

Report from the Folic Acid Public Stakeholder Meeting

Sigrid Gibson on behalf of the Food Standards Agency

The views and facts expressed in this report are those expressed by the delegates who attended and spoke at the meeting.

Introduction

The Food Standards Agency, together with the UK Health Departments, held a public stakeholder meeting on 18th March at the Queen Elizabeth II Conference Centre, London, to discuss the proposal to fortify flour with folic acid. The purpose of the meeting, as outlined by the Deputy Chair of the Food Standards Agency, Suzi Leather, was to provide a further opportunity for discussion and debate following the formal consultation exercise. It was emphasised that no decision would be made at the meeting, rather that the points raised would help the Food Standards Agency to formulate its views before their Board meeting in Aberdeen on 9th May 2002. Ninety people attended the meeting from the fields of science, medicine, consumer rights and food production (a list of delegates can be found on the Food Standards Agency's website www.food.gov.uk). Five speakers representing the main areas of the debate made presentations, with two hours of open discussion in the afternoon.

Folic acid and the prevention of disease

Professor Alan Jackson (Director of the Institute of Human Nutrition, University of Southampton and Chair of the Scientific Advisory Committee on Nutrition, SACN) outlined the main rationale for the proposal to fortify flour with folic acid. He said that COMA had considered a range of evidence from different studies on the effects of folic acid supplementation at levels from 400 µg to 4 mg per day in preventing neural tube defects (NTDs), which occur very early in

foetal development. Folate status is known to be low in up to 10% of teenage girls and in around 30% of people over 65 years, many of who have a more severe level of deficiency.

Poor folate status is associated with anaemia, high homocysteine levels (a risk factor for cardiovascular disease, CVD) and may be associated with poor mental function and cancer. Folic acid is the synthetic form of the vitamin, but naturally occurring folates in the matrix of foods appear to be less effective in raising folate status and even very high consumption of fruit and vegetables would not achieve the amount effective in preventing NTDs.

The COMA panel (Department of Health 2000) had to weigh the evidence of potential benefit of folic acid against a risk of harm occasioned by the 'masking' of any vitamin B₁₂ deficiency, whose prevalence in the older population was estimated at the time to be about 150 000 people. Untreated vitamin B₁₂ deficiency can progress to neuropathy and eventually paralysis. COMA considered that on balance, the benefits outweighed the risks and examined various options for action. Different levels of fortification for flour were modelled using data from national surveys, from which it was concluded that 240 µg/100g food as consumed would have significant effect in preventing NTDs.

Spina bifida and hydrocephalus

Andrew Russell (Executive Director of the Association for Spina Bifida and Hydrocephalus) explained the nature of conditions such as Spina Bifida and Hydrocephalus, which could include severe physical disability, kidney, bone and skin problems and, in a high proportion of cases, learning difficulties (80% of children with spina bifida have hydrocephalus). Not surprisingly many of these children and their families experience a heavy burden of physical and mental stress and there is often inadequate social and primary care provision. At present the only alternative 'prevention' is abortion,

Correspondence: Dr Louis Levy
Louis.Levy@foodstandards.gsi.gov.uk

with around 1000 abortions per year for NTDs detected in pregnancy. Many of those born at term were not detected as NTD at scan. In Mr Russell's view, fortification of flour with folic acid provides a rare opportunity to significantly reduce the incidence of this serious disability, following in the tradition of protecting the population from significant health risks. It is cheap, effective and safe and can be used alongside supplementation, which fails to reach the group with unplanned pregnancies.

As to the risks, those on anticonvulsant medication need additional folic acid and this does not appear to interfere with their treatment. With regard to B₁₂ deficiency, it was suggested that this must be dealt with separately through GPs. Other potential benefits in reducing CVD could also be substantial. Following the fortification of cereal products in the US, in one year the rate of NTD births fell by 20 per cent, while heart attacks among the elderly fell by 34%. People who were concerned about additions to their food would do well to remember that many foods have additives that are added for technological reasons, not on grounds of public health. Mr Russell concluded that it would be culpable not to fortify and it was now decision time.

Folic acid fortification and possible risks to older people from unrecognised vitamin B₁₂ deficiency

Professor Sir John Grimley Evans (Professor of Clinical Geratology, University of Oxford and Chair of the Committee on the Nutritional Aspects of Food and Nutrition Policy) discussed the possible risk of harm arising from high levels of folic acid among people with undiagnosed vitamin B₁₂ deficiency. He estimated that the number of older people with a B₁₂ deficiency was closer to 500 000 (or 1 in 15 of over 65s) compared with the 150 000 cited in the COMA report.

Deficiency of vitamin B₁₂ was rarely due to inadequate diet but rather to lack of ability to absorb B₁₂, or to insufficient stomach acid to release the vitamin from food. There were two potential dangers in folic acid supplementation: the delayed diagnosis of B₁₂ deficiency, and the theoretical risk that the rate and severity of spinal cord damage would be enhanced by folic acid. On the former, the British National Formulary warns doctors not to give folic acid to older people without first excluding B₁₂ deficiency, and to do so would be negligent. On the second there is no clear evidence, and indeed a trial would be unethical. He emphasised that the diagnosis of B₁₂ deficiency is not always clear-cut since B₁₂ levels in blood may not always be low. Using

two other blood tests, for methylmalonic acid and homocysteine, Professor Grimley-Evans' team found a prevalence of vitamin B₁₂ deficiency of 3–4% among under 65s and 5% among older people in the Oxford Healthy Ageing project.

Professor Grimley-Evans advocated the following compromise, a 'win-win' solution, which would enable the immediate fortification of flour while maintaining protection for older people from B₁₂ deficiency. The 'free' GP check at age 75 could be used to test blood homocysteine levels, which are raised in both folate and B₁₂ deficiency. This could be followed by opportunistic testing of 65–74 years olds, with a public awareness campaign. A research portfolio was needed for age 65 + to provide more data on the incidence of B₁₂ deficiency at various ages, the best way of diagnosing and preventing it and the optimum level of folic acid needed. This, Professor Grimley-Evans said, would allow for immediate fortification with benefit to older people and a safeguard for those with B₁₂ deficiency. 'Overage' – the addition of more than the stipulated amount of folic acid for legal and technical reasons – would also cease to be a concern. He concluded by saying that the Agency should not separate the B₁₂ issue from the folic acid fortification debate; it should tackle them together to avoid conflict.

Technical issues associated with fortification of flour with folic acid

Alex Waugh (Director-General of the National Association of British and Irish Millers, NABIM) outlined the practicalities for the milling industry in the UK. Sixty flour mills produce 99% of the total yearly tonnage of flour (4.5million tonnes) and 60% of this is made into white bread (15% into other breads). Calcium, iron, thiamin and nicotinic acid are already added by law to flour (other than wholemeal flour) but only calcium is added at levels higher than those lost in processing. Mr Waugh emphasised that folic acid fortification is a public health decision that government must make and fund. Voluntary adoption is unlikely if there are concerns about health implications related to vitamin B₁₂, or the impact of long-term fortification on the general population. It is technically feasible to add folic acid in the micronutrient mix, with an error of around 5–10%, but there are also potential inconsistencies in the final product due to variable baking losses that average 20–30%. Giving consumers the choice of unfortified products would lead to multiplication of product lines with cost implications. Labelling could also cause con-

fusion where flour is an ingredient in other products. If the mandatory fortification route is chosen this should be implemented via the existing bread and flour regulations, which exclude wholemeal flour. Millers of organic flour also oppose the current mandatory addition of nutrients to bread on consumer choice grounds. Exports might be affected and some countries have cited fortification as a barrier to trade. This is particularly relevant to products such as biscuits and cakes.

Fortification of flour with folic acid: a consumer perspective

Sue Davies (Principal Policy Advisor for the Consumers' Association, with responsibility for food issues) explained that this issue required careful balancing of the principles of allowing consumer choice while also ensuring consumer safety. There was a clear benefit to women and children, with an estimated 40% reduction in risk of NTDs. Supplementation alone is ineffective since up to half of all pregnancies are unplanned (and folic acid needs to be taken from around the time of conception). The main risk of fortification is masking of B₁₂ deficiency, which affects many older people but other affected groups include some vegans and ethnic minority communities. Taking the COMA option of fortification with 240 µg folic acid per 100 g flour food as consumed, approximately 7% of women would receive more than 600 µg per day, and 38 NTD affected births per year would be prevented. On the other hand, 0.6% of over 50s would be exposed to a folic acid intake of more than 1000 µg per day. Ms Davies said that the option of increasing intake of folate-rich foods has greater appeal to many, but natural folates are less effective than folic acid at raising folate status and recommended intakes are difficult to achieve without eating liver, which is not appropriate for pregnant women and vegetarians. Extending the present voluntary fortification of foods has advantages in that such products raise red blood cell folate, and are readily available at minimal increased cost. Around 80–90% of breakfast cereals are currently fortified with folic acid at levels of 125–250 µg/100 g or higher and some soft grain white breads are also fortified. Voluntary fortification allows consumers to choose unfortified products but there is the disadvantage that intakes would be difficult to control due to variable consumption and the increasing range of fortified products on the market. One also might want to ensure that foods that were being fortified were consistent with healthy eating advice. Mandatory fortification of flour, while ensuring

that women were getting enough folic acid early on in pregnancy, could lead to a lack of consumer choice unless there were alternatives.

In summary, Consumers Association would like the following points addressed before any decision is made: (1) the need for effective public health monitoring and treatment of B₁₂ deficiency; (2) a feasibility study to assess whether consumers would still have a choice over whether or not to be consuming high levels of folic acid; (3) proper evaluation of what the experiences have been abroad (for example the USA where universal fortification was introduced in 1997); (4) a consideration of the conclusions of the imminent report of the expert group on vitamins and minerals; (5) establishment of mechanisms for monitoring and enforcement of folic acid levels in food. Crucial to any solution on fortification is the issue of communication, not only about the benefits of taking folic acid for women of child bearing age but also clear labelling and warnings, and clear explanation as to why this approach is being taken. It is useful to look at the way the Food and Drug Administration has approached this in the US and the information that they put on their web site.

Chairman's summary

Suzi Leather (Deputy Chair of the Food Standards Agency) summed up the issues presented in the morning. No one was in favour of NTD births or neuropathy. The core issue was how can we protect against the first without increasing the risk of the second? It was not just a question of feasibility and cost. It was about taking a public health approach to an issue that could balance the needs of one sector of the population against another. Ms Leather also welcomed the new information that the prevalence of B₁₂ deficiency was wider than first thought. One thing was certain, diet and education alone were not enough to raise the folate status of pregnant women.

Panel discussion and interactive question-time

During the morning session, delegates were invited to make written comments that were then collated into themes to help focus the afternoon debate. Individuals' questions and comments can be found on the Food Standard Agency's website (www.food.gov.uk). The discussion forum in the afternoon raised many questions and views from the audience. The main issues are categorised here thematically, rather than in the order discussed, since some issues were returned to at different times in the proceedings.

Background issues

What is the position of other countries with regard to the acceptability of fortification with folic acid?

Alex Waugh commented that this varies between countries. The French are very much against fortification of flour, others are more pragmatic and Scandinavia is resistant to fortification in general. Otherwise in Europe fortification with folic acid is not much discussed, perhaps because the NTD incidence in most countries is lower than in the UK.

Is the incidence of NTD-affected pregnancies higher in Scotland?

Andrew Russell commented that there is a higher incidence of NTD pregnancies in the west coast of Scotland, compared to elsewhere in Britain. Dr Martin Donaghy (Scottish Health Executive Department) commented that the rate in Scotland overall was twice that in England and Wales. Evidence points to a genetic susceptibility, with other Celtic populations (Wales, Ireland Cornwall, etc.) also appearing to have a higher incidence. There may also be dietary factors as well. A case for 'special circumstances' may need to be made in proposing folic acid fortification to the European Commission.

What is the number of NTD-affected pregnancies as opposed to births?

Professor Nicholas Wald (Wolfson Institute) said that for every NTD birth there are approximately 9–10 terminations of pregnancy, always a tragedy in the life of a family. This doesn't take into account the number of miscarriages due to NTDs.

Benefits: The US experience of fortification

Are there any lessons to be learned from the US experience?

Professor Wald said that over the last 20 years about a quarter of the population of the US, including the elderly, have been taking vitamin supplements including folic acid at 400 µg. There has been no hint of any adverse effect and, in general, all the major diseases have been coming down. NTD incidence has fallen by approximately 20% as a result of their fortification policy, which is at 140 µg/100 g grain.

Dr Alan Long (Vega Research) made the point that there was one group, those with coeliac disease, who would not benefit from the proposed fortification, as they needed to avoid wheat products. In the US, grain products other than wheat were also fortified.

How confident can we be that we can ascribe the positive outcomes in the US to folic acid fortification?

Professor Wald said he was reasonably confident for two reasons. First, the effect coincided with what one would expect from the dose-response data and, secondly, the timescale (1–2 years) was consistent with the introduction of fortification.

Risks

Is there a risk we could see a rise in cancer in 20 or 30 years time?

Professor Malcolm Law (St Barts and Royal London School of Medicine) commented that the associations between cancer and folate are very much in the direction of folic acid preventing cancer. There is very good evidence from the US Nurses Health study that folic acid helps to prevent colon cancer. He thought there were no grounds for serious concern that folic acid fortification would increase the incidence of cancer in Britain.

Professor Grimley-Evans stated that the possibility of unknown long-term effects was something that was debated by the working group of COMA. However, he emphasised it was extremely difficult to recognise long-term minor effects against the background of other changes occurring. The only way to be sure there was an effect was to do a randomised control trial, but it was not feasible to carry those out over such a long period of time.

Professor Jackson said there was a need to keep an open mind on untoward effects. Folic acid is not normally ingested in this form (except in fortified products) and would be taken at levels above normal consumption. However the fact that there have been many people in US at this level without obvious effects, gave some reassurance.

Can we say with confidence that the US experience shows that there is no risk of masking B₁₂ deficiency?

Unfortunately no, according to Professor Grimley-Evans. The starting points were different for Britain and for the US, and so the trends would be different. The

primary care of older people was better in the US, because doctors are paid for investigations. There may be more undiagnosed B₁₂ deficiency in the UK. His proposed solution would be to tackle this in parallel to fortification.

Is there any evidence of accelerated neurological damage with folic acid supplementation?

Professor John Dickerson (former Professor of Medicine at St Bartholomew's) said that this concern originally arose when people with pernicious anaemia (B₁₂ deficiency) were treated with folic acid. He had examined the data and found no evidence that folic acid made the neurological symptoms of B₁₂ deficiency worse.

Does folic acid increase the incidence of multiple births?

Professor Helga Refsum (University of Bergen) commented that some studies have shown an increase in the rate of twin births. Such births are associated with an increased risk of complications, some of them serious, and these might exceed the benefit of preventing NTDs.

Anthony Wright (Institute of Food Research, Norwich) commented that an increased frequency of twins with folic acid supplementation was not surprising if it were overcoming a metabolic block. It was a question of the balance between NTDs and defects that may arise as consequence of multiple births. Professor Grimley-Evans commented that the most plausible explanation for twin births was that folic acid is acting as an antiabortifacient. If this is the case, perhaps there are ethical issues about not fortifying?

Professor Wald was not persuaded about a link with multiple births. A large study in China showed no effect. The evidence at present was completely open on twins and miscarriages.

Carol Sobkowiak (Society for Research into Hydrocephalus in Spina Bifida) agreed that in the study in Northern China, NTDs had been reduced by 70% over 2–3 years with no evidence of an increase in twins. However, Rose Ford commented that the dramatic reduction in NTDs in the China study could not be extrapolated to the UK because their starting level was much higher and genetically they were different. Even with the 400 µg supplement, their NTD incidence remained above that of the UK.

Folate status in the UK

Which is the best way to improve the folate status of pregnant women?

Dr Robert Fraser (Royal College of Obstetrics and Gynaecology) argued that fortification is the only way forward for the particularly high-risk group of disadvantaged teenaged girls with unplanned pregnancies.

Dr Wendy Doyle (British Dietetic Association) agreed that it is very difficult to improve the diets of these mothers, the majority of whom also say that they can't afford to take supplements and do not always have GPs who are supportive in providing folic acid supplements. She supported fortification.

Dr Maureen Beauchamp (National Council of Women) made the related point that poverty is a cause of ill health, and fortification of the cheapest bread would get it to the risk groups we want to look after. Others could buy the wholemeal/unfortified bread if they want. Jane Kellett, speaking from personal family experience also made a similar point that bread would reach the target groups, teenagers and old people, while folic acid supplements were beyond the knowledge of pregnant teenagers.

Is there a public health problem of low folate status in other age groups?

Professor Jackson reminded the audience of the evidence from National Diet and Nutrition Surveys. The folate status of the population is not particularly good. The quality of folate status varies with age group, being better in younger children than in teenage children, but it is particularly bad in older people. Leaving NTDs aside, there was a need to do something about folic acid just to achieve normality of function. There was also a wider issue of poor nutrition amongst the elderly that needed to be addressed at some point.

How should low folate status in the elderly be tackled?

Professor Grimley-Evans felt that the public health approach should be modified by individualisation of the dose. Some older people will need their B₁₂ deficiency treated before folate deficiency and a lot of elderly people would need more folate than is available by fortification.

Professor David Smith (University of Oxford) agreed that the nutritional state of the elderly was of great concern but thought the proper approach was to target

the at-risk groups, whereas he considered mandatory fortification unethical. He emphasised the need to do proper clinical trials to evaluate the impact of folic acid and B₁₂ on endpoints such as dementia, cardiovascular diseases and cancers. In this regard, Dr Robert Clarke (University of Oxford) subsequently informed the audience of a randomised control trial currently underway in the UK with 12 000 patients given folic acid and vitamin B₁₂, compared with placebo. In about 3 or 4 years from now, he said, we should have clear evidence on the benefits of various regimens.

Professor Wald, taking issue with Professor Smith, said that independent groups in Britain, America, Israel, Australia and New Zealand had all concluded that on the balance of the evidence, folic acid is safe. The concerns were hypothetical. He argued that to continue not to fortify is unsafe, leading to pregnancies and children that are handicapped, when this could be avoided.

Should we be using a pharmacological solution to address a dietary problem?

Several participants raised concerns about the pharmacological approach implied in fortification. Professor Jackson commented that the level of folic acid required to achieve NTD prevention is way above what could be achieved by diet. He acknowledged that this was of some concern. If we had a clearer idea of mechanisms this could open up the possibility of a physiological approach. But there is a real problem to be addressed, and we should not wait for complete level of understanding before going ahead with an intervention that clearly produces benefit, provided that we are comfortable that it is not associated with unreasonable harm.

Can vitamin B₁₂ be given orally? Should fortification with vitamin B₁₂ be contemplated at the same time as folic acid?

Professor Grimley-Evans said that at the moment treatment for vitamin B₁₂ deficiency is in the form of B₁₂ injections. COMA had considered giving it as an oral supplement, and whether vitamin B₁₂ could go in the bread at the same time as the folic acid. But they were not sure what oral dosage would be appropriate for the different range of causes of B₁₂ deficiency. At a conservative estimate it might turn all the bread pink, so the idea was not pursued further.

Another participant commented that some people might need less B₁₂ because the major cause of B₁₂ defi-

ciency is now thought to be lowered stomach acidity, with intrinsic factor still intact. However Professor Grimley-Evans commented that this approach (adding B₁₂ at a low level) could have the effect of lulling people into a false sense of security.

Is it ethical to force-feed one million people to save one NTD affected birth?

Professor Refsum raised this point and considered the ratio unacceptable. She also had concerns about potential adverse effects on some people (e.g. those with folate-responsive conditions). She claimed that the reason there was no evidence was because there had been no studies. In her view there was a need to get the data on the table and treat the right people in the right way.

Professor Brian Wharton (Institute of Child Health) estimated that fortification would prevent about 1 NTD per 1000 births, against around 50 per 1000 people over 65 years put at nutritional risk, unless Professor Grimley-Evans' very extensive policy could be put into operation. The statistic looked very one sided in favour of the babies.

Professor Grimley-Evans commented that we shouldn't be trying to balance one group against the other, but to try to do right by all groups. Playing off neural tube defects against risks to elderly people would take us down the wrong path of discussion.

What would be the impact on children, who may have higher folic acid intakes from fortified foods?

Professor Jackson said he couldn't tell without doing the computations what the change of consumption would be for the different age groups.

Costs of screening for vitamin B₁₂ deficiency

Would the costs of screening for B₁₂ deficiency be outweighed by the health benefits?

Professor Grimley-Evans answered that health checks were currently a 'right' but what is offered varies and often depends on patient request. Routine screening for deficiency might therefore reduce health inequalities and have significant benefits to health and health care costs. In the US the number of elderly with disability has been reduced by 2 million. The costs might be considerable, but so might the benefits.

What would be the cost of screening for homocysteine?

Homocysteine tests at the moment cost the laboratory about £3–4 per test, which could come down to £1 or so as the volumes increase. Homocysteine ‘point of care’ tests should be available in the next couple of years or so. The total would come to £8 million but this is not counting the cost of administering the tests within primary care settings.

Consumer liberty

It is unacceptable that there will not be adequate public or parliamentary debate on this issue. It deserves discussion on the floor of the House of Commons.

Suzi Leather said that the Agency shared the view that stakeholder debate is vital and this meeting was evidence of that. MPs with an interest in folic acid had been invited. In addition, the Department of Health and the Food Standards Agency had held a formal consultation, the outcome of which was in the public domain on the Department of Health and the Food Standards Agency websites. Furthermore, when the Agency Board meet in May that policy debate would also be held in public, and the minutes published.

What is being done to protect choice?

Sue Davies said that it was vital, if the decision were for mandatory fortification, that consumers still had access to unfortified flour and products. There was a concern that unfortified products, e.g. wholemeal flour, might cost more and these issues needed to be looked into.

Technical issues

What is the likely ‘overage’ of folic acid in flour? What have we learned from the US experience? What procedures have the millers to monitor this overage?

Dr Clarke explained that since the modelling was carried out in Britain, several studies have reported in the US that the degree of overage is approximately 100%. This implied the intake is double what the FDA initially predicted. Given the same degree of overage here, that would suggest that perhaps 10% of the male population could have an intake greater than 1 mg.

Alex Waugh said he doubted that the US figures were

due to mistaken over-addition but speculated that it might instead represent a deliberate policy to ensure that every single loaf hit the target. In the UK, since the millers and bakers had little chance of recovering their cost from the market, they wouldn’t add more than they need to. It is feasible to attain reasonable accuracy over a batch.

How much would it cost to add folic acid to bread?

Alex Waugh estimated the cost was about £35 000 per tonne of folic acid with 10 tonnes being required in addition to the capital and labour costs involved. One member of the audience queried these sums and calculated the cost as much lower. Alex Waugh replied that, paradoxically, it was because the cost was so small to fortify each loaf that it was unlikely to be recovered from retailers or consumers.

If only certain loaves were fortified and carried health claims, how much extra would the consumer have to pay for them?

Alex Waugh replied that he didn’t know the answer to this question. It would introduce logistic complications, not least for the retail shelf and would tend to put up the cost to the consumer.

Peter Wood (Federation of Bakers) explained that, for industry, the choice has to be mandatory or nothing. It was not a practical proposition for the industry to volunteer to supplement breads. Nor could they be expected to provide a range of alternatives. He was also concerned that, given the degree of uncertainty of the side-effects, the industry could find itself being sued for compensation at some future time. Even if, as in the case of MMR, the medics were unequivocal in saying there was no risk, cases might still be brought. He emphasised that the industry was neither for nor against this mass fortification on moral or ethical grounds; it was not their decision. Other participants from industry made similar points.

Why was bread chosen as the vehicle?

Professor Grimley-Evans explained that COMA decided on bread primarily because there was a national precedence for fortifying bread (and fats) since World War 2. They considered fats but shifts in the balance of spreads being used made it difficult to estimate what the doses would be. With bread, the distribution of folic acid intakes through the population could be modelled. It

was also known to be feasible from the manufacturers' point of view

Professor Jackson said that the COMA group had considered a number of options, but had to identify a staple, which the target audience would consume, and be able to fortify it in a way that could be reasonably regulated, so that the intake across the population groups could be determined.

Can organic flour be exempt from fortification?

Suzi Leather commented that it is not exempt at the moment. The current rules on additions of nutrients (referred to elsewhere) include organic flour.

How has the consumer in the US responded to fortified bread?

There appears to have been no drop in confidence in bread in the US. Sue Davies commented that this was a good example of successful consultation.

Is folic acid fortified bread available now? How popular was it?

A small number of soft grain breads are fortified with folic acid, but this tends to be at the premium end of the market. There was a comment that this should be the other way around, with fortified bread at the lower end of the market and premium bread unfortified to allow the choice that some people want.

Ms Gill Fine (Sainsbury plc) commented that Sainsbury's had produced a fortified standard white loaf (at no extra cost) around about the time of the HEA supplements campaign, but had to withdraw it because it wasn't selling. The awareness level may not have been high enough at the time. That is why communication is so important, she said.

Which group of consumers is most likely to buy fortified foods?

Ms Fine said they hadn't done this analysis but fortification wasn't necessarily high on the list of reasons of why people buy foods unless they have a particular concern. Most buy for taste and price.

Which other foods are fortified with folic acid?

On a voluntary basis, the majority of breakfast cereals are now fortified with folic acid alongside other vitamins. A number of dairy product companies have added folic acid and other vitamins to special ranges of milk

although they are not allowed to call it 'milk' under the compositional requirements

The future

Professor Jeya Henry (Food Standards Agency Board Member) observed that many questions had been raised in relation to the US experience for which we had no answers. He said that despite the differences between the UK and the US, there was a need to review the US experience, as this would inform the Board at its future meeting.

What are the potential timelines for fortification? How long would the process be?

Mr Tom Murray (Food Standards Agency) stated that it would take a minimum of 12 months for the statutory base to be implemented from the time the health ministers made a decision. The Agency Board would look at the proposal in May, and make a recommendation to the 4 health ministers (for Scotland, Wales, England, Northern Ireland). Then, if ministers agreed, they would be looking at a statutory mechanism for each of the countries, it would go through a 3-month consultation period on the specific legislation. When UK ministers had approved a legislative approach it would be notified to the European Commission and EU member states and there is a 3-month standstill period, during which time the Commission and other member states have to comment and agree whether it goes forward. The regulations would then be finalised and laid in Parliament under a negative resolution procedure. Regulations would then come into force with a possible lead-in to allow manufacturers time to comply. If all was straightforward it could take 12 months, if not then it could be longer.

Chair's closing remarks

In concluding the discussion, Suzi Leather acknowledged that folic acid fortification was one of the most difficult issues the Agency has had to consider. The debate had heard scientific and ethical arguments on both sides and she thanked the speakers and the audience for their participation. She reminded the audience that a report of the meeting would be on the website www.food.gov.uk.

Action since stakeholder meeting

The Food Standards Agency considered the issues relating to the implementation of folic acid fortification of

flour, in order to give advice to Health Ministers in the UK on the way forward on possible action at its open meeting on 9 May 2002. A note of this meeting can be found on the Agency website at www.food.gov.uk/multimedia/pdfs/paperfsa020601.pdf.

The Agency Board could not recommend to Health Ministers the mandatory fortification of flour with folic acid at this stage, but agreed to review the evidence as soon as further information could be obtained. Of particular interest in this would be the experience of other countries in relation to the impact of increased folate

intakes on older people and also evidence from work on Alzheimer's disease and cardiovascular disease. The Agency has now provided advice to all UK Health Ministers and this is available on the agency website at www.food.gov.uk.

Reference

Department of Health (2000) *Committee of Medical Aspects of Food Policy. Report on Folic Acid and the Prevention of Disease*. London: The Stationery Office.