



Llywodraeth Cynulliad Cymru  
Welsh Assembly Government

Department of Health,  
Social Services & Public Safety  
An Roinn Sláinte  
Seirbhísi Sóisialta agus Sábháilteachta Poiblí

**Report from the  
Folic acid public stakeholder meeting**

**Food Standards Agency  
And UK health Departments**

**18 March 2002**

**Queen Elizabeth II Conference Centre, London**

Written by Sigrid Gibson on behalf of the Food Standards Agency

April 2002

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 18<sup>th</sup> 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. Five speakers representing the main areas of the debate made presentations, with two hours of open discussion in the afternoon.

Professor Alan Jackson is the Professor of Human Nutrition and Director of the Institute of Human Nutrition in the University of Southampton and Honorary Consultant in Clinical Nutrition for the Southampton University Hospitals NHS Trust. He trained in paediatrics at the University of Cambridge and University College Hospital London. He was the Director of the Tropical Metabolism Research Unit in the University of the West Indies, carrying out research on metabolic adaptation and undernutrition. He is the chair of the Scientific Advisory Committee on Nutrition.

Andrew Russell is the Executive Director of the Association for Spina Bifida and Hydrocephalus. His career has been spent working with disability organisations in the voluntary sector.

Professor Sir John Grimley Evans is Professor of Clinical Geratology at the University of Oxford. He is also consultant physician in Geriatric and General Medicine at Oxford Radcliffe Hospitals. He was previously Professor of Medicine (Geriatrics) at the University of Newcastle upon Tyne. He has training and experience in medicine and epidemiology at the Universities of Cambridge, Oxford, Michigan, London and the Medical Research Unit, Wellington, New Zealand. Professor Grimley Evans was the chair of the Committee on the Nutritional Aspects of Food and Nutrition Policy.

Alex Waugh is the Director General of the National Association of British and Irish Millers. He has worked in a number of roles for NABIM since 1987. Prior to joining NABIM, he worked on an arable farm and in the building industry.

Sue Davies is the principal Policy Advisor for the Consumers' Association, with responsibility for food issues. Prior to working for the Consumers Association she worked on food safety issues within a Local Authority Environmental Health Department.

## **Morning Session**

### **Speakers presentations**

#### **Folic acid and the prevention of disease**

Professor Alan Jackson, outlined the main rationale for the proposal to fortify flour with folic acid.

COMA had considered a range of evidence from different studies on the effects of folic acid supplementation at levels from 400µg to 4mg 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 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 B-12 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 240µg/100g<sup>1</sup> would have significant effect in preventing NTDs.

#### **Spina Bifida and Hydrocephalus**

Andrew Russell 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, with around 1000 abortions per year for NTDs detected in pregnancy. Many of those born at term were not detected as NTD at scan.

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<sup>1</sup> N.B. COMA concluded that universal folic acid fortification of flour at 240µg/100g in food products as consumed would have significant effect in preventing NTD-affected conceptions and births without resulting in unacceptably high intakes in any group of the population

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 3.4 per cent. 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. He 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 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 65's) 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 65's and 5% among older people in the Oxford Healthy Ageing project.

He 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 year olds, with a public awareness campaign. A research portfolio was needed for 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, he 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.

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 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.

He 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 per cent. Giving consumers the choice of unfortified products would lead to multiplication of product lines with cost implications. Labelling could also cause confusion 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 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 240µg folic acid per 100g flour<sup>1</sup>, approximately 7% of women would receive more than 600µg 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 1000µg per day.

She 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 125-250µg/100g 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 and 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 we can 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. She 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.

## **Afternoon session**

### **Panel discussion and interactive question-time**

During the morning session, delegates were invited to make written comments which were then collated into themes to help focus the afternoon debate. Individual questions and comments are collated in the annex to this report. 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 (ASBAH) 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 Dept 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): 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 Nicholas Wald said that over the last 20 years about a quarter of the population of USA 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/100g grain<sup>2</sup>.

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 USA, 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 Nicholas 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 yrs) 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 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 John 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 Alan 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 USA at this level without obvious effects, gave some reassurance.

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<sup>2</sup> All US grain products have to be fortified with folic acid at a level of around 140 micrograms of folic acid per 100g in the final product

### **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 USA, and so the trends would be different. The primary care of older people was better in the USA, since doctors are paid for investigations. . There may be more undiagnosed B12 deficiency in 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 Dickinson (former Professor of medicine at St Bartholomew's) said that when 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 from the 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 from 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 anti-abortifacient. If this is the case, perhaps there are ethical issues about not fortifying?

Professor Nicholas 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 Sobkoviak (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 Frazer (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 GP's 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 Alan 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 neural tube defects 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 John 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 three or four years from now, he said, we should have clear evidence on the benefits of various regimens.

Professor Nicholas 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 Alan 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 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 deficiency 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 Helga Refsum (University of Bergen) 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?**

A: Alan 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 USA 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 lab 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 (Deputy Chair of the Food Standards Agency) said that the Agency shared the view that stakeholder debate is vital and this meeting was evidence of that. MP's 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 web sites. 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, (Consumers Association) 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?**

Robert Clarke, (Oxford) 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 one milligram.

Alex Waugh (NABIM) 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 John Grimley Evans explained that COMA decided on bread primarily because there was a national precedence for fortifying bread (and fats) since the World War II. 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 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.

Gill Fine (Sainsbury's) 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?**

Gill Fine said they hadn't done this analysis but fortification wasn't necessarily high on the 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 USA, there was a need to review the US experience, as this would inform the Board at its future meeting.

### **What are the potential time lines for fortification? How long would the process be?**

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 stand still 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 then 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](http://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.

## **ANNEX: DELEGATE QUESTIONS**

'Would the use of Metafolin (6S-5-Methyltetrahydro-folic acid), the natural folate form, be a better choice as a fortificant than folic acid (as it would circumvent any concerns of vitamin B12)?

Paul Finglas (Institute of Food Research)

'The COMA report has focused very much on NTD affected births. Are there any figures, which relate to how fortification will reduce NTD affected pregnancies, and therefore unnecessary and distressing miscarriages and terminations, too?'

Nicole Duckworth (Action Research (Medical Research Charity))

'In the USA, the FDA planned an increase in intake of folic acid by 100µg daily through fortification, but the actual change in intake of folic acid was 200-240µg daily due to "overage". Can you reassure us that this extent of overage (of two folds or so) will not occur in the UK? If what happened in the US also applied in the UK, the model on page 100 of the COMA report would suggest that 1 in 10 people would have a daily intake of folic acid greater than 1000µg'

Dr Robert Clarke (University of Oxford)

(1) 'How many cases of NTD's were prevented per year since the fortification of breakfast cereals?' (2) 'If fortification beyond 240µ/100g does not improve the number of NTD significantly, why should women take supplements on top of flour fortification?' (3) 'The group of women who need to take supplements are most likely going to be the group at risk. How do you propose to improve supplement uptake?'

Pansy Ho (Waitrose Limited)

How much is modern hygiene reducing intakes of B-Vitamins?

Alan Long (VEGA)

(1) How can we be sure that older people get enough folic acid, given that they often have reduced appetites? (2) What about diet-watchers (of all ages) who eat less bread and pastry? (3) How about people with coeliac disease?

Professor John Grimley Evans (University of Oxford)

(1) If excess intake of folic acid is naturally expelled, does this have any bearing on the risk factors for the B12 deficiency group? (2) The incidence of NTD's is variable throughout the UK with Scotland reportedly having a significantly higher incidence than other sectors, this should not be dismissed. Is it possible that delegates may have access to speakers detailed presentation material (a copy of the powerpoint presentation slides would aid and assist understanding of complex but related issues).

Andy Wynd (Scottish Spina Bifida Association)

(1) 'When will there be clarity on the causal link between homocysteine levels and cardiovascular disease?' (2) The EU-SCF and US-FNB have reviewed the safety of folic acid- how convinced is the FSA about the reliability of the safe upper intake level for folic acid, established by the expert groups?

Maurice Smith (Unilever Bestfoods)

(1) 'How can we be sure that supplemented wheat flour will reach potential mothers?' (2) Should we not also supplement other flours?'

Colin Michie (NHS District General Hospital)

'Isn't the real subtext the CVD homocysteine story (for which evidence was not deemed strong enough to go forward) i.e. expected 20-40% in CVD?'

Dr Ruth Ash (The University of North London)

'Would like more discussion on increasing Folic Acid in relation to the really big health issues that affect everyone: - (1) Cancer-do we know anything? (2) CVD's - How much weight do the US data carry i.e. a third in reduction of heart attacks post fortification?'

Clifton Gay (Food Standards Agency)

Please comment on the following: 'Folic Acid fortification and (1) Extra non-identical twin births (2) genetic selection (3) Cancer?'

Anthony Wright (Institute of Food Research-Norwich)

'If spina bifida is linked to gross folate deficiency, what neural damage is being done by intermediate levels of folate deficiency?'

Professor Robert Pickard (British Nutrition Foundation)

'What do the panel members understand to be the positions of other EU countries on this issue?'

Dr John Mason (Freelance Journalist)

(1) 'What are the potential timelines for folic acid fortification, assuming a positive view? (2) Would the FSA wait for a more definitive view from the USA and other countries before any decision (regarding results of fortification with outcomes)?'

George Zajicek (Axis-Shield PLC)

'Does the US experience, in which about 25% of the population (including older persons) have taken a daily vitamin supplement containing nearly double the proposed UK folic acid fortification level, provide compelling evidence of safety given the fact that there has been over 1 billion person years of exposure without any suggestion of, or evidence, for harm-and no indication at all that disease due to B12 deficiency has increased?'

Professor Nicholas Wald (Wolfson Institute of Preventive Medicine)

'Is there any evidence in the USA of B12 masking since fortification of flour in 1998?'

Carole Sobkowiak (Society for Research into Hydrocephalus and Spina Bifida)

'Given that folic acid has been in operation in the US for some years now, is there any evidence from the US that this has led to an increase in neuropathy in the elderly ( due to excessive consumption of folic acid)?'

Jeya Henry (Food Standards Agency Board member)

(1) 'B12 screening in over 75s- will it prevent peripheral neuropathy? (2) If so, what is the current incidence and by how much will it be increased by introducing folate fortification? (3) Is it possible to get copies of the slides?'

Martin Donaghy (Scottish Executive)

(1) 'If B12 deficiency is diagnosed, what is the corrective regime used by the GP? (2) It may be cheaper to routinely inject B12 rather than routinely test, and both are invasive. Would free B12 added as a fortifiant increase blood levels as an alternative?'

David Godfrey (Nutragen)

(1) 'Would the costs of GP screening of the over 75s be outweighed by the health benefits?' (2) How soon could these screening facilities be introduced?'

Dr Maggie Paun (Helen Clarke MP, House of Commons)

(1) 'There is an increasing body of evidence to suggest that folate supplementation increases fertility. Multiple births result in a significant increase in maternal and neonatal mortality. Has this been weighed against the NTD benefit?' (2) Has any consideration been given to targeting vulnerable groups (folate cycle polymorphism carriers)? (3) Fortification with folate only decouples normal dietary links between folate: B12: B6. Has any consideration been given to supplementation with a mix of folate: B12: B6 in normal dietary ratios?'

Dr Paul Haggarty (Rowett Research Institute)

'Has the panel considered the effects of chronic exposure of the foetus to unmetabolized folic acid?'

Mary McNabb (South Bank University)

'Is it right to expose so many people to a substance that may cause adverse effects?'

Professor Helga Refsum (University of Bergen, Norway)

(1) What is the cost of folic acid- what would it add to a loaf of bread? (2) Who pays the costs of current supplements under bread and flour regulations. (3) Wouldn't it be wise to dose wholemeal bread as well? (4) The problem of childbearing women is they number 600 thousand, yet the proposed amount to dose is 50 million people! What is the EU position on this? Especially Sweden's experience if any? (5) The US results of dosing seem very impressive since 1997, did I miss a reference to the dosing of the over 65s- were there any adverse/positive affects noted?

A.A Spencer (A.A Spencer)

(1) 'The beneficial effects of folic acid on oral clefts, can we hear more? (2) Possible risk of increased miscarriage rates with folic acid, can we be assured that the Chinese trial applies here and excludes this risk?'

Cynthia Clarkson (National Childbirth Trust)

(1) 'What provision will the FSA put in place for consumer choice? (2) What would be the legislative procedure for dealing with whatever folic acid provision in the UK is finally decided upon.'

Felicity Mawson (Public)

'Can organic flour be exempt from fortification?'

Sue Wood (Soil Association)

(1) 'Why does one read in GP surgeries a recommendation to avoid eating liver- a valuable source of folic acid- surely overdosing of vitamin A is, at most, academic?'

Anne Worby (Public)

'If flour is to be fortified on a mandatory basis across the UK (not just in England) (a) who will inform the consumer about its presence in flour? (b) how will it be labelled (when other fortificants are not i.e calcium (c) what will happen to the Health Education Authorities folic acid symbol scheme which encourages voluntary fortification at 'source of' and 'rich in' levels across different food categories (d) what averages are acceptable and how will this be monitored (e) will unfortified flour still be permitted to all consumer choice (f) will gluten free flour also be fortified?'

Gill Fine (Sainsburys Supermarkets)

1) Since the prevalence of NTD fell in England and Wales (at a faster rate than seen in the US following fortification) is there any extra need for compulsory fortification in the UK (2) the COMA report recommended fortification to prevent some NTD. Did Professor Jackson argue that there are other compelling reasons for fortification (3) the evidence for supplementation to prevent NTD incontrovertible. Is it correct to extrapolate from supplementation to compulsory fortification without trials (similar to those used in assessing supplementation) (4) have the FSA and their advisors approached other experts in clinical/public health trials to determine the feasibility of fortification trials- (as was done for example with fluoride many years ago) with contemporary (not sequential) controls. (5) if the FSA recommends compulsory fortification, should ministers consider also (a) a compensation scheme for patients with subacute degeneration of cord etc when diagnosis has been delayed. (b) resources for universal testing of over 75 yr. olds (6) how confident are we (50%? 98%) that the only complication of a very high dietary folate/folic acid level are neurological problems in older people?

Brian Wharton (Institute of Child Health)

## Delegate List

Mr David	Alexander	National Consumer Council
Dr Ruth	Ash	University of North London
Dr Margaret	Ashwell	Ashwell Associates
Ms Carole	Asobkowiak	Society for Research into Hydrocephalus in Spina Bifida
Dr Chris	Bates	MRC Human Nutrition Research
Dr Maureen	Beauchamp	NCWGB
Ms Susan Denise	Bell	Airdale NHS Trust
Dr Jon	Bell	Food Standards Agency
Miss Maeve	Brady	Food and Drink Federation
Dr Maureen	Bruce	Scottish Executive Health Department
Dr Rachel	Burch	Leatherhead Food Research Association
Ms Sue	Burrell	Allied Technical Centre
Ms Anne	Campbell	Scottish Food Advisory Committee
Ms Sam	Church	Food Standards Agency
Dr Robert	Clarke	University of Oxford
Ms Cynthia	Clarkson	National Childbirth Trust
Dr Jo	Clarkson	National Assembly for Wales
Mr Nicholas	Constantine	Food Standards Agency
Dr Adrienne	Cullum	Department of Health
Ms Sue	Davies	Consumer Association
Mr Chris	Dabner	National Association of Master Bakers
Professor C John	Dickinson	Queen Mary University of London
Ms Patricia	Dodds	Food Standards Agency (Scotland)
Dr Martin	Donaghy	Scottish Executive Health Department
Mr Richard	Doughty	
Dr Wendy	Doyle	British Dietetic Association
Ms Nicole	Duckworth	Action Research Press Office
Ms Melanie	Every	Royal College of Midwives
Ms Gill	Fine	J Sainsbury Plc
Mr Paul	Finglas	Institute of Food Research
Ms Sylvia	Fitzgerald	
Mr Robert	Fraser	University of Sheffield
Mr Clifton	Gay	Food Standards Agency
Ms Sigrid	Gibson	Sig-Nuture Consultancy
Mr David	Godfrey	Nutragen
Dr Gail	Goldberg	British Nutrition Foundation
Dr Juliet	Gray	
Professor Sir John	Grimley Evans	Oxford University
Dr Paul	Haggarty	Rowett Research Institute
Mr Richard	Hayhurst	HCCDeFacto Group plc
Professor Jeya	Henry	Food Standards Agency Board
Ms Pansy	Ho	Waitrose Ltd
Ms Jennifer Jane	Kellett	
Professor Alan	Jackson	Institute of Human Nutrition, Southampton
Mr Malcolm	Law	St Barts and Royal London School of Medicine
Ms Suzi	Leather	Food Standards Agency
Dr Louis	Levy	Food Standards Agency
Mr Alan	Long	Vega Research
Dr John	Mason	Freelance
Ms Felicity	Mawson	

Mr Robert	Mayes	Health Media
Ms Mary	McNabb	South Bank University
Dr Colin	Michie	Ealing Hospital NHS Trust
Mr Phil	Morgan	Food Standards Agency (Wales)
Mr John	Morris	British Retail Consortium
Dr D J	Moul	MCA
Ms Helen	Munro	Consumers for Health Choice
Mr Tom	Murray	Food Standards Agency
Dr Hannah	Noel	HCCDeFacto Group plc
Ms Fiona	O'Broin	Nutricia Dietary Care
Dr Maggie	Paun	House of Commons
Ms Emma	Peacock	Food Standards Agency
Professor Robert	Pickard	British Nutrition Foundation
Mr Geoffrey	Podger	Food Standards Agency
Dr Monique	Raats	University of Surrey
Dr Sheela	Reddy	Department of Health
Professor Helga	Refsum	University of Bergen
Ms Pamela	Reid	Food Standards Agency (Scotland)
Mr John	Robinson	Food Standards Agency
Mr Andrew	Russell	ASBAH
Mr Bob	Safford	Unilever
Mr Lewis	Scott	Merck Limited
Professor Mary	Seller	Kings College London
Mr Leon	Simms	Food Standards Agency
Professor David	Smith	University of Oxford
Dr Maurice	Smith	Unilever Best Foods
Dr Marnie	Sommerville	Scottish Food Advisory Committee
Mr Arthur	Spencer	AA Spencer - Pharnomina
Dr David	Stewart	Food Standards Agency (Northern Ireland)
Ms Maureen	Strong	Meat and Livestock Commission
Ms Gillian	Swan	Food Standards Agency
Ms Margaret	Tremayne	Food Standards Agency
Ms Penny	Viner	HFMA
Professor Nicholas	Wald	Wolfson Institute of Preventative Medicine
Mr Ben	Walters	Food Standards Agency
Mr Alex	Waugh	NABIM
Professor Brian	Wharton	University College London
Ms Anna	Wheeler	Unilever Best Foods
Mr Peter	Wight	Marks & Spencer plc
Ms Gill	Winfield	ASBAH
Ms Sue	Wood	Soil Association
Dr Mark	Woolfe	Food Standards Agency
Mr Anthony	Wright	Institute of Food Research
Ms Lisa	Wrigley	
Mr Andrew	Wynd	Scottish Spina Bifida Association
Ms Orla	Yates	Food Standards Agency
Mr George	Zajicek	Axis-Shield