence on targeted campaigns is weak; they would however not be effective for unplanned pregnancies.
- **Q.** Do the regulations for organic foods prohibit the addition of synthetic additives? How would this be dealt with if there was mandatory fortification with folic acid? Would organic foods be exempt? Alison Tedstone responded that nutrients were already added to organic white and brown flour.

Thursday 19 April 2007 (09:00 – 09:45)

Folic Acid (Part 2)

Presentation on Technical Issues

9. Gill Fine welcomed Alex Waugh, the Director General of the National Association of British and Irish Millers, to the meeting. Gill Fine informed Board members that this was the final part of the folic acid briefing.
10. Alex Waugh gave a presentation to the Board on the technical issues (presentation slides are attached at Annex 6). Board members raised the following points:
 - **Q:** Clarity was sought on the purpose and benefit of the current nutrients (B vitamins thiamine and niacin, calcium, iron) added to bread and flour. Alex Waugh responded that these had been added to flour and bread for a long time. Alison Tedstone added that Agency analysis shows that more people were not meeting dietary recommendations in these particular nutrients, especially young women. Without these nutrients added, there may be more iron deficiency anaemia, and possibly bone diseases. However, ensuring adequate calcium intake for healthy bone formation was a lifetime issue, unlike folic acid supplementation during pregnancy, which was required for an immediate, short term issue;
 - **Q.** Why did some industry prefer the voluntary route for fortification? **A.** Alex Waugh confirmed that many breakfast cereals and margarine spreads were already fortified with folic acid. He suggested that companies had invested effort into the unique branding and marketing of these products and did not want to lose these commercial benefits;
 - **Q.** It was expected that fortified products would need to be labelled clearly for consumers. How would this be achieved? **A.** Alex Waugh confirmed that current regulations did not require the labelling of flour as being fortified. It would be for FSA lawyers to advise on the labelling aspects regarding folic acid fortification;
 - **Q.** Had any tests been done to assess the level of folic acid which was cooked out of products, to ascertain the remaining yield? **A.** Alex Waugh responded that, in terms of folic acid addition to flour, there was no loss. However, there was variable loss when flour was cooked depending on the type of product, water content and level of heat applied. From studies, bread was found to have around a 25% cooking loss of folic acid, whereas cooking loss from small products such as biscuits was greater. Alison Tedstone further clarified that there was currently only data available from the Netherlands on this issue, though it was understood that the Irish were carrying out some research;
 - A Board Member said that it would be useful to know the consumption patterns of flour containing products by gender across the population. It was

not clear if the SACN modelling data had been based on all flour containing products. It was also noted that the Irish and US data suggested that young women ate less cereal products. Alison Tedstone noted that the SACN modelling was based on estimates of wheat flour consumption so it took into account all wheat containing products. Board members would be supplied with further details of the range of fortified products that were considered. As the consumption of bread by women was uniform, this was considered to be the most appropriate route. The Chair noted that the Board paper in May would need to provide some detailed dietary analyses;

- **Q.** Mandatory fortification may not be favoured by the UK industry due to the associated costs and trade issues. However, folic acid fortification had proved to be a success in the US. Was there any knowledge which could be drawn upon from sister organisations in the US which had overcome the cost/trade issues of mandatory fortification? **A.** Alex Waugh responded that folic acid fortification was “virtually” mandatory in the US. Around 90% of flour sold in the US was currently “enriched” with folic acid;
- It was agreed that the May Board paper should include details of the situation in other countries, such as Chile, and whether approaches taken were mandatory or voluntary. Alison Tedstone noted that Chile had successfully introduced mandatory fortification with folic acid and the number of births with NTDs have significantly reduced. Only US, Canada and Chile, had reported the affect of fortification on NTDs. However, for Chile, published data on cancer trends had not been found. Alex Waugh added that the industry’s view was that if the mandatory fortification option was chosen, the simplest mechanism would be to provide for this under the existing bread and flour regulations. However, in his view the industry’s overall position was that this was a public health issue and for the government, not the industry, to decide;
- A Board Member noted that the current voluntary fortification of other foods such as fat spreads, and the issue of overage, was an important issue which the Board would need to take into account. Alex Waugh noted that margarine manufacturers were reducing the level of folic acid added to margarines. He was not certain whether this had been taken into account in the SACN modelling of folic acid dosages. However he understood the presence of folic acid in breakfast cereals had been used to assess overage by SACN. Alison Tedstone clarified that a third of low fat spreads were fortified in the UK, and two companies producing these had agreed to lower the level of folic acid in response to the SACN modelling work;
- **Q.** In terms of the suggested impact on the export of flour and flour-based products, was it not possible to operate separate lines for non-fortified and fortified versions of products? **A.** Alex Waugh responded that this was impractical as all flour based products tend to be produced on one production line with labelling covering all language requirements;
- **Q.** The amount of fortification in other foods was an important element. Had any consideration been given to prohibiting the fortification of other foods? **A.** Rosemary Hignett responded that EU legislation had recently been agreed

which intended to open up markets to fortified foods. Certain consumer markets in the EU had opposed to fortified foods (e.g. Denmark) in the past. Since a harmonised regime was being introduced it might be difficult to introduce statutory rules in the UK which would close the UK market to some fortified foods. It might be more appropriate to look at a voluntary approach to limiting fortification of folic acid in other products. Further information would be provided in the Board paper;

- **Q.** What were the cost implications for millers in respect of fortifying flour with folic acid? **A.** Alex Waugh responded that this would be broadly neutral;
- Was it possible to quantify the impact on trade? Alex Waugh responded that this was difficult to estimate and would depend on the reactions of consumers and buyers in other countries. It was not possible to predict, and the only way to quantify this was to go ahead and see what happened.

Conclusions from the Briefing Session on further information required for May Board

11. The Chair asked Board members to confirm whether these briefing sessions had provided them with the information they required.
12. Board members agreed that more clarification was required on some of the technical aspects. There were particular concerns on how changing behaviour would affect the dynamics of the market. It was assumed that if the mandatory route was followed, imported flour would be exempted which would offer choice to consumers. It would be helpful to get some projections on what might happen to the imported flour market. It would also be useful to draw on the experience of other countries who already fortified flour with folic acid, and the impact this had had on trade, as well as health and public perception issues. There also needed to be greater clarity on the dietary intake of the target group.
13. The Chair summarised that the Board had requested the following additional clarifications to be included in the May Board paper:
 - more detail and analysis of dietary intake patterns for flour containing products;
 - information to assess the impact on trade of mandatory fortification;
 - an explanation of the possible route to control voluntary fortification;
 - more information on the legal position, including the labelling aspects;
 - further detail on consumption patterns, including the bread and biscuits issue, and the effect of folic acid across all age groups and genders;
 - more information and lessons learnt from other countries which already had folic acid fortification in place.
14. In summary, Gill Fine noted that it would be very difficult to provide a projection on trade impacts, but the FSA would endeavour to garner what information there was on this. It was agreed that any information which was available earlier would be sent to the Board in advance. The Board would also receive the ethics report and consumer research report in advance of the meeting.

15. It was agreed that a summary of this briefing session would be published on the FSA website at the same time as the May Board paper.