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Open consultation

Proposal to add folic acid to flour: consultation document

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1. Summary

The UK government and devolved administrations are seeking views on the proposal to introduce mandatory fortification of flour with folic acid. This is to help reduce neural tube defects (NTDs) in foetuses by raising the folate levels of women who could become pregnant.

'Mandatory fortification of flour with folic acid' means the legal requirement to add folic acid to flour.

The policy objectives of this consultation are to:

- reduce the incidence of NTDs, by increasing dietary intake of folic acid, and blood folate levels, in women who could become pregnant
- ensure there is no increase in the number of people exceeding the guidance level for folic acid intake
- minimise the administrative burden and any competitive impact on businesses
- ensure the proposals are proportionate, effective and ultimately enforceable

Relevant here are the existing Bread and Flour Regulations 1998, which detail the current fortification requirements in the 4 countries.

An impact assessment (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour>) has been prepared to accompany this consultation which should be read alongside this consultation document.

2. Neural tube defects

Neural tube defects (NTDs) are birth defects of the brain, spine, or spinal cord of the foetus where a fault in the development of the spinal cord and/or surrounding vertebrae can leave a gap in the spinal cord meaning the cord does not form properly or may be damaged.

Sometimes the skin and muscle over the spine is missing leading to a high risk of infection.

NTDs arise in the first few weeks of pregnancy, often before a woman even knows that she is pregnant.

The 2 most common NTDs are spina bifida and anencephaly. These are potentially devastating conditions that vary in severity between individuals. Some cases can be minor (for example, closed and minor bone abnormalities) which will have little impact on the ability to lead a full and active life. But in more severe cases (for example, open and involving the spinal cord), the conditions can be fatal or have significant impact on the life of the person affected and on the life of their family.

The damage caused to certain nerves means that the infant can be born paraplegic – that is with paralysis and loss of sensation of the legs and other functions such as bladder and bowel control can also be affected.

Anencephaly is when a major part of the brain and scalp does not develop.

3. Number of pregnancies affected

It is estimated that about 1,000 NTD-affected pregnancies are diagnosed each year in the UK¹. This may result in termination, miscarriage, death shortly after birth, 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 and some very minor cases of spina bifida may remain undetected.

4. Folic acid and neural tube defects

Folate is a water-soluble vitamin also known as vitamin B9. It is found naturally in many foods, such as green leafy vegetables. Folic acid is the synthetic form of folate. It is used in the fortification of food (such as breakfast cereals) and in supplements ('vitamin tablets'). The term 'folate' is an umbrella term that includes natural folates and synthetic folic acid. Folate cannot be made, or stored, by the body and must therefore be provided daily from the diet.

The levels of folate in individuals varies by age and population group. While folate deficiency is not a major problem for those eating a balanced diet, many people do not achieve recommended intakes.

The consequences of folate deficiency are that pregnant women are at greater risk of giving birth to infants with NTDs; and in all adults, a particular type of anaemia can result from long-term folate deficiency. More information is available on NHS Choices (<https://www.nhs.uk/conditions/vitamin-b12-or-folate-deficiency-anaemia/>) or the British Dietetic Association factsheet (<https://www.bda.uk.com/foodfacts/home>).

An estimated 90% of women aged 16 to 49 have a folate status below the level recommended to reduce the risk of an NTD-affected pregnancy. An estimated 28% of girls aged 11 to 18 years, 15% of boys aged 11 to 18 years and 7% of adults have low blood folate levels, putting them at risk of anaemia².

There is strong evidence that many NTDs can be prevented by increasing women's intake of folic acid, and advice is provided to women who could become pregnant.

However, in the UK, it is estimated that around half of pregnancies are unplanned (<https://publichealthmatters.blog.gov.uk/2018/06/26/health-matters-reproductive-health-and-pregnancy-planning/>). NTDs occur in the first 4 weeks of pregnancy, before many women know that they are pregnant. Even in those pregnancies that are planned, many mothers do not take folic acid supplements or modify their diet to increase folate intake before conception and up until the 12th week of pregnancy. It is estimated that only one-fifth of women report taking folic acid before pregnancy, which rises to three-fifths of women once their pregnancy is confirmed (<https://www.gov.uk/government/publications/health-matters-reproductive-health-and-pregnancy-planning/health-matters-reproductive-health-and-pregnancy-planning>).

Attempts to increase folate levels through education have had limited effect. This has led to calls for mandatory fortification of flour with folic acid to provide a background dietary intake to help raise folate levels in women who could become pregnant. Fortification would also help the wider population meet recommended folate intake levels.

5. Current advice to women who are thinking of having a baby

The UK government and devolved administrations recommend that women who could become, or plan to become, pregnant should take a daily supplement (tablet) of 400 micrograms of folic acid before conception and up until the 12th week of pregnancy (<https://www.nhs.uk/common-health-questions/pregnancy/why-do-i-need-folic-acid-in-pregnancy/>).

They are also advised to increase their daily intake of folate by eating more folate-rich foods and foods fortified with folic acid.

This advice would continue irrespective of whether flour is fortified with folic acid. Women who have had a previous NTD-affected pregnancy, or have a history of spina bifida or similar in their family (or that of the baby's father) are advised to take 5 milligrams³ of folic acid every day until the 12th week of pregnancy.

In addition, women who have diabetes and those taking anti-epileptic medicines are advised to consult their doctor, as they may need to take a higher dose of folic acid.

Folic acid 400 microgram supplements are widely available in supermarkets, chemists and health food shops. The cost of those folic acid tablets varies depending on where you buy them, but starts from less than 1p per tablet (from £1 for 180 tablets) for supermarket (or similar) own-brand products. Higher strength folic acid tablets (4 milligrams and over) are available on prescription.

Health education messages about NTDs and the need for folic acid supplementation are provided in a range of settings targeted at women of childbearing age. Government websites⁴ provide information on healthy lifestyle advice during pregnancy including the importance of folic acid supplementation.

However, these messages may not have reached the women in time to increase their folate intake before conception, hence the call for intervention to achieve a reduction in NTD-affected pregnancies, and the resulting impact on families and the NHS.

6. Reasons for proposing to add folic acid to flour

In the UK, some foods such as breakfast cereals are voluntarily fortified with folic acid. However, these fortified foods are not routinely consumed by all sections of the population and may not reach women from the most deprived areas on lower incomes, who also tend to have lower intakes of folic acid supplements.

Despite voluntary fortification, data from the last 9 years shows folate intakes of women who could become pregnant have continued to decline (<https://www.gov.uk/government/statistics/ndns-time-trend-and-income-analyses-for-years-1-to-9>) and are particularly low in areas of deprivation. There is therefore an opportunity to increase women's background dietary intake of folate to a level which offers greater protection against NTD-affected pregnancies.

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. In fact, it has the highest consumption rates across any group of the adult population, with an estimated 90% of people consuming products that contain flour. For example: biscuits, baked goods such as cakes, pastries such as croissants, some stuffing or gravy mixes.

However, with respect to flour used to make bread specifically, to put it into context, an estimated 29% of women consume very little bread and therefore consume less than 10g of flour from bread a day.

The Scientific Advisory Committee on Nutrition (SACN) (<https://www.gov.uk/government/groups/scientific-advisory-committee-on-nutrition>) recommends mandatory folic acid fortification of flour to improve the folate status of women most at risk of NTD-affected pregnancies (see 'SACN reports').

Mandatory fortification has successfully reduced rates of NTDs in other countries.

7. Potential adverse effects of mandatory folic acid fortification

For the vast majority of people, folate intakes from the usual diet, including food supplements recommended for women who could become pregnant, do not pose a health risk.

Despite this, some consumers may not wish to eat foods with added folic acid due to personal preference. In addition, people taking certain medication may be advised to monitor their intake of folic acid or avoid folic acid supplements because of potential interactions with their medication (<https://bnf.nice.org.uk/interaction/folic-acid-2.html>). We will ensure that due consideration is given to this if the policy is implemented.

There are concerns that consistent high intakes of folic acid from supplements could potentially increase the risk of masking ('hiding' or 'disguising') vitamin B12 deficiency in people with a condition known as pernicious anaemia.

Pernicious anaemia is an autoimmune condition that affects the stomach and prevents the body from absorbing vitamin B12. It is more common in older individuals and is the most common cause of vitamin B12 deficiency.

Clinical signs of vitamin B12 deficiency are anaemia and big red blood cells and/or neurological impairment (damage to the nervous system). High intakes of folic acid can help treat the anaemia symptoms but not the B12 deficiency. However, the symptoms associated with anaemia are often the reason that people with vitamin B12 deficiency seek medical advice. Therefore, high folic acid intakes could delay the diagnosis of B12 deficiency. If vitamin B12 deficiency is not treated this can, though rarely, lead to irreversible neurological damage. Good medical diagnostics reduces this small risk further.

In its reports, SACN considered in depth the potential risks associated with sustained high doses of folic acid. The risks considered were:

- masking/exacerbation of low vitamin B12 status
- cognitive decline in older individuals
- cancer (prostate, breast, colorectal and overall risk)
- the long-term effects of unmetabolized (not processed in the body) folic acid in the body

SACN concluded that folic acid intakes up to 1 milligram per day are not associated with masking anaemia associated with vitamin B12 deficiency and noted that the prevalence of B12 deficiency, with or without anaemia, did not increase after mandatory fortification was introduced in the US.

SACN found no effect of folic acid supplementation on cognitive decline in older individuals. Evidence of a link between excess folic acid intake and cancer is inconsistent. SACN concluded that despite the inconsistencies and limitations in the data, the overall picture does not suggest a detrimental effect of folic acid on cancer risk.

A further potential concern is the long-term effects of unmetabolized folic acid in the systemic circulation (the passage of blood around the body). However, there is no clear relationship between folic acid consumption and levels of unmetabolized folic acid in the systemic circulation, and the data is insufficient to assess whether the presence of unmetabolized folic acid in the systemic circulation is related to any adverse health outcomes.

8. Safe intake limit for folic acid

In February 2019 the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) (<https://cot.food.gov.uk/>) published a statement giving its opinion that the maximum intake of folic acid from supplements should be 1 milligram per day (1,000 micrograms) (<https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2019/cot-folic-acid-statement>). This followed a reconsideration of the evidence on the safety of folic acid.

COT agreed that there was some evidence of masking of pernicious anaemia at intakes of 5 milligrams per day but little evidence at intakes of 1 milligram per day. How the risk of masking B12 deficiency differs with increasing intakes of folic acid above 1 milligram was unclear.

COT also noted that if diagnoses of pernicious anaemia become more reliable then it would not be necessary to stipulate an upper limit for folic acid.

9. Scientific Advisory Committee on Nutrition reports

In 2017, SACN updated its previous reviews of the effect of folic acid on specific health outcomes, in response to a request from Food Standards Scotland (FSS). SACN's 2017 report (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) concluded that its previous recommendations (published in 2006 (<https://www.gov.uk/government/publications/sacn-folate-and-disease-prevention-report>) and 2009 (<https://www.gov.uk/government/publications/sacn-report-to-cmo-on-folic-acid-and-colorectal-cancer-risk>)) remained unchanged and it continued to recommend mandatory folic acid fortification of flour to improve the folate status of women most at risk of NTD-affected pregnancies.

SACN recognised that there were some potential risks associated with excess intakes of folic acid. It therefore recommended that mandatory fortification of flour should be accompanied by restrictions on voluntary fortification of other foods with folic acid, and clear guidance on the use of folic acid supplements. This was to ensure there is no increase in the numbers of people with intakes of folate above the recommended upper level.

10. Food Standards Scotland modelling exercise

FSS has carried out a modelling exercise (<https://www.foodstandards.gov.scot/publications-and-research/publications/stochastic-modelling-to-estimate-the-potential-impact-of-fortification-of-f>) to explore the potential impact of fortification of bread or wheat flour with folic acid on intakes of folate in the UK and to estimate the effectiveness and safety of the different options for the purpose of reducing the number of NTDs.

Results of the modelling indicate that mandatory folic acid fortification of flour would be expected to reduce the prevalence of low folate intakes, resulting in a reduction in the number of NTD-affected pregnancies. The modelling showed that the potential reduction in risk is roughly double, assuming the same level of fortification, if all flour is fortified, compared to fortifying bread flour only. At the same time, capping of voluntarily fortified foods and supplements would be expected to reduce the prevalence of intakes above the recommend upper level (see impact assessment (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour>) for further information). This conclusion is consistent with previous UK modelling in SACN's 2006 report.

11. Other countries adding folic acid to flour

The use of flour, specifically wheat flour, as a product for folic acid fortification has been adopted in more than 60 countries world-wide (including Australia, Canada and the US). Its primary advantage compared with fortifying other foods is that flour is widely consumed in some form or other.

Countries that have mandated folic acid fortification have seen falls in rates of NTDs of between 16% and 58%, and have not identified increased risks associated with fortification. However, these countries may not have similar diets or populations to the UK.

Currently, no EU country has a policy of mandatory fortification of flour with folic acid.

12. What flour is currently fortified and how

The Bread and Flour Regulations 1998 (<http://www.legislation.gov.uk/uksi/1998/141/contents/made>) (BFR) require the fortification of non-wholemeal wheat flour that is:

- milled in the UK, or imported into England, Scotland or Wales from a country outside of the European Economic Area (EEA), providing that the flour has not already been legally placed on the market in an EEA country
- intended to be placed on the market or used in production in England, Scotland or Wales

The Bread and Flour Regulations (Northern Ireland) 1998

(<https://www.legislation.gov.uk/nisr/1998/24/contents/made>) (BFR NI) require the fortification of non-wholemeal wheat flour that is:

- milled in the UK, or imported into Northern Ireland from a country outside of the EEA, providing that the flour has not already been legally placed on the market in an EEA country
- intended to be placed on the market or used in production in Northern Ireland

Both sets of regulations exempt flour intended for use in the manufacture of communion wafers, matzos, gluten, starch or a concentrated preparation used to facilitate the addition of the required fortificants to flour.

Both sets of regulations require flour within their scope to be fortified with calcium (for health), and with the following vitamins and minerals (to restore nutrients lost during the milling process):

- iron
- niacin (nicotinic acid or nicotinamide, also known as vitamin B3)
- thiamin (also known as vitamin B1)

This mandatory fortification is as a result of domestic (not EU) requirements. Its cost is borne by the industry.

The National Association of British and Irish Flour Millers (NABIM) indicates in their UK flour milling industry facts and figures 2018 report (<http://www.nabim.org.uk/the-flour-milling-industry>) that in excess of 60% of UK flour production is of non-wholemeal wheat flour. The remainder is mostly starch manufacture and wholemeal flour.

We are proposing that the BFR definition of non-wholemeal wheat flour is the baseline for considering this folic acid fortification proposal. Other products, such as gluten free, are not covered by the BFR, which is another reason that it is important to maintain a clear message about the continued need for folic acid supplements for all women who could become pregnant.

13. Wider implications for the Bread and Flour Regulations

Following this consultation, any decision on mandatory folic acid fortification would be considered by all UK countries, and the Department for Environment, Food and Rural Affairs, which holds responsibility for the existing requirements for flour fortification. Should resulting decisions require a legislative change (either to amend existing rules or create new legislation), we would consider at that point what this means for the BFR and the BFR NI.

This would also take into account any other potential changes to the BFR and BFR NI (not specifically related to folic acid fortification) which might be required following EU Exit and beyond. We would endeavour to consider all potential amendments to the existing BFR at the same time in order to reduce impacts on business and potential resultant costs to consumers.

This consultation is not intended to cover those aspects.

14. Restriction on folic acid in existing voluntarily fortified foods

If the response to this consultation indicates that flour should be fortified with folic acid, we would work with industry to consider what impact this may have on voluntary fortification of other products and food supplements, to ensure people do not exceed the recommended maximum intake.

Any resulting changes would be brought in over an agreed period of time to ensure manufacturers and other stakeholders have time to familiarise themselves and adapt as necessary. This would also take into account practical issues such as labelling alterations with an aim of minimising the burden of any changes.

The restriction of folic acid in voluntarily fortified products was considered as part of the modelling exercise undertaken by FSS, which included scenarios where such products and supplements had the folic acid amount capped rather than excluded. The results indicated that there are combinations of mandatory folic acid fortification with capping of voluntary fortification and supplements that can achieve reductions in NTD risk, whilst also decreasing the prevalence of both low intakes and intakes above the recommended maximum intake.

15. Conclusion

This consultation document has laid out the baseline proposal for mandatory fortification of non-wholemeal wheat flour in the UK with folic acid to help reduce the number of NTD-affected pregnancies. Additional information is provided in the impact assessment (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour>).

Taking into account all this information, you are asked to consider the consultation questions.

16. Consultation questions

Click on the questions to answer for you or your organisation.

Proposal to add folic acid to flour

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?

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.9922695133/>)

Which products should be included

Which of the following do you think mandatory fortification with folic acid should apply to? Please choose one. (<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.2671904851/>)

- just non-wholemeal wheat flour in the UK (the most commonly used type)
- just non-wholemeal wheat flour used to make bread in the UK
- all flour in the UK, including wholemeal and other grains
- 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

Alternative approaches

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?

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.6048318033/>)

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?

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.6740241792/>)

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

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.6740241792/>)

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

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.6740241792/>)

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

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.6740241792/>)

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?

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.3417778692/>)

Impact assessment

Do you agree or disagree with the provisional cost/benefit analysis outlined in the impact assessment? (<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.5604754829/>)

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

(<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.5604754829/>)




Do you think there are any other benefits, costs or wider impacts of this policy proposal that have not been mentioned yet? (<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.5604754829/>)

Practicalities for businesses

What are the practical issues that need to be thought about for mandatory fortification with folic acid? (<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.3492497921/>)

Are there any further trade implications for industry that need to be considered? (<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.3492497921/>)

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.) (<https://consultations.dh.gov.uk/flour/ef256a11/consultation/subpage.2019-06-06.3492497921/>)

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1. DHSC analysis of data from the Office for National Statistics (<https://www.ons.gov.uk>) on total number of births and the European Surveillance of Congenital Anomalies (<http://www.eurocat-network.eu/>) on prevalence of NTDs per 10,000 births. 
 2. The National Diet and Nutrition Survey (<https://www.gov.uk/government/statistics/ndns-time-trend-and-income-analyses-for-years-1-to-9>) estimates that in the UK 90% of women of childbearing age have a red blood cell folate level lower than the threshold for optimal avoidance of folate-sensitive foetal NTDs. 
 3. Conversion: 1 milligram (mg) equals 1,000 micrograms (µg). 
 4. Vitamins, supplements, and nutrition in pregnancy - NHS (<https://www.nhs.uk/conditions/pregnancy-and-baby/vitamins-minerals-supplements-pregnant/>), Start4Life - NHS (<https://www.nhs.uk/start4life>), Bump baby and beyond e-book - NHS Wales (<http://www.wales.nhs.uk/document/239354/info/>), Every Child Wales (<http://everychildwales.co.uk/>), Food Standards Scotland - Pregnancy (<https://www.foodstandards.gov.scot/consumers/healthy-eating/life-stages/pregnancy>), Ready Steady Baby (<https://www.nhsinform.scot/ready-steady-baby>), nidirect Folic Acid (<https://www.nidirect.gov.uk/folic-acid>). 