

# Proposal to add folic acid to flour

## Consultation Response

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### 1. Do you agree or disagree with the proposal for mandatory fortification of non-wholemeal wheat flour in the UK with folic acid to help prevent neural tube defects?

The BDA strongly supports the proposal to fortify flour in the UK with folic acid to reduce the risk of neural tube defects. We are not convinced that restricting this to just non-wholemeal wheat flour is the most effective policy.

This is a policy that has been a very long time coming. In 1991, the Medical Research Council<sup>1</sup> published a report recommending that white flour in the UK was fortified with folic acid as this had been shown in other countries to reduce the risk of neural tube defects (NTD) in foetuses. Mandatory fortification with limits on voluntary supplementation was backed by the Scientific Advisory Committee on Nutrition (SACN) in 2006<sup>2</sup> and again 2017<sup>3</sup>. The Welsh and Scottish Health Ministers wrote to the then Health Secretary, Jeremy Hunt in December 2017<sup>4</sup> to urge him to implement UK wide fortification of flour.

We are pleased to have joined many other organisations, including SHINE, the Spina Bifida charity, the Royal College of Obstetricians and Gynaecologists and many others in welcoming this proposal and encouraging its adoption. This was most recently articulated in a joint consensus statement signed on 9<sup>th</sup> September 2019.

Many years of fortification with folic acid in many countries around the world has consistently proved effective in reducing NTDs while having no demonstrable negative impact on health. We also have direct experience of the benefits of fortification of other micronutrients, such as iron, in foods in the UK, with fortified breads and breakfast cereals now providing a significant proportion of many people's iron intake.

NTDs are a serious health condition. Conditions such as spina bifida cause moderate to severe disability leading to significant suffering and higher health care costs. The prevalence of NTD pregnancies is 1.28 per 1000 total births (19% live births, 81% terminations and 0.5% stillbirths and foetal deaths  $\geq 20$  weeks' gestation). A recent study<sup>5</sup> estimated that more than 2000 NTD pregnancies could have been prevented since 1998 had the UK adopted flour fortification when countries such as the US and Canada did the same. The failure to act on this straightforward policy recommendation made nearly 30 years ago has been a missed opportunity for those families affected.

The most effective way to reduce the risk of NTD's in individual women, is the intake of folic acid supplements (400ug daily) prior to conception. This is still an important health message that requires strong and consistent communication to women considering pregnancy. However, a significant proportion of pregnancies are unplanned, and taking supplements requires knowledge and organisation, and so this method cannot be fully effective on a population-wide basis, especially among younger women, and those with less access to health information. According to the NDNS<sup>6</sup>, 91% of women of

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<sup>1</sup> <http://www.thelancet.com/pb/assets/raw/Lancet/pdfs/issue-10000/folic-acid.pdf>

<sup>2</sup> <https://www.gov.uk/government/publications/sacn-folate-and-disease-prevention-report>

<sup>3</sup> <https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>

<sup>4</sup> <https://news.gov.scot/news/folic-acid-in-flour-1>

<sup>5</sup> <https://adc.bmj.com/content/archdischild/early/2015/11/13/archdischild-2015-309226.full.pdf>

<sup>6</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/699241/NDNS\\_results\\_years\\_7\\_and\\_8.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/699241/NDNS_results_years_7_and_8.pdf)

childbearing age (16 to 49 years) in the UK as a whole had a red blood cell folate concentration below the threshold (748nmol/L) indicating elevated risk of NTDs. This figure has been rising. Voluntary, self-supplementation has clearly not worked for many women.

## 2. Which of the following do you think mandatory fortification with folic acid should apply to? Please choose one.

- All flour in the UK and other non-wheat products such as 'gluten free'

The BDA believes that a wider range of flours, including gluten-free products, should be fortified for a number of reasons:

- Although it has previously been recommended that only non-wholemeal wheat bread flour be included, evidence shows that people's consumption habits have shifted considerably since the first recommendation was made to fortify in 1991<sup>7</sup>. Overall bread consumption has fallen significantly from 819g per person per week in 1993 to just 532g per person per week in 2016/17. White bread, consumption has fallen at an even faster rate so to limit to only white-bread flours would have much less impact.
- Similarly, focusing on non-wholemeal flours directly contradicts advice for people to consume more whole-grain and wholemeal foods.
- An increasingly diverse UK population consume a much wider variety of flours and flour-based products than in the past, and interest in "alternative" flours has grown. Data from NABIM highlights the growth in flour production for purposes other than bread, biscuits and cakes and the decline in flour for bread<sup>8</sup>. The US is currently considering widening its fortification programme to include corn-based flours in recognition of the higher consumption levels of these flour types amongst the Hispanic community.
- It is argued that wholemeal can be excluded as it already had higher natural levels of folate. However, according to McCance and Widdowson the difference is 16 micrograms in white flour per 100g, and 27 micrograms per 100g in wholemeal<sup>9</sup>. Neither is sufficient at current levels to realistically improve the blood folate status of women. There may be value however in excluding specialist non-wheat flours with high folate content (e.g. soya flour)

## 3. 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?

We strongly believe that fortification needs to be accompanied with a wider effort to encourage all sexually-active women of child-bearing age to take a regular folic acid supplement. It is clear that even with fortification, folate status will only be improved in those that consume flour, and even then, not in sufficient amounts in all cases to optimally reduce the risk of NTDs. Therefore, we are clear that this is **not an alternative**, but instead a *further* policy that is necessary alongside fortification.

This could include more clearly discussing the role of folic acid prior to pregnancy in school science and PHSE lessons, public health campaigns and more robust and regular marketing. Government may wish to consider wider provision of free folic acid supplements without prescription, as is currently possible for limited numbers of people through the Healthy Start Scheme<sup>10</sup>. It is worth noting that folic acid being provided as part of Healthy Start itself is actually likely to be of limited use as a woman needs to have been taking the supplement before they became aware that they were pregnant.

<sup>7</sup> <https://www.gov.uk/government/statistical-data-sets/family-food-datasets>

<sup>8</sup> <http://www.nabim.org.uk/download/document/8186b1094ce8cce81d4fe19ca71f57c7>

<sup>9</sup> Finglas P.M et al (2015) McCance and Widdowson's The Composition of Foods, Seventh summary edition. Cambridge: Royal Society of Chemistry p32

<sup>10</sup> <https://www.healthystart.nhs.uk/healthy-start-vouchers/healthy-start-vitamins/>

Advances in surgical treatments for those with a diagnosis of spina bifida are welcome, and can improve outcomes for an unborn baby, but they are not a cure for spina bifida. A baby diagnosed with spina bifida will always have spina bifida, even after surgical intervention. Health and social challenges for babies who undergo surgery may be lessened through surgery, but current evidence suggests they will still face a lifetime of on-going issues. Surgery is not an option for a diagnosis of anencephaly.

#### **4. 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? & 5. How could we make sure these groups or individuals are supported or not affected negatively?**

There is concern that increasing intakes of folic acid will lead to masking of vitamin B12 deficiency in older adults. However, the World Health Organisation suggests that this can be prevented by fortifying or supplementing with vitamin B12. This would have the added benefit to dealing with B12 deficiency, aside from any folic acid issues. Folate status is actually worse in older people than the population as a whole<sup>11,12</sup>, so there could in fact be benefits of fortification for this group. The FSA advises a daily intake of 200mcg for older adults.

Increasing numbers of people with type 2 diabetes adhere to a low-carbohydrate or very low-calorie diet as a means to manage and even reverse their diabetes. In both cases, intakes of refined grains (in bread or other products) will reduce significantly. Given the significant number of people with type 2 diabetes who may consider these approaches, it is important that they are given specific advice on taking folic acid supplements if they are a woman of child-bearing age.

The same would be true of any person who has a health condition that requires them to change their diet to avoid or reduce the intake of cereals, such as people with Coeliac Disease (who avoid gluten containing cereals) or those on a FODMAP diet for the treatment of IBS or other conditions. Although we would recommend that gluten-free flour was included for fortification, some people choose to avoid gluten by consuming alternative sources of starchy carbohydrate, such as rice or potatoes. Again, it will be important that these groups receive specific communications to ensure they utilise folic acid supplementation prior to pregnancy.

We have seen arguments that certain (commonly occurring) gene variants for MTHFR means they should avoid folic acid in favour of methyl folate. The argument is that these people are unable to process folic acid properly. Prof Anne Molloy, of Trinity College Dublin (who has advised the World Health Organisation on folic acid) has confirmed that their fears are unfounded; because these gene variants can lead to a lower blood folate through difficulty processing natural dietary folate, there is potentially an even greater need for folic acid<sup>13</sup>.

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

No comment.

#### **7. How could we make sure these businesses are supported or not affected negatively?**

Most of the burden of introducing folic acid fortification, in particular to non-white flour, would be in the initial capital expenditure on fortification infrastructure (including changes to manufacturing processes, changes to labelling etc.). Once fortification processes are in place, the cost of fortifying is very small – estimated for example in Canada at as little as US\$0.5 per metric tonne of flour<sup>14</sup>. The government may wish to provide direct support to flour millers to introduce fortification through direct investment or fiscal measures designed to reduce the up-front cost.

<sup>11</sup> <https://www.nutrition.org.uk/nutritionscience/life/older-adults.html?showall=1>

<sup>12</sup> <https://www.sciencedaily.com/releases/2018/06/180626113338.htm>

<sup>13</sup> <https://www.shinecharity.org.uk/spina-bifida/mthfr-gene>

<sup>14</sup> <https://www.bmj.com/content/363/bmj.k4348/rr>

## **8. 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?**

We understand the desire to minimise the small risk of people exceeding the 1mg daily intake by introducing limitation on voluntary fortification. However, any limit that is set must ensure that there is minimal impact on the benefits that women of childbearing age may be having from voluntary fortification. However, it is clear that whether or not a limit is placed on voluntary fortification, very few people will exceed the tolerable upper limit.

We do not want to undo any benefit from fortification of flour by reducing other sources significantly. Therefore, we disagree that there should be limits on voluntary fortification of **all** other food products. We do not wish to see folic acid intake increased in one area only to decreased elsewhere. Reducing voluntary fortification from foods such as breakfast cereals could disadvantage women who eat them in preference to bread, by lowering their folate intake, instead of increasing it.

We believe that advice to women should still be to consume a 400mg supplement, and we do not believe that this should be limited. There may be a need to limit folic acid content on more general vitamin supplements not specifically aimed at women of child bearing age.

## **9. Do you agree or disagree with the provisional cost/benefit analysis outlined in the impact assessment?**

We broadly agree with the provisional analysis, although it clearly lacks financial detail at the moment. We agree with the analysis of other options, although we believe that a wide range of flours should be considered for the reasons outlined within that analysis, namely that “certain ethnic or cultural groups may benefit. It is also important to ensure that anyone who is on a gluten-free diet is properly catered for.”

We believe that the assessed benefits in terms of reduced NTDs may be conservative (based on much larger reductions in other nations), but agree that this is a sensible approach at this stage. A 15-20% reduction would still be a significant and worthwhile impact to have.

We believe the significant increase (roughly double) from just bread-flours to all non-wholemeal flours is a strong argument in favour of that approach.

## **10. Can you provide any additional evidence to inform the impact assessment?**

No comment

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

Although the consequential costs of NTDs on parents and families are recognised, it is acknowledged that this is difficult to quantify. It is important to factor in more clearly the impact that a miscarriage or termination as a result of an NTD (which is the outcome in the majority of NTD pregnancies) has on parents and wider family.

Other methods for treatment, such as pre-natal surgery, are expensive to the NHS, and inherently risky. While it is encouraging that these are available, any reduction in the need to utilise them would be a benefit.

There is some evidence<sup>15</sup> of possible reduction in deaths from stroke - the decline in deaths from stroke in USA and Canada accelerated significantly after fortification with folic acid, but remained constant in UK, which had no mandatory fortification.

## **12. What are the practical issues that need to be thought about for mandatory fortification with folic acid?**

A key practical consideration will be the timeline over which it is reasonable to implement the policy. We believe that it should be possible to introduce fortification within two years, as was the case in the US in the 1990s<sup>16</sup>.

We also note that this consultation does not specifically articulate an amount of folic acid for fortification, even though this is clearly a key issue. It will be very important both for ensuring that folic acid fortification is effective, and for making changes (if necessary) to voluntary fortification levels.

We will also need to consider how this intervention will be evaluated and tested for impact. We believe government should ensure blood folate status remains a part of future National Diet and Nutrition Surveys, and fund research into whether NTD rates fall as a result of the introduction of the policy. After continuing to monitor consumption habits, it may be necessary to revisit the policy if it does not have the desired impact, or if there are further shifts in consumption habits which may render it less effective.

How folic acid will be labelled will be an important consideration. For professionals assisting patients' specific diets, being able to see how much folic acid is included within any given food will be important. At the moment all folate or folic acid in food has to be labelled as "folic acid" (except for infant formula regulations where "folate" is used). A consistent approach, which ensures that things are labelled correctly would be helpful.

## **13. Are there any further trade implications for industry that need to be considered?**

No comment

## **14. 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 comment

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<sup>15</sup> Improvement in Stroke Mortality in Canada and the United States, 1990 to 2002 Quanhe Yang, PhD; Lorenzo D. Botto, MD; J. David Erickson, DDS, PhD; Robert J. Berry, MD; Christie Sambell, PhD; Helen Johansen, PhD; J.M. Friedman, MD, PhD

<sup>16</sup> <https://academic.oup.com/heapro/article/20/4/375/2182080>

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