

## **Consumers' Association's response to the consultation on the Committee on Medical Aspects of Nutrition and Food Policy's (COMA) report on folic acid and the prevention of disease**

### **Introduction**

Consumers' Association welcomes the opportunity to comment on the important issue of possible universal fortification of flour with folic acid. The issues that this raises are complex and we do not currently consider that they have been adequately addressed within the consultation document. We can see potential benefits from mandatory fortification, but there are also risks. Those that could potentially benefit from fortification are different to those who may be placed at risk. In addition, there are technical issues that are outstanding and must also be resolved before we could support such a measure. Our concerns are set out in more detail below in response to the specific questions raised in the consultation document.

### **Background**

Folic acid/folate is needed for the synthesis of many fundamental substances in the body. The classic symptom of deficiency is megaloblastic anaemia. More recently it has been suggested that adequate folic acid in the diet may reduce the risk of neural tube defects in infants, and there is some evidence that it may play a role in reducing the risk of cardiovascular disease. There is also some speculation about its benefits in neuro psychiatric disorders. The Committee on Medical Aspects of Food Policy (COMA) focused on the role of folic acid in reducing the risk of first time occurrence of neural tube defects. It advised that further corroboration is needed before public policies are developed specifically for folic acid and cardiovascular disease, but if projections from observational studies were accurate, fortification of food with folic acid could be of widespread benefit to the population.

On the other hand, although there is classically plenty of leeway between dietary requirements and toxicity for folic acid, there are concerns about high intakes of folic acid. These relate primarily to its potential to delay diagnosis of vitamin B12 deficiency. Folic acid can effectively treat the megaloblastic anaemia that arises from B12 deficiency (and which can play a role in its diagnosis), but it will not prevent the neural degeneration associated with vitamin B12 deficiency. It is also suggested that at levels of above 1 mg a day folic acid may exacerbate this degeneration. A further concern is that folic acid may interact with some drugs, particularly the older anti-epilepsy medicines. The Expert Group on Vitamins and Mineral (EGVM) is currently reviewing the safety of folate as part of its work establishing safe upper limits for vitamins and minerals.

### **Specific comments**

Q1. Is it desirable and acceptable to fortify all wheat flour (and by extension, all products made with wheat flour) with folic acid?

There are three main routes to increasing the dietary intake of folic acid: encouraging an increased consumption of folate rich foods; encouraging women who are planning to become pregnant to use folic acid supplements preconceptionally; and fortification of foods with folic acid. The recommendation of a UK expert committee in 1992 was to use all three of these strategies, with voluntary fortification of breads and breakfast cereals. This approach has been the basis of a national campaign to increase folic acid intake for the reduction of neural tube defects.

It is important to carefully consider the advantages and disadvantages of each of these options since the current proposals partially arise from concern about the likely effectiveness of these measures. Mandatory fortification could also have implications for future emphasis on these other strands.

### 1. Increased intake of folate rich foods

<b>Advantages</b>	<b>Disadvantages</b>
More acceptable to some women as being 'natural' and 'safe'.	Folate in foods is only half as bioavailable as synthetic folic acid, and it is also not as stable to e.g. heat.
No concerns about high intakes.	Liver is one of the richest sources, but it is recommended that pregnant women (because of the potentially high vitamin A content) do not eat this.
	Without eating liver, it is difficult to achieve the recommended increase with diet alone which also raises issues for vegetarians.
	The extra expense of buying folate rich foods may present difficulties for women on lower incomes.
	Studies which have compared the effectiveness of different strategies have shown that increasing consumption of folate rich foods only did not increase red blood cell folate significantly (Gregory EJCN 51:554, 1997).

### 2. Increased use of folic acid supplements

<b>Advantages</b>	<b>Disadvantages</b>
Folic acid is about 90 per cent bioavailable (50 per cent more than folate), and is more stable. However, the bioavailability from fortified foods is less well established.	About half of pregnancies in the UK are unplanned, and by the time women know they are pregnant it is getting late to take the supplement. One study showed that only 30 per cent of women had followed the recommendations. (Wild, Lancet 350:30, 1997)
The dose taken by individuals is controlled	Unless the supplements are prescribed, they have to be bought by the woman. This may present a barrier to women on low incomes, particularly if they do not have appropriate support from health professionals.
With appropriate information and support, the individuals taking the supplements should be in the right target group.	
Studies which have compared the effectiveness of different strategies have	

shown that increasing consumption of supplements increased red blood cell folate significantly (Gregory EJCN 51:554, 1997)	
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### 3. Increased folic acid fortification of breads and cereals (voluntary)

Advantages	Disadvantages
Many people eat bread and/or cereals, and so this would help address the issue of folic acid intake in women who have unplanned pregnancies.	Some people may consume too much folic acid (see below)
Studies which have compared the effectiveness of different strategies have shown that increasing consumption of folic acid fortified foods increased red blood cell folate significantly (Gregory EJCN 51:554, 1997)	People who eat lower amounts of energy only have relatively small increases in folic acid intake. Those who consume large amounts of food eg. young men, are most at risk of consuming 'too much'.
An intervention study that excluded fortified foods resulted in a 27 per cent decrease in folic acid intakes, and a significant reduction in red blood cell folate (Cuskelly, AmJ ClinNutr 70:234, 1999).	Bread and cereals may not be appropriate vehicles for folic acid for those from ethnic groups who do not eat these foods.
The increased cost for consumers should be minimal.	

It seems that it is unrealistic to increase folic acid/folate intake to the levels necessary to prevent neural tube defects by dietary means alone, and 50-70 per cent of pregnant women may not take supplements appropriately. It is therefore possible that fortification could be a safety net. However, it is important to ensure that whilst bringing benefits to some parts of the population, other groups are not unnecessarily put at risk. The long-term effects of increased folic acid consumption by the whole population also need to be carefully considered.

Q2. If fortification is considered to be desirable, should it be compulsory or voluntary?

#### a) Voluntary vs. mandatory fortification

From 1995 to 1998 the Health Education Authority (HEA) in England ran a campaign to increase folic acid consumption amongst women of childbearing age. This had several components including: supporting health professionals; an advertising element; education; encouraging provision of supplements at the recommended dosage, particularly licensed supplements; and encouraging bread and cereal manufacturers to fortify their foods with folic acid. This last component was based on motivating fortification by increasing awareness of the issue amongst the public and professionals, and also by developing a folic acid flash scheme. Foods which met certain compositional criteria, were able to carry an 'F' flash on the packaging.

The HEA reported that the number of breakfast cereals fortified with folic acid increased from 101 in 1996 to 112 in 1997. The number of types of loaf that were fortified increased from 8 in 1995 to 20 in 1997. By 1997 the majority of retailers were producing their own label brands of white soft grain fortified bread.

Thus, whilst the voluntary fortification of breads and cereals provides a safety net, there are a number of problems with it.

- Since voluntary fortification does not happen within a rigorous public health and legislative framework, it is possible that people who are at risk of vitamin B12 deficiency may be consuming large quantities of fortified foods. Without detailed dietary records, health professionals would not be aware of this pattern of consumption.
- Bread and cereals are not part of the usual dietary pattern of some ethnic groups and cultures.
- Those in higher social classes consume more breakfast cereals. For example the Dietary and Nutritional Survey of British Adults showed a graded intake in breakfast cereals with those in higher social classes eating more, particularly of the high fibre types.
- Breakfast cereals may be promoted on the basis of added nutrients, whilst containing relatively high amounts of sugar and salt.

On the other hand, provided consumers are given clear information, voluntary fortification means people can choose to avoid fortified products if they wish to do so.

Mandatory fortification addresses most of the issues raised above with voluntary fortification but also has several disadvantages. It would result in loss of choice for consumers. Other countries that have introduced 'mandatory' fortification have kept a range of non-fortified products available to help resolve this issue. But apart from choice, mandatory fortification raises safety concerns for some groups in the population; and technical issues. There may also be cost implications for the industry and therefore for consumers.

#### b) Potential risks of mandatory fortification for some population groups

Our main concern with COMA's proposal is that increased folic acid intake may effectively treat the anaemia that results from vitamin B12 deficiency, but not delay the later neural degeneration. Since detecting the anaemia has traditionally been part of the diagnosis, it may take doctors longer to pick up cases of vitamin B12 deficiency, and by the time they do there may be irreversible neural damage. Folic acid may exacerbate this neural damage.

Most vitamin B12 deficiency is caused by the destruction of cells in the stomach that are necessary to absorb the vitamin. This is particularly a condition of older people. The prevalence is approximately 1 per cent in people aged over 60, rising to nearly four per cent in those aged over 75. In addition, many people may have sub clinical deficiency or may not have been diagnosed. At the proposed levels of fortification about 0.6 per cent of people aged over 50 would consume more than 1 mg folic acid per day.

The COMA report itself says that it would be perverse to maintain a position of sub-optimal folate intakes in the population, in order to facilitate the detection of vitamin B12 deficiency. Any fortification policy would need to be accompanied by increased vigilance in regard to B12 deficiency. It has been pointed out that the anaemia only occurs with 60-70 per cent of cases of vitamin B12 deficiency, and that diagnosis should be based upon the patient's history and special investigations. In addition more specific and sensitive methods are becoming available to diagnose the deficiency. Thus, in order to address this concern new measures would be required, for example, health professionals would need to be supported in understanding the interactions between folic acid and vitamin B12; in identifying any individuals or groups who are likely to be at risk; and in making accurate diagnoses of vitamin B12 deficiency at as early a stage as possible. However, people who are at risk may not necessarily go to their GP. The consultation document unfortunately fails to consider in enough detail how this important issue could be addressed. It is essential that this is resolved before any decision can be taken regarding fortification.

Another group who could be affected are vegans, who consume little vitamin B12 in their diets. Long-standing advice that vegans should supplement their diet with additional vitamin B12 may help to reduce their risk. Another group who might be at risk are patients taking some anti epileptic medications. This group also needs to be carefully considered although there is already

good awareness among health professionals for the need for appropriate clinical practice in relation to this group.

Q3. Compulsory fortification would have the effect of restricting consumer choice - is this acceptable? Should any provision be made for those who wish to buy wheat flour products without added folic acid?

In the USA, a range of unfortified products continues to be available for those who do not wish to purchase fortified foods. If our outstanding concerns could be addressed a similar approach may be possible in the UK with most products being fortified, but with a range of unfortified products available so that people who have for one reason or another do not wish to buy the fortified version, do not have to do so. Such an approach would need to be supported by an effective information campaign. We would like to see the feasibility of this fully examined before a decision is reached. The US experience should be assessed in more detail to ensure that any lessons they have learnt are fully taken into account.

Q4. If compulsory fortification of flour were to be introduced should restrictions be placed on the level of folic acid that could be added to products other than flour on voluntary basis? If so, what form should they take?

Before a decision can be made on whether to require mandatory fortification, the conclusions of the Expert Group on Vitamins and Minerals with regard to folate should be carefully considered. Based on this, consideration should be given to the appropriateness or otherwise of further voluntary fortification if there is a risk of excess folic acid being consumed.

Q5. Should folic acid be included on ingredient lists of affected flour and products containing it?

If the outstanding issues can be satisfactorily addressed and a policy of mandatory fortification adopted, all folic acid fortified foods should be clearly labelled. The most appropriate form of labelling could be investigated in the exercise described under Q6/7.

Q6. Would fortification detract from the public health message on supplementation for women of childbearing age? Should claims on fortified products be restricted/prohibited to reduce the risk of this happening?

Q7. If so, should the wording of folic acid content and related health claims be the subject of guidance or controlled by statutory measures?

The desirability of a health claim linking folic acid with neural tube defects should be explored with consumers, using appropriate research techniques. It would be important to establish the benefits and any negative consequences of such a claim. If the research indicated that a claim would be regarded positively by consumers, would not be misleading in any way and would not have any adverse effects on the other strategies to increase folic acid/folate intake (diet and supplements), a claim could be developed. At the moment, the most appropriate route for this in the absence of legislation on health claims would be within the framework of the Joint Health Claims Initiative (JHCI). We would however be opposed to the use of any claims that implied that the products concerned had medicinal effects.

Q8, 9,10, 11 and 12. Technical difficulties in fortification; degree of overage; variability of folic acid in the final product; cost implications; and how long it would take for industry to fortify flour.

These are important questions, for which detailed responses are necessary from industry. We were disappointed that they could not be addressed in the consultation document and a decision on the appropriateness of mandatory fortification can not be made until these technical aspects have been fully considered and addressed. The modelling carried out by COMA was theoretical. In the report it was recognised that in order to achieve a certain level of fortification, it is usual for the industry to add more of the fortificant than is necessary (an overage). In this case, that would be undesirable because of the possible adverse effects on some groups in the population. It would also be necessary to allow for changes in levels during processing and mixing with other ingredients, to ensure a final level that corresponded to the recommendations.

In 1998 CA analysed more than seventy fortified foods in the UK and Ireland. In 75 per cent of cases the level given for added vitamins and minerals was significantly inaccurate. Strict quality control procedures, good manufacturing practice, monitoring, and enforcement would need to be an essential part of any mandatory fortification policy.

### Consumer attitudes

**In the consultation paper, there were no specific questions about the views of consumers on fortification. Some background information is given here, and as mentioned previously, CA believes that research with consumers is necessary before mandatory fortification proceeds.**

In 1998 CA ran two focus groups to find out what consumers thought about fortified foods. One was a group of parents, and the other a group of people with an active interest in eating healthily. Both groups were confused about the benefits of added nutrients, although generally they thought they were a good thing and did not realise that there could be risks from taking too much of certain vitamins. This emphasises the importance of any mandatory fortification initiative being accompanied by measures to ensure that consumers are well informed.

In 1999 a report was published on consumer awareness and attitudes to food fortification in Europe (Gaussin AL, Scand J Nutr, 43:122S). In this omnibus survey, British consumers had one of the highest rates of awareness of food fortification (83 per cent). 79 per cent of British consumers agreed that there should be food fortification as long as there is no risk to health. 87 per cent of British consumers believed that consumers should have the choice of buying fortified foods. In the same survey, 52 per cent of British respondents knew that there was a link between folic acid and the prevention of neural tube defects (the highest level in the five countries included in the survey).

**In summary, consumers appear supportive in some situations, although they prefer to retain a choice, and this needs to be considered in the context of a lot of confusion about health and micronutrient relationships.**

### Conclusions

Increasing folic acid levels in the diet has the potential to have a real impact on reducing the number of children born with neural tube defects, as well as reducing the numbers of distressing spontaneous or planned abortions. Although the evidence remains inconclusive, there is also the possibility that folic acid may have benefits in contributing to reducing the risk of cardiovascular

diseases, as well as having a more obvious role in ameliorating the folate deficiencies that exist amongst an unknown proportion of the population.

There are drawbacks in attempting to achieve this increase through dietary means alone, or through relying upon women to take supplements. Voluntary fortification of bread and cereals has played a useful role in supporting these strategies. However, the lack of a systematic approach may result in people who could suffer adverse effects consuming more than is desirable, whilst some of those who could benefit may not eat the fortified foods for cultural or economic reasons.

We can therefore see benefits in requiring fortification of flour with folic acid. However, there are some groups in the population who could be adversely affected and we do not consider that the issues that relate to them have been adequately addressed at this stage. Two of these groups, vegans and people taking certain classes of drugs, are readily identifiable, and with good information provision and professional support it may be possible to avoid adverse effects. Those suffering from vitamin B12 deficiency, who tend to be older people, could be placed at increased risk. Strategies need to be adopted and implemented to ensure that this risk is minimised. This could include raising awareness of the issue amongst professionals, and encouraging use of more specific tests for the diagnosis of vitamin B12 deficiency.

We are also concerned that the technical feasibility of fortification at the level recommended by COMA has not been examined in enough detail. A decision cannot be reached until this has been addressed. Bearing in mind the undesirability of high intakes for certain groups in the population, it would be essential to be confident that the levels of folic acid in food reflected and did not exceed the recommendations. In this respect, a decision should not be made until the Expert Group on Vitamins and Minerals has reported on safety of folate.

To summarise our position, we can see the benefits of mandatory fortification, but would need to see the following addressed before we could reach a decision:

- We would need to be satisfied that those suffering from B12 deficiency could be effectively diagnosed and treated, and are therefore not put at risk.
- Public health monitoring of the prevalence of the various stages of vitamin B12 deficiency would need to be instituted.
- The feasibility of making alternative products available that are not fortified to ensure that consumers can still have a choice would need to have been established.
- The technical feasibility of fortifying flour to the levels recommended and any issues that may arise relating to quality control would need to have been satisfied.
- An assessment of experiences from abroad, for example the US, and any resulting implications of mandatory fortification would need to have been conducted and any issues arising, addressed.
- We would need assurance that fortification with folic acid would not lead to adverse effects as a result of higher intakes across the population, and therefore that the advice of the EGVM had been considered before deciding on the best approach.
- Mechanisms for monitoring and enforcement of folic acid levels in foods would need to be in place if fortification were made mandatory.
- A new educational campaign would need to be initiated, since consumers are not clear about the reasons, and benefits of fortification. (The usefulness of dietary change and supplements should continue to be part of the overall message).

- Any specific needs of those on low incomes and ethnic groups would need to have been considered in more detail and addressed as they may not have access to the fortified products.
- There would have to be a requirement for all folic acid fortified foods to be clearly labelled.
- Consumer research would need to have been undertaken to explore the desirability of a health claim linking folic acid with neural tube defects. It would be important to establish the benefits and any negative consequences of such a claim.

**Consumers' Association  
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