

# Joint Response from Action on Salt & Action on Sugar to the Proposal to Add Folic Acid to Flour

# Action on Salt

Action on Salt (formerly Consensus Action on Salt & Health, CASH) is an organisation supported by 24 expert members and working to reduce the salt intake of the UK population to prevent deaths, and suffering, from heart disease, stroke, kidney disease, osteoporosis, stomach cancer and obesity.

## **Action on Sugar**

Action on Sugar is a group of experts concerned with sugar and obesity and its effects on health. It is working to reach a consensus with the food industry and Government over the harmful effects of a high calorie diet, and bring about a reduction in the amount of sugar and fat in processed foods to prevent obesity, type 2 diabetes and tooth decay.

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# Proposal to add folic acid to flour

• Do you agree or disagree with the proposal for mandatory fortification of nonwholemeal wheat flour in the UK with folic acid to help prevent neural tube defects?

## Agree

We welcome the proposed mandatory fortification but we recommend all flours to be fortified.

Folate plays an important role in foetal development and in 1991 the Medical Research Council (MRC) funded study, carried out by Professor Nick Wald and colleagues, found that most cases of neural tube defects (NTD) can be prevented by increasing folic acid intake immediately prior to pregnancy and in the early stages of pregnancy<sup>1</sup>. According to the impact analysis, 1,000 pregnancies a year in the UK are diagnosed with serious NTDs, and the estimated incidence rate is 12.64 cases per 10,000 births. These may result in termination, miscarriage, neonatal death, or long-term disability to the baby of varying severity. The true number of affected pregnancies is probably higher because some women will miscarry before diagnosis, a cause of distress in itself, and some minor cases of spina bifida may remain undiagnosed.

Given that the strong evidence of the benefits of fortification have been known for years, and are accepted globally, failure to fortify flour has been a missed opportunity for public health and a tragedy for those affected. The Government's Scientific Advisory Committee on Nutrition (SACN) has previously recommended mandatory fortification in 2006, 2009 and 2017<sup>2,3,4</sup> and the Committee on Medical Aspects of Food and Nutrition Policy (COMA) recommended this in 2000<sup>5</sup>. It is good to see that the totality of evidence on folic acid is



now taking precedence over food industry objections to benefit the health of mothers and their babies.

# **Proportionality**

Since the 1991 report of the MRC Vitamin Study<sup>1</sup>, guidance has existed for pregnant women to take folic acid. Despite this, data from the National Diet and Nutrition Survey (years 7&8) suggests an estimated 90% of women aged 16-49 years have a folate status below the level recommended to reduce the risk of an NTD-affected pregnancy and in addition, an estimated 28% of girls aged 11-18 years, 15% of boys aged 11-18 years and 7% of adults have low blood folate levels, putting them at risk of anaemia<sup>6</sup>. Fortification with folic acid could help prevent this.

This consultation highlights that in the UK between 700 and 900 pregnancies each year are affected by NTDs that can cause severe disabilities but one affected pregnancy for every working day in the year could be prevented with folic acid fortification. In the absence of fortification many affected pregnancies will be diagnosed antenatally leading to a therapeutic abortion. Fortification will therefore not only prevent affected live births but also medically induced abortions and the associated costs and risks on physical health and mental health.

While official advice on folic acid supplementation exists, supplements may not be taken early enough, particularly if the pregnancy is unplanned. This increases the risk of an NTD-affected pregnancy. The problem is more prevalent amongst adolescent women, less well-off families and in deprived areas<sup>7</sup>.

Flour is already fortified with two minerals and two vitamins (iron, calcium, thiamin and niacin) and there is no rational reason not to add folic acid at an adequate level designed to prevent most cases of this serious and sometimes devastating disorder. State intervention is a justified and proportional response.

# **Relevance of intervention**

Across the UK, non-wholemeal wheat flour is already an established vehicle for fortification and is consumed regularly by most women who could become pregnant, regardless of their income and their folate intakes. The consultation highlights that an estimated 90% of people consume products that contain flour including biscuits, baked goods such as cakes, pastries such as croissants, some stuffing or gravy mixes. However, an estimated 29% of women consume very little bread and eat less than 10g of flour from bread a day. Therefore, all flour would need to be fortified to provide the most benefit to public health.

## Public acceptability

People living in approximately 81 countries already accept fortification of their foods with folate, and there is no reason to suggest it would not be acceptable in the UK. It's a move backed by Royal Colleges, including the Royal College of Paediatrics and Child Health<sup>8</sup>, the Royal College of Obstetricians and Gynaecologists<sup>9</sup>, Governments in Scotland and Wales<sup>10</sup>,



in addition to food manufacturers and many other experts. Government now needs to implement this simple, highly effective public health measure.

## Social equality

Fortification of flour would allow all women of child-bearing age to increase their folic acid intake without changing their purchasing behaviour or their diet.

Despite voluntary fortification of products such as breakfast cereals, data from the National Diet and Nutrition Survey (NDNS) shows folate intakes of women who could become pregnant have continued to decline and are particularly low in areas of deprivation<sup>6</sup>. Women have been advised to take folic acid supplements prior to pregnancy. However, in practice about two-thirds of women do not do so for a multitude of reasons, and this failure to take folic acid is particularly high in less advantaged groups in society<sup>7</sup>.

## Precedence

There is a clear precedence for mandatory fortification of flour - as of October 2017, 81 countries worldwide have mandatory folic acid fortification and have reported reductions in rates of NTDs of between 16% and 58% with no known adverse effects. Mandatory fortification in the UK is long overdue and would bring us in line with many other countries around the world, including:

Antigua and Barbuda, Argentina, Australia, Bahamas, Bahrain, Barbados, Belize, Benin, Bolivia, Brazil, Burkina Faso, Burundi, Cameroon, Canada, Cape Verde, Chile, Colombia, Costa Rica, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Fiji, Ghana, Grenada, Guatemala, Guinea, Guyana, Haiti, Honduras, Indonesia, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Kosovo, Kuwait, Kyrgyzstan, Liberia, Mali, Mauritania, Mexico, Moldova, Morocco, Mozambique, Nepal, Nicaragua, Niger, Nigeria, Oman, Palestinian Authority Territory, Panama, Papua New Guinea, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, Senegal, Sierra Leone, Solomon Islands, South Africa, Suriname, Tanzania, Togo, Trinidad and Tobago, Turkmenistan, Uganda, United States of America, Uruguay, Uzbekistan, Yemen, Zimbabwe. In addition, DR Congo, Qatar and the United Arab Emirates have voluntary fortification with the majority of flours fortified<sup>11</sup>.

## Which products should be included

- Which of the following do you think mandatory fortification with folic acid should apply to? Please choose one:
  - $\circ$  just non-wholemeal wheat flour in the UK (the most commonly used type)
  - o just non-wholemeal wheat flour used to make bread in the UK
  - o all flour in the UK, including wholemeal and other grains
  - o all flour in the UK and other non-wheat products such as 'gluten free'
  - there are no products that should have mandatory fortification with folic acid

We believe all flour in the UK and other non-wheat products such as 'gluten-free' should be fortified.



Around 29% of women consume very little bread and therefore all flour would need to be fortified to benefit public health. This would cover all products with flour such as bread and pastries but also products for coeliacs. Coeliac disease currently has a prevalence of one in 100 and more than 500,000 people are living with undiagnosed coeliac disease<sup>12</sup>.

We believe all flour should be fortified to cover wholemeal flour in addition to nonwholemeal wheat flour. The Government recommends we should eat 30g of dietary fibre per day for digestive and heart health but NDNS data shows adults aged 19 to 64 years eat 19g per day on average<sup>6</sup>. Switching from non-wholemeal to wholemeal products is a simple way to increase fibre intake.

• Are there any alternative ways of helping reduce the number of neural tube defects that you may prefer, other than our proposal for mandatory fortification of flour with folic acid?

Uptake of folic acid supplements is low - just 1/3 of women on average take folic acid at the right time of their pregnancy<sup>7</sup>. The lowest uptakes seen in Afro-Caribbean women (17%) and those aged under 20 (6%). More worryingly, a study of 22,000 women from 18 European countries revealed that only 17% knew that folic acid could reduce the risk of NTDs<sup>13</sup>, suggesting that more work needs to be done to raise women's awareness of current recommendations. Therefore, a public health campaign to encourage supplement intake should be built into other information and activities targeted at young people and backed up with adequate training for health professionals.

# How individuals and businesses are affected

• Are there any particular groups or individuals that might be negatively affected by mandatory fortification of flour with folic acid, or miss out on the benefits?

There is no evidence that high levels of folic acid intake are harmful. A recent review by the Committee on Toxicity (COT)<sup>14</sup> suggested that folic acid intake should be limited to 1mg or less per day, due to concerns that a folic acid intake of 5mg/day or more might exacerbate neuropathy from vitamin B12 deficiency. However, this was based on a flawed analysis described in the US Institute of Medicine (IoM) report of 1998. The flawed analysis was identified in 2018 and the correct analysis provided no such suggestion, a conclusion robustly supported in a paper from the US Centers for Disease Control (CDC)<sup>15</sup> and by many health experts in the UK.

The observation that folic acid intakes of 5mg or more can relieve the anaemia of vitamin B12 deficiency described over 50 years ago as masking B12 deficiency was not considered a problem by the IOM but was mistakenly presented as a potential harm through possibly delaying the diagnosis of vitamin B12 deficiency. However this is extremely unlikely to be true and the notion of folic acid masking B12 deficiency should be abandoned, as concluded by the US Public Health Service (CDC)<sup>15</sup>.



The public health message must be simple and clear and guidance to the food industry especially must be easy to follow – it would be confusing to issue guidance to industry to increase folic acid levels in products while decreasing voluntary fortification to ensure folic acid intakes do not go above a certain level. This could be viewed as a risk by the industry.

• How could we make sure these groups or individuals are supported or not affected negatively?

As mentioned above, there would be no negative impacts.

• Are there any businesses that might be negatively affected by mandatory fortification of flour with folic acid, or miss out on the benefits?

No. If fortification of all flour is made mandatory this will create a level playing field for millers and grain merchants. Fortification will enhance the nutritional value of all flours and grains. The cost of fortification is small and is likely to be borne by industry. Under current voluntary measures only the most responsible companies bear the cost of fortification and are therefore at a competitive disadvantage, despite working in the interests of public health.

• How could we make sure these businesses are supported or not affected negatively?

The grain and milling industry must be engaged and full guidance provided. Abandoning the 1mg upper limit is justified on medical and scientific grounds, and doing this will reduce confusion for businesses who may already be engaging in voluntary fortification. Guidance to the food industry especially must be easy to follow – it would be confusing to issue guidance to industry to increase folic acid levels in products while decreasing voluntary fortification to ensure folic acid intakes do not go above a certain level. This could be viewed as a risk by the industry.

## **Voluntary fortification**

• If the fortification of flour with folic acid is made mandatory, do you agree or disagree that there should be limits on voluntary fortification of other food products and/or supplements with folic acid?

No, there is no need for such limits. The basis for introducing such limits arises from setting the 1mg upper limit which was based on a flawed statistical analysis. Industry should be encouraged to continue to voluntarily fortify other products, including breakfast cereals.

## Impact assessment

• Do you agree or disagree with the provisional cost/benefit analysis outlined in the impact assessment?

Fortification occurs at the manufacturing level and is low cost. Many foods in the UK are fortified with vitamins and minerals, including iron fortification of breakfast cereals and



vitamin D fortification of low fat spreads. Flour in the UK is already fortified with thiamin, niacin, calcium and iron and therefore the additional fortification with folic acid will not be novel for the food industry.

• Can you provide any additional evidence to inform the impact assessment?

We feel the estimates of NTD reductions (8-25%) are conservative. In South Africa, reductions of 30.5% were observed<sup>16</sup>, Chile saw a 40% reduction<sup>17</sup>, Canada a 46% reduction<sup>18</sup> and – for an encephaly and spina bifida only – Argentina saw a 58–60% reduction<sup>19</sup>.

Furthermore, the cost of fortification is minimal and far less than the cost of lifetime care of people with spina bifida. Folic acid fortification could also prevent abortions and the costs associated with these. Fortification of flour with folic acid is a highly effective public health measure both from a medical and humane perspective and also on the basis of financial savings to the families involved, the NHS and Social Services

• Do you think there are any other benefits, costs or wider impacts of this policy proposal that have not been mentioned yet?

N/A

## **Practicalities for businesses**

• What are the practical issues that need to be thought about for mandatory fortification with folic acid?

Simple and clear guidelines are required. Strong evidence shows there is no need for upper limits and therefore mandatory and voluntary fortification can progress in parallel. Guidance to the food industry especially must be easy to follow – it would be confusing to issue guidance to industry to increase folic acid levels in products while decreasing voluntary fortification to ensure folic acid intakes do not go above a certain level. This could be viewed as a risk by the industry.

• Are there any further trade implications for industry that need to be considered?

No

• Are there any effects on small businesses and medium businesses that need to be considered? (Small and medium sized businesses are businesses with fewer than 250 employees.)

No

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