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Consultation outcome

Proposal to add folic acid to flour: consultation response

Updated 21 September 2021

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Executive summary

There are approximately 1,000 pregnancies each year in the UK that are affected by 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. NTDs can be fatal or can have a serious impact on the life of the person affected and on the life of their family.

There is strong scientific evidence that increasing dietary intake of folate and blood folate concentration in woman who can, or plan to become pregnant can help reduce the risk and number of pregnancies affected by NTDs. In the UK, women who could become pregnant are advised to take a daily supplement (400 micrograms) of folic acid (synthetic form of folate) prior to conception and up until the 12th week of pregnancy. However as approximately half of pregnancies are unplanned, many women do not take folic acid supplements during this time period.

After undertaking a public consultation on the proposal to introduce mandatory fortification of UK flour with folic acid, the UK Government and devolved administrations have carefully considered the responses received and intend to proceed with the mandatory fortification of non-wholemeal wheat flour and legislate on this basis.

The mandatory addition of folic acid to flour (fortification) will help increase blood folate concentration across the UK population, including those women who could become pregnant, which would contribute to a reduction in the risk and number of NTD-affected pregnancies in the UK.

After undertaking a public consultation on the proposal to introduce mandatory fortification of UK flour with folic acid, the UK Government and devolved administrations have carefully considered the responses received and intend to proceed with the mandatory fortification of non-wholemeal wheat flour and legislate on this basis.

The fortification of flour with folic acid is considered to be an effective method for reaching those with pregnancies that are unplanned and those women that do not take folic acid supplements before pregnancy.

The UK Government and devolved administrations believe that this policy has a significant role to play in reducing the number of NTD-affected pregnancies and will have wider positive health impacts on families and the NHS.

While this policy aims to benefit population health, the UK Government and devolved administrations will work with stakeholders, including businesses across the bread and flour industry, to ensure that the policy and the timings of any resulting amendments to legislation can be delivered in a way to minimise the burdens and impact on industry. The UK Government and devolved administrations reached consensus to take forward fortification of non-wholemeal wheat flour (as represented in the consultation and accompanying impact assessment as the 'baseline option'). This is already an established vehicle for fortification in the UK, and there was agreement not to fortify wider than the flour that is presently fortified.

Introduction

In 2019, the UK Government and devolved administrations launched a public consultation on the proposed policy of mandatory fortification of flour with folic acid to help prevent neural tube defects (NTDs) in foetuses. The consultation launched on 13 June 2019 and closed on 9 September 2019.

The public consultation was UK-wide, the Department of Health and Social Care (DHSC) and devolved administrations worked alongside the Department for Environment, Food and Rural Affairs (Defra), Food Standards Scotland (FSS) and the Food Standards Agency in Wales and Northern Ireland, who are each responsible for the overarching flour legislation in each of their respective countries, to develop the policy proposal. This was to ensure the development of the consultation and any resulting decisions were taken on a UK-wide basis, minimising the impact on trade and assisting with rate of compliance across industry.

The consultation received responses from 1,438 participants. Of these responses 1,419 participants responded to the online English-language version of the consultation and one participant responded to the online Welsh language version. In addition, 22 participants submitted their response to DHSC via email (4 of these also responded online and therefore were only counted once). The responses received came from a wide range of stakeholders (see below section on 'Characteristics of respondents' for further information).

This document provides a summary of the responses by question and an analysis of these responses. The document also sets out the UK Government and devolved administrations' response to the feedback received. This document informs stakeholders, including businesses, on the UK Government's and devolved administrations' next steps that will be undertaken including the delivery of policy and implementation of legislation.

Following analysis of the feedback to the consultation, the UK Government and devolved administrations have decided to implement a policy of mandatory fortification of non-wholemeal wheat flour in the UK, as represented in the consultation and impact accompanying assessment as 'the baseline option'.

The UK Government and devolved administrations are grateful to all of the organisations and individuals that took the time to respond to the consultation.

Background

The public consultation sought views on the proposal to introduce mandatory fortification of flour with folic acid. 'Mandatory fortification of flour with folic acid' means the legal requirement to add folic acid to flour. This proposal aims to help reduce NTDs in fetuses by raising the dietary intake of folic acid and blood folate concentrations in women who could become pregnant.

Neural Tube Defects (NTDs)

NTDs are birth defects of the brain, spine, or spinal cord of the foetus. The most common NTDs are spina bifida, anencephaly and encephalocele. NTDs arise in the first few weeks of pregnancy, often before a woman even knows that she is pregnant. As noted in the accompanying impact assessment to the consultation

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/808698/folic-acid-impact-assessment.pdf), it is estimated that approximately 1,000 NTD-affected pregnancies are diagnosed each year in the UK. These may result in termination, miscarriage

(<https://www.nhs.uk/conditions/miscarriage/>) (loss of a pregnancy during the first 23 weeks), loss of a pregnancy 23 weeks onwards, stillbirth (<https://www.nhs.uk/conditions/stillbirth/>), death shortly after birth, or long-term disability of varying severity.

Folate and folic acid supplements

Folate is a water-soluble vitamin that is found naturally in many foods such as green leafy vegetables. Folic acid is the synthetic form of folate and it is used in the fortification of foods and in food supplements.

The reference nutrient intake (RNI) which is the recommended guidance amount) for adults is 200 micrograms per day. Dietary intake of folate varies by age and population group and many people do not achieve the RNI. The consequence of folate deficiency in pregnant women is that they are at a greater risk of giving birth to infants with NTDs, and there is strong evidence that many NTDs can be prevented by increasing women's dietary intake of folate. 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/conditions/vitamins-and-minerals/vitamin-b/>). Women are also advised to increase their daily intake of folate by eating more folate-rich foods and foods fortified with folic acid.

In Great Britain (GB), it is estimated that around half of pregnancies are unplanned. Even in those pregnancies that are planned, many women do not take folic acid supplements or do not modify their diet to increase folate intake. 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. The National Diet and Nutrition Survey (NDNS) (years 9-11) (<https://www.gov.uk/government/statistics/ndns-results-from-years-9-to-11-2016-to-2017-and-2018-to-2019>) estimates that in the UK 89% of women aged 16 to 49 years have blood folate concentrations that may result in an increased risk of an NTD-affected pregnancy.

Folic acid fortification

Despite voluntary fortification of some foods such as breakfast cereals, data from 2008 to 2019 (<https://www.gov.uk/government/statistics/ndns-results-from-years-9-to-11-2016-to-2017-and-2018-to-2019>) shows that folate intakes of women of all age groups across the UK have continued to decline. Furthermore, the report from the NDNS survey (years 1-9) (<https://www.gov.uk/government/statistics/ndns-time-trend-and-income-analyses-for-years-1-to-9>) notes that folate intake across all age groups increases with increasing income. This suggests folate-rich or fortified foods are not routinely consumed by all sections of the population, especially women on lower incomes. 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 as it is currently subject to mandatory fortification with calcium, iron, thiamin and niacin, under The Bread and Flour Regulations 1998 (<https://www.legislation.gov.uk/ukSI/1998/141/introduction>) (BFR) and The Bread and Flour Regulations (Northern Ireland) 1998 (<https://www.legislation.gov.uk/nisr/1998/24/contents/made>) (BFRNI). The fortification with iron, thiamin and niacin is to restore nutrients lost during the milling process and the fortification of calcium is for health. As shown in the Impact Assessment (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour>) analysis of NDNS data (2015-2016) (<https://www.gov.uk/government/statistics/ndns-results-from-years-7-and-8-combined>) indicates that non-wholemeal wheat flour has the highest consumption rates across any group of the UK adult population, with 92% of people consuming products that contain this form of flour.

Mandatory fortification has successfully reduced rates of NTDs in other countries (see 'Other countries adding folic acid to flour' in the consultation document (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>)).

Policy objectives

The main policy objectives of the proposal are to:

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

Policy aims

The Scientific Advisory Committee on Nutrition (SACN) advises the UK Government and devolved administrations on nutrition related matters. In their reports from 2006 (Folate and Disease Prevention) (<https://www.gov.uk/government/publications/sacn-folate-and-disease-prevention-report>) and 2009 (Folic Acid and Colorectal cancer risk: Review of Recommendation for mandatory folic acid fortification) (<https://www.gov.uk/government/publications/sacn-report-to-cmo-on-folic-acid-and-colorectal-cancer-risk>), SACN recommended the mandatory folic acid fortification of flour to improve the folate status of women most at risk of NTD-affected pregnancies. In the 2017 SACN report (Update on Folic acid) (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>), SACN concluded that its previous recommendations remained unchanged and continued to recommend the mandatory folic acid fortification of flour.

As shown in the consultation document FSS 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. A number of their modelling options have been depicted in the accompanying impact assessment to the consultation (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/808698/folic-acid-impact-assessment.pdf).

Responses

The consultation asked respondents for their views on the overall proposal for the mandatory fortification of non-wholemeal wheat flour in the UK (the most commonly used type) with folic acid, as well as alternative options for mandating folic acid fortification in different products. Alternative fortification options in scope included:

- fortifying only non-wholemeal wheat flour which is 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'
- no products should be fortified with folic acid on a mandatory basis

This summary of the consultation response has characterised the respondents according to their demographic (population) characteristics, such as age, location for example, and summarises the answers and free-text responses (where relevant) to each of the consultation questions.

The free-text box allowed respondents to provide a justification for their answers and respondents raised several topics in response to the questions. These have been grouped into discrete themes some of which are further explored in the annexes.

Characteristics of respondents

In total, the consultation received 1,438 responses from a range of individuals, organisations and businesses including those across the food industry and non-government organisations. The English-language digital consultation received 1,419 responses, one response was received to the Welsh-language version of the consultation and 22 responses were received via email, of which 4 also responded online and were only counted in the analysis once.

Most respondents (88%) self-identified as individuals, with the remainder representing businesses, non-governmental organisations and public sector bodies.

Over 100 respondents identified themselves as working in the health sector, and a further 50 identified as working in the “heritageartisan milling” sector.

Several respondents had raised direct family experience of NTDs including spina bifida and other birth defects.

The majority (72%) of the respondents reported living in England, 2% reported living in Wales, 6% reported living in Scotland, and 1% reported living in Northern Ireland. A further 2% were from other locations not specified and 16% did not provide their location.

Summary of responses per question

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

Summary of responses

When asked about the proposal to introduce mandatory fortification of non-wholemeal wheat flour in the UK with folic acid, 53% of respondents agreed with the proposal and 39% of respondents disagreed with the proposal. A further 5% did not know whether they agreed or disagreed with the proposal and 3% of participants did not respond to this question.

Of the respondents who had an opinion on the proposal (92% of the total respondents) those in the health sector were more supportive with 85% in favour, whilst respondents in the heritage and artisan milling sector were the most opposed with only 35% in agreement.

In Scotland, Wales and Northern Ireland 67%, 68% and 68% of respondents who had an opinion on the proposal were in favour of the baseline proposal (although the sample numbers are low). The proportion of respondents in support of the proposal in England was slightly lower at 57%.

The proportion of respondents who were also in support of the proposal (if they had an opinion) but did not provide their location was similar at 59%.

Businesses (excluding the heritage and artisan milling sector) were marginally supportive (56% in favour if they had an opinion), whereas 35% of businesses from the heritage and artisan milling sector were supportive.

UK Government and devolved administrations' response

After considering feedback to the consultation to the proposal to add folic acid to flour, the UK Government and devolved administrations have agreed in principle to take forward the mandatory requirement to fortify flour in the UK with folic acid to help prevent NTDs. Further

details on which products this will apply to are provided in the UK Government and devolved administrations' response to question 2 below.

Question 2. Which products should mandatory fortification apply to?

Summary of responses

Respondents were asked to provide a more detailed view on the scope of the policy in relation to the types of flour and products that the proposed fortification should extend to.

When asked in more detail about different fortification options around 55% of respondents supported the mandatory fortification of some form of flour in the UK but had differing opinions of what this should be.

The baseline option of fortifying non-wholemeal wheat flour with folic acid had support from 9% of participants, similarly the option to fortify all types of flour, including wholemeal and other grains received 9% support. Fewer respondents (3%) were in support of the option to fortify non-wholemeal wheat flour that is only used to make bread. The option to fortify all types of flour, and other non-wheat products, such as gluten-free received 34% support.

Thirty-eight per cent of respondents expressed support for no mandatory fortification of folic acid in the UK. The reasons for this view and the UK and devolved administrations' responses can be found in the sections on questions 4 and 11 below as well as throughout the document.

Finally, 7% of respondents did not answer the question.

UK Government and devolved administrations' response

After considering feedback to the consultation, the UK Government and devolved administrations have agreed in principle to take forward the mandatory fortification of non-wholemeal wheat flour in the UK with folic acid (baseline option).

The requirement to add folic acid to non-wholemeal wheat flour will be in addition to the 4 fortificants (calcium, iron, thiamin and niacin) that are already added to this form of flour under the BFR and BFR NI. By opting to undertake this option and not fortifying beyond the type flour that is presently fortified, the UK Government and devolved administrations have ensured that individuals can avoid purchasing this type of flour and products containing it if they so wish. They will be able to purchase unfortified wholemeal flour and other milled grains and flours including those that are 'gluten free'.

The responses to the public consultation demonstrated each proposal had some (albeit variable) levels of support however there was no single option which commanded majority support of the respondents' preferences. We understand that some respondents may view the decision to implement the baseline option of fortifying non-wholemeal wheat flour with folic acid as either too strong or not strong enough. However, we consider it to be a reasonable approach to help increase folate intake in women who could become pregnant and allow us to monitor the impact of fortification to ensure that the tolerable upper levels of folic acid are not exceeded in a significant number of the population.

Question 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?

Summary of responses

The consultation asked participants to suggest other ways of reducing the number of NTD-affected pregnancies other than the proposal for mandatory fortification of flour. Over half of the participants (1097) responded to this question including 711 free-text responses. The most popular suggestion to help reduce the number of NTDs was the need for greater education in relation to folate and folic acid supplementation (279 responses via free-text). The free provision (either a free prescription or where no prescription is necessary) of folic acid supplements to women who could become pregnant was suggested by 181 respondents.

Some respondents also suggested using natural folate for fortification.

Forty respondents suggested using folate (5-methyl-THF) rather than folic acid due to concerns about the risk to some members of the population who have a mutation in the gene coding for methylenetetrahydrofolate reductase (MTHFR), an enzyme involved in folate metabolism.

Thirty respondents suggested the use of natural folate over synthetic folic acid.

We will now respond to these 3 suggestions for alternative ways of helping reduce the number of NTDs in turn.

Education

The general importance of education in relation to folate intake and folic acid supplementation and its importance in helping to prevent NTDs was raised by 279 respondents in their free-text responses.

Specific concerns raised include the issue of the limited public awareness of the importance of folic acid supplementation prior to conception and during the first 12 weeks of pregnancy, respondents noted that the importance was not always conveyed by medical professionals in family planning clinics and in appointments with midwives.

Queries also included whether the importance of folate intake and NTD risk and prevalence and folic acid supplementation is included in the curriculum of health care professionals and in the school curriculum in subjects such as Food Technology (F.T), Personal, Social, Health and Economics (P.S.H.E) or Biology.

Across the UK there is no standard method for providing information on folic acid supplementation and its importance in preventing NTDs in fetuses to women who could or are planning to become pregnant. The method of information transmission to women who could or are planning to become pregnant is down to the individual health board.

Common methods for highlighting the importance of folate and folic acid supplementation prior to conception and during the first 12 weeks of pregnancy include the distribution of leaflets and the recommending of apps (<https://www.nhs.uk/apps-library/category/pregnancy-and-baby/>).

Annex A below provides further information on folate and folic acid supplementation education policies and programmes across each of the devolved administrations.

The UK Government and devolved administrations acknowledge that using education and promoting public health messages to raise awareness of folate and folic acid supplementation in the population remains important and this will continue. Annex A below provides further information on folate and folic acid supplementation education policies and programmes across each of the devolved administrations.

We acknowledge that previous attempts to raise dietary intakes of folate through education have had a limited effect, particularly amongst younger women and some socio-economic groups. Therefore, further intervention is required to make progress in reducing the number of NTD-affected pregnancies and the fortification of non-wholemeal wheat flour with folic acid is our way of helping to achieve this.

Free provision of folic acid supplements

The idea of providing free folic acid supplements (either a free prescription or where no prescription is necessary) was raised by 181 respondents with some specifically suggesting the provision of free folic acid supplements to women who could become pregnant from lower socio-economic backgrounds.

UK Government and devolved administrations' response

Targeted approaches to increase folate intake exclusively in women who could become pregnant, such as the provision of free folic acid supplements, are often difficult to implement in practice and uptake is often low. Therefore, the UK Government and devolved administrations have reached agreement to take forward the fortification of non-wholemeal wheat flour with folic acid, the aim of this population-based approach is to ensure the majority of women who could become pregnant benefit.

There are a significant number of unplanned pregnancies in the UK. The fortification of non-wholemeal wheat flour with folic acid will support pregnancies where women may not be aware that they are pregnant until it is too late for folic acid supplements to be of use, and for those sections of the community who may not engage with government advice regarding folic acid supplements.

In England, Wales and Northern Ireland, some pregnant and breastfeeding women on low incomes are eligible for vouchers for free 'Healthy Start vitamins' including folic acid through the Healthy Start Scheme (<https://www.healthystart.nhs.uk/getting-vitamins/>). Individuals are only eligible for the scheme once they are at least 10 weeks pregnant, and the purpose of vitamin supplements provided under the Healthy Start scheme is not to provide folic acid from pre-conception.

Since 2017, all pregnant women in Scotland are provided free Healthy Start Vitamins from the point of notifying, or booking with, maternity services. Work has progressed over several years to ensure that all women are encouraged to book with maternity services prior to 12 weeks gestation, across all Scottish Index of Multiple Deprivation (SIMD) quintiles. This target has been achieved and only a small minority of women book later than 12 weeks, usually younger or older women. There are no qualifying criteria for this in terms of weeks gestation. This does not provide the benefits of folic acid supplementation from when it is advised (prior to conception and during the first 12 weeks of pregnancy).

Natural folate

Forty respondents proposed that the natural folate was used in the mandatory fortification of flour as opposed to folic acid, which is the synthetic form, due to some members of the population having a genetic mutation on the **MTHFR** enzyme.

Apart from some differences in how natural and synthetic folates are digested and absorbed in the gut, both forms are processed into a type of folate that can be used by the body. These processes involve a number of enzymes, one of which is **MTHFR**. There are different 'variants' of the **MTHFR** enzyme due to slight differences in the DNA sequence of the **MTHFR** gene that carries the instructions for making the enzyme. The most common is the CC genotype. There is also a TT genotype, with approximately 10% of the UK population possessing this type.

Individuals with the TT genotype produce a **MTHFR** enzyme which is less active and results in lower blood folate concentrations for the same dietary intake of folate compared to those with the CC genotype. **SACN's** 2017 report (Update on folic acid) (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) noted that blood folate concentrations of individuals with the TT genotype are about 16% lower for the same dietary intake of folate compared with individuals with the CC genotype.

Mothers or infants with the TT genotype have significantly greater risk of an NTD-affected pregnancy than those with the CC genotype.

UK Government and devolved administrations' response

The UK Government and devolved administrations have considered the consultation responses and acknowledge that those with the **MTHFR** gene mutation have a reduced capacity to process folate resulting in lower blood folate concentrations.

However, the evidence shows that an increased folic acid intake will raise blood folate concentrations, which in turn reduces the risk of an NTD-affected pregnancy. This is why we have agreed to take forward the fortification of non-wholemeal wheat flour with folic acid. The aim of this population-based approach is to ensure the majority of women who could, or plan to become pregnant including those with a **MTHFR** gene mutation benefit.

Thirty respondents held the opinion that synthetic folic acid is not the best option and were of the view that natural folate may be a more acceptable option.

Natural folate and folic acid are digested and absorbed by the gut differently. However, both forms are processed into the same form of folate that can be used by the body and this form of folate is called 5-methyl tetrahydrofolate (5-MTHF).

In their 2017 Update on folic acid (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) report, **SACN** noted that folic acid is widely used for food fortification and in supplements because it is more stable in foods than natural folates and is better absorbed.

The health effects of folic acid have been widely researched and its safety was considered specifically in **SACN's Folate and Disease Prevention** (<https://www.gov.uk/government/publications/sacn-folate-and-disease-prevention-report>) report in 2006 and **SACN's Update on Folic acid** (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) report in 2017. Research has demonstrated that folic acid is effective in the prevention of **NTDs**.

Additionally, several respondents also raised, the importance of healthy eating and the importance of increasing folate intake through diet, some of these respondents were also of the view that natural folate is more beneficial than folic acid. The importance of the population consuming a healthy and balanced diet is something all governments of the UK strongly support. Annex A below provides further information on the UK Government and devolved administrations' response on the importance of healthy eating.

UK Government and devolved administrations' response

The UK Government and devolved administrations acknowledge that there are other forms of folate available.

We have considered the evidence and have agreed to take forward the fortification of non-wholemeal wheat flour with folic acid, which is relatively stable in food and is also easily absorbed when taken orally as a supplement or in fortified foods. We believe that the fortification of non-wholemeal wheat flour with folic acid will be effective in increasing blood folate levels in women who could become pregnant and therefore help in reducing the risk of NTDs.

The UK Government and devolved administrations recommendation to women who could become, or plan to become, pregnant to 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/conditions/vitamins-and-minerals/vitamin-b/>) will remain once the policy to fortify flour with folic acid has been implemented.

The importance of the population consuming a healthy and balanced diet is something all governments of the UK strongly support. Annex A below provides further information on the UK Government and devolved administrations' response on the importance of healthy eating.

Question 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?

Summary of responses

The consultation asked respondents to comment on any groups or individuals that might be negatively affected by mandatory fortification of flour with folic acid or miss out on the benefits, 881 responses were received to this question including 795 free-text responses.

Common responses which highlighted potential negative impacts of the proposal include 144 respondents who discussed individuals with MTHFR genetic mutations, other genetic mutations or those who are allergic to folic acid would be negatively affected. The UK Government and devolved administrations' response to the impact on individuals affected by MTHFR genetic mutations is explored further in the consultation response to question 3 above.

Seventy-five respondents were concerned that the policy would negatively impact heritage and artisan millers and this is explored further in the consultation response to question 6 below.

A summary of groups or individuals which were considered to be negatively affected and were highlighted in the consultation responses are provided below:

- 119 respondents raised concerns that the whole population will be negatively affected by a loss of free choice
- 84 respondents raised that those consuming high intakes of folic acid will be negatively affected, as it may result in unmetabolised folic acid
- 54 respondents drew attention to folic acid playing a role in the masking of pernicious anaemia (an autoimmune condition that affects the stomach and prevents absorption of vitamin B12)
- 38 respondents highlighted that folic acid may interfere with disease treatments and medications and so will negatively impact these individuals
- 163 participants noted those who do not consume food made from non-wholemeal wheat flour, for example those who are gluten-intolerant or those that consume food made from other types of flour may miss out on the benefits associated with the proposal

A number of participants also noted there are a number of other population groups or individuals which may miss out on the benefits of this proposal, Annex B below provides further detail on the UK Governments and devolved administrations' response to the concerns of some respondents who highlighted other population groups or individuals who could be affected by this policy.

The whole population

A hundred and nineteen respondents held the view that the whole population would be negatively affected due to a loss of free choice. Some respondents noted that mandatory fortification could be considered as 'mass medication' and an example of the government acting as 'nanny state' due to the application of the policy at a population level, rather than individual level.

UK Government and devolved administrations' response

After considering feedback to the consultation, the UK Government and devolved administrations have agreed to take forward the mandatory fortification of non-wholemeal wheat flour with folic acid (baseline option).

The requirement to add folic acid to non-wholemeal wheat flour will be in addition to the 4 fortificants (calcium, iron, thiamin and niacin) that are already added to this form of flour under the BFR and BFR NI. By opting to undertake the baseline option to add folic acid to non-wholemeal wheat flour and not fortifying wider than the type of flour that is presently fortified, the government and devolved administrations have ensured that individuals are able to avoid fortified flour if that is their choice. These individuals will be able to consume unfortified wholemeal flour and other non-wheat products including those that are 'gluten free'.

High intakes of folic acid

Eighty-four respondents raised concerns over the potential effect of high levels of folic acid consumption leading to the presence of unmetabolised folic acid (UMFA) in the blood and they hold the view unmetabolised UMFA may lead to adverse health conditions.

SACN considered the relationship between folic acid intake and the presence of UMFA in the blood in their 2017 report Update on Folic acid (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>). The report concluded that there was no clear dose-response relationship between folic acid intake and the appearance of UMFA in the body's systemic circulation (blood

circulation). UMFA comprises a relatively constant proportion (1 to 3%) of total folate in the body regardless of a person's age or level of folate intake. This suggests that the concentrations of UMFA found in the blood do not reflect intakes that are above the body's capacity (ability) to metabolise folic acid. SACN noted there were insufficient data to assess whether the presence of UMFA in the blood is related to any long-term adverse consequences on health.

UK Government and devolved administrations' response

Scientific evidence suggests that the presence of unmetabolised folic acid in the blood is not representative of intakes above the ability of the body to metabolise folic acid into a form which can be absorbed.

The relatively low levels of folic acid currently in most fortified foods, or which have been modelled in flour as part of this policy proposal ensures that the number of individuals meeting the tolerable upper level for folic intake does not largely increase (the accompanying impact assessment to the consultation notes that without restrictions on voluntary fortification an estimated 0.417% of the population currently exceed the tolerable upper level). Further details on the full policy will be finalised at a later date including the assessment of the need to limit voluntary fortification of other products.

The UK Government and devolved administrations have considered the feedback to the consultation alongside the evidence and agreed to take forward the mandatory fortification of non-wholemeal wheat flour with folic acid (baseline option).

Pernicious anaemia

54 respondents suggested that folic acid plays a role in the masking of pernicious anaemia (an autoimmune condition that affects the stomach and prevents absorption of vitamin B12).

In people with vitamin B12 deficiency, high dose folic acid supplementation can improve the symptoms of anaemia. This can make it more difficult to detect the vitamin B12 deficiency which can lead to the damage of nerves and the spinal cord. This can result in severe disability if the deficiency continues undetected.

The consultation proposal provided information from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on upper guidance levels for supplemental folic acid (see section on 'Safe intake limit for folic acid' in the consultation proposal (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>)). The evidence suggested that supplemental folic acid intakes up to 1 milligram a day are not associated with the masking of pernicious anaemia.

In addition, the 2006 SACN report on Folate and Disease Prevention (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/338892/SACN_Folate_and_Disease_Prevention_Report.pdf) concluded that folic acid intakes up to 1 milligram per day are not associated with masking anaemia associated with vitamin B12 deficiency.

Evidence identified in the SACN 2017 Update on folic acid (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) report suggests that the prevalence of vitamin B12 deficiency with or without anaemia did not increase after mandatory folic acid fortification in the USA.

UK Government and devolved administrations' response

There is no evidence that folic acid can mask the diagnosis of vitamin B12 deficiency at doses up to 1 milligram per day in the short term. Evidence considered in the SACN 2017 report suggests that the prevalence of vitamin B12 deficiency with or without anaemia did not increase after mandatory fortification in the USA (SACN, 2017).

The UK Government and devolved administrations have considered the feedback to the consultation alongside the evidence and agreed to take forward the mandatory fortification of non-wholemeal wheat flour with folic acid (baseline option).

Disease treatments and medications

38 respondents raised concerns that folic acid might interfere with treatments and medications for different conditions such as cancer and epilepsy.

These concerns included the potential interference of folic acid with the absorption of anticonvulsant drugs such as lamotrigine (medication used for bipolar and epilepsy) and chemotherapy treatments that are anti-folate medications such as methotrexate.

As shown in the impact assessment accompanying the consultation the UK Government and devolved administrations considered these issues and the relevant scientific evidence when preparing the consultation on the policy proposal (see section on 'Potential adverse effects of mandatory folic acid fortification' in Proposal to add folic acid to flour: consultation document (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>)).

Analysis of NDNS data indicates that individuals who are likely to exceed the tolerable upper level for folic acid are likely to be taking supplements (the impact assessment which accompanied the consultation notes that approximately 0.4% of the population already exceed the tolerable upper level). The relatively low levels of folic acid currently in most fortified foods, or which have been modelled in flour as part of this policy proposal are not enough to reach the tolerable upper level alone (1 milligram per day).

The proposed level of fortification of folic acid in flour in this policy is under consideration, but the impact assessment notes that the maximum proposed levels range from 100 micrograms of folic acid per 100 grams of flour to 450 micrograms of folic acid per 100 grams of flour, these proposed levels ensure that the number of individuals meeting the tolerable upper level for folic intake does not greatly increase. The modelling undertaken as part of the impact assessment shows that an increase in daily folic acid intake of 60-100 micrograms is required to see significant benefits in a reduction of NTDs, and this minimum can be achieved by fortifying by approximately 200 micrograms of folic acid per 100 grams of flour.

In 2006, SACN concluded that evidence from a small number of studies suggested that the dose of folic acid provided by mandatory fortification is unlikely to have an adverse impact on anticonvulsant drug metabolism (Folate and Disease Prevention) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/338892/SACN_Folate_and_Disease_Prevention_Report.pdf). This was based on studies of the anti-epileptic drug (AED) phenytoin. SACN did not reconsider this risk in its 2017 report (Update on folic acid) (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>).

Evidence for an interaction between folic acid and medications can be found in the product information of licensed products.

Information on interactions between specific drugs and folic acid supplements is usually available in a medicine's summary of product characteristics (SmPC) which is then summarised in the British National Formulary (BNF), a joint publication of the British Medical Association and the Royal Pharmaceutical Society. The BNF website provides further information on what constitutes an interaction (<https://bnf.nice.org.uk/interaction/introduction.html>). It notes that 2 or more drugs given at the same time can exert their effects independently or they can interact. Many interactions are harmless, and even those that are potentially harmful can often be managed.

The BNF website provides information on the potential interactions between folic acid as a supplement and certain medications for cancer and epilepsy (antiepileptic drugs (AEDs)).

The BNF does not provide consideration for interactions between medications and folic acid fortified foods. The BNF does not provide information relating to interaction with the medication lamotrigine and folic acid supplements.

UK Government and devolved administrations' response

The UK Government and devolved administrations considered the tolerable upper level of folic acid consumption and the interaction of folic acid with treatments and medications for different conditions such as cancer and epilepsy when preparing the consultation on the policy proposal and conducting the impact assessment.

The relatively low levels of folic acid currently in most fortified foods, or which have been modelled in flour as part of this policy proposal ensures that the number of individuals meeting the tolerable upper level for folic intake does not greatly increase (the impact assessment accompanying the consultation notes that without restrictions on voluntary fortification an estimated 0.417% of the population currently exceed the tolerable upper level). Further details on the full policy will be finalised at a later date including the assessment of the need to limit voluntary fortification of other products.

We would recommend that individuals taking medications speak to their GP or healthcare professional if they have concerns about potential interactions. Information on how the presence of folic acid will be included on the ingredients list on labels can be found under the section on question 5 below.

Those who do not consume food made from non-wholemeal wheat flour

163 respondents noted that those who do not consume products made from non-wholemeal wheat flour may not benefit from the implementation of this policy as it applies to the baseline option.

UK Government and devolved administrations' response

By opting to undertake the baseline option of fortifying non-wholemeal wheat flour with folic acid, the UK Government and devolved administration's note that not all will explicitly benefit from this policy. The burdens upon business were considered and it was agreed not to fortify wider than the flour that is presently fortified. However, we intend on engaging with industry in relation to the voluntary fortification of gluten-free products.

Question 5. How could we make sure groups or individuals are supported or not affected negatively?

Summary of responses

The consultation asked how the government can support groups or individuals and ensure that any negative impacts of the policy are mitigated, 810 responded to this question including 667 free-text responses. The free-text responses included 294 respondents who were against mandatory fortification in principle. These responses did not provide suggestions or methods for supporting groups and individuals who may be affected by the mandatory fortification of flour with folic acid.

99 respondents believed that greater education on the benefits of dietary folate intake and folic acid supplementation would help these groups and individuals. The importance of education was raised frequently in response to question 3 above, Annex A below contains further information on folate and folic acid supplementation education policies and programmes across the devolved administrations.

54 respondents believe that clear labelling on products and advertising and promoting the change in policy would help. The same number of respondents said that adding folic acid to gluten-free and other flours would help those with coeliac disease or are gluten intolerant missing out on the benefits of folic acid fortification if the policy is limited to non-wholemeal wheat flour.

UK Government and devolved administrations' response

We have carefully considered the opinions of the respondents' in relation to mitigating any potential negative impacts of the policy.

As noted in response to question 3, education is important in ensuring that groups and individuals understand the importance of folate, NTD risk and folic acid supplementation and are supported to understand the rationale behind the policy. Annex A below contains further information on folate and folic acid supplementation education policies and programmes across the devolved administrations.

In accordance with the mandatory food information requirements set out in Regulation (EU) No 1169/2011 (<https://www.legislation.gov.uk/eur/2011/1169/contents>) the presence of folic acid will be shown in the ingredients listing of non-wholemeal wheat flour alongside the other mandatory fortificants (calcium, iron, thiamin and niacin).

Our existing legislation provides a requirement for accurate and honest labelling with regards to the sale of food. This will ensure that consumers are aware of the presence of folic acid when they purchase non-wholemeal wheat flour and pre-packed products containing non-wholemeal wheat flour. A suitable lead-time for when the policy will take effect will ensure that the change in fortification policy is made clear to groups and individuals.

Those with coeliac disease make up approximately 1% of the population (<https://www.nhs.uk/conditions/coeliac-disease/>). While limiting mandatory fortification to non-wholemeal wheat flour will not benefit those who avoid gluten, we intend on considering with industry how voluntary fortification of gluten-free products might be considered to help extend this policy to those foods.

However, individuals with coeliac disease are likely to receive appropriate advice in relation to folate intake from specialists such as health care professionals.

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

Summary of responses

The consultation asked about the impact of the fortification proposal on industry. There were 765 responses to this question including 450 free-text responses. Around a third of respondents (222) noted that small scale and traditional flour mills and flour manufacturers may be negatively affected by the policy and 71 respondents noted that bakers and bread-makers may also be negatively affected.

UK Government and devolved administrations' response

We understand the concern of industry about the impact of widening the existing mandatory fortification requirements. We engaged with industry prior to launching the consultation and will continue to do so during the implementation of the policy. Fortifying non-wholemeal wheat flour with folic acid will mitigate the burden on industry as it will not result in subjecting other types of flour to the existing mandatory fortification requirements. We do understand the concerns raised by small and micro businesses and we will continue the engagement with heritage and artisan milling stakeholders (the Society for the Protection of Ancient Buildings (SPAB) Mills Section and the Traditional Cornmillers Guild).

Defra (<https://consult.defra.gov.uk/food/consultation-on-amending-domestic-food-legislation/>) and the devolved administrations intend to embark on a wider review of the existing BFR to address certain technical matters and following various requests from industry.

The UK Government and devolved administrations will consider the timings of this policy in the light of any other legislative changes in order to support implementation. This will include whether any exemptions should be considered for small businesses such as heritage and artisan millers.

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

Summary of responses

The consultation questioned which methods can be used to support businesses to ensure that the policy does not affect them negatively.

There were 703 responses to this question with 444 free-text responses. The most common responses included the view that fortification should not be introduced (raised by 162 respondents). These responses did not provide suggestions or methods for supporting businesses who may be affected by the mandatory fortification of flour with folic acid.

In their free-text responses, 132 respondents requested exemptions for small businesses, traditional mills, windmills and water mills. Many of these respondents specified that exemptions should be applied to small scale producers with a production under a certain tonnage of flour per year. A further 68 respondents noted a desire for subsidies and other financial compensation due to the potential negative effects of the policy.

UK Government and devolved administrations' response

The UK Government and devolved administrations, reached consensus to take forward fortification of non-wholemeal wheat flour, which is already an established vehicle for fortification in the UK and will consider the timings of this policy in the light of any other legislative changes in order to support its implementation.

The baseline option of mandatory fortification of non-wholemeal wheat flour is considered to be the most practical option that will deliver the policy objective of reducing the number of NTDs while limiting the impact on businesses.

Each devolved administration will be commencing detailed engagement with industry on the detail of the policy and its implementation. This engagement will include the consideration of exemptions for small businesses, traditional mills, windmills and water mills as raised by a number of respondents. It is our intention to consider the policy alongside other wider changes that may be required under the BFR. The timing of this will be confirmed.

Question 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?

Summary of responses

Respondents were asked if the fortification of flour with folic acid is made mandatory, should there be limits on the voluntary fortification of other food products and/or supplements with folic acid. Thirty-one per cent of those who responded (440) agreed that there should be limits, 19% disagreed with the proposal to limit voluntary fortification (278), 32% neither agreed nor disagreed (454) and 19% (266) did not provide a response.

In the 2006 SACN report on Folate and Disease Prevention and their 2009 report to the Chief Medical Officer (CMO) 'Folic Acid and Colorectal cancer risk: Review of Recommendation for mandatory folic acid fortification', SACN recommended the mandatory fortification of flour with folic acid to improve the folate status of women most at risk of NTD-affected pregnancies. SACN stipulated that this should only be introduced alongside restrictions on voluntary fortification and clear guidance on the use of folic acid supplements. This was to ensure that there would not be an increase in the numbers of people with folic acid intakes above the upper guidance levels. SACN re-affirmed this recommendation in the 2017 report Update on folic acid (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>). In addition, in keeping with their previous recommendations, SACN stipulated that implementation of mandatory folic acid fortification should be accompanied by measures for monitoring folic acid intakes and blood folate concentrations of the population. This was to ensure mandatory folic acid fortification did not lead to an increase in the proportion of the population with folic acid intakes above upper guidance levels.

Further information on the scientific opinions of COTI can be found in the section on the 'Safe intake limit for folic acid' in the consultation proposal (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>).

UK Government and devolved administrations' response

The impact assessment that accompanied the consultation (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>) indicates around 0.4% of the population already exceed the tolerable upper level advised by COT, although that may include some women who are following medical advice to take higher doses of folic acid supplements due to being at an increased risk of an NTD-affected pregnancy, or if prescribed a higher dose for other reasons. The consultation proposal provided information from COT on upper guidance levels for supplemental folic acid. The evidence suggested that supplemental folic acid intakes up to 1 milligram a day are not associated with the masking of pernicious anaemia.

The modelling in the impact assessment shows the baseline option will result in a very small increase in the number of people exceeding the tolerable upper level. Details on the exact levels of folic acid will be finalised prior to implementation.

The updated impact assessment which will be published alongside the draft legislation will detail the considerations behind the levels of folic acid used and whether that indicates a need for additional monitoring of folic intake and blood folate levels. Population folic acid intakes and blood folate concentrations are currently monitored through the NDNS (<https://www.gov.uk/government/collections/national-diet-and-nutrition-survey>).

A summary of Question 9. Do you agree or disagree with the provisional cost/benefit analysis outlined in the impact assessment? and Question 10. Can you provide any additional evidence to inform the impact assessment?

Summary of responses to question 9

34% of participants (487) did not provide a response to question 9.

24% of participants (342) agreed with the analysis included in the impact assessment, 16% of respondents (226) disagreed with the analysis, 27% (383) neither agreed nor disagreed.

Summary of responses to question 10

There were 405 responses to question 10, including 17 respondents that provided additional evidence and information links, 128 participants provided additional free-text responses. The impact assessment accompanying the consultation proposal included the likely costs, benefits and impacts of the leading options.

32 respondents questioned the benefits of mandatory fortification and held the view that mandatory fortification will lead to health issues, and 29 did not believe that the full costs has been published and were unsure as to whether the policy could be considered to be cost-effective. 27 respondents saw the benefits of mandatory fortification and considered it to be beneficial to health.

UK Government and devolved administrations' response

The UK Government and devolved administrations acknowledge the concerns raised by respondents.

The UK Government and devolved administrations' response on the concerns raised on the possible links between mandatory folic acid and health of population groups and individuals affected by the policy can be found in question 4 above and Annex B below (impacts on other

population groups and individuals).

An updated impact assessment will be published alongside the legislation, to consider the consultation responses and to include more detail on the cost/benefit analysis. This will supplement the earlier information provided in the impact assessment accompanying the consultation.

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

Summary of responses

Comments on other benefits, costs or wider impacts of this policy proposal were received from 574 participants and included 278 free-text responses.

The most frequently mentioned potential disadvantages to the policy included the view that the folic acid fortification policy will result in illnesses in the population, mask pernicious anaemia (vitamin B12 deficiency) and cause issues for those with the MTHFR genetic mutation (71 respondents). These concerns have been addressed in the UK Government and devolved administration's response to question 4 above and further information is also shown in Annex B below.

Conversely, 31 respondents noted that mandatory fortification would have other savings in relation to healthcare. The impact assessment that accompanied the consultation proposal noted that savings to the NHS may also be significant, particularly for babies that currently survive an NTD with disabilities requiring long-term care. The benefits in terms of cost of treatment, family impacts and economic benefit have not yet been quantified, but will be driven primarily by the number of NTDs prevented. The updated impact assessment that will accompany the draft legislation will provide further details that will quantify the likely impact on health and social care services.

Furthermore, 50 respondents noted that the policy could have impacts on small mills including traditional mills, windmills and water mills and 21 respondents were concerned that the whole population would be affected by loss of consumer choice and any costs of the policy could be passed onto the consumer.

Common benefits of the policy raised by respondents include the general folic acid health benefits to the whole population (33 respondents).

UK Government and devolved administrations' response

The impact assessment that accompanied the consultation and the modelling produced by Food Standards Scotland (FSS) indicates that the policy will reduce the number of NTDs across the UK and will therefore reduce the number of lifelong health implications for those with associated conditions. A reduction in NTD cases and affected pregnancies will result in reduced NHS treatment costs for these conditions at a population level, as well as benefitting the individuals and their families. We are grateful to participants for emphasising this.

We will continue to engage with industry, including small mills such as traditional mills, windmills and water mills and further details on how we aim to limit negative effects on these businesses can be found in the UK Government and devolved administration's response to question 12 below.

In relation to loss of consumer choice (119 respondents were concerned that the whole population would be affected by loss of consumer choice which is addressed in question 4 above), the fortification of non-wholemeal wheat flour means that consumers will still be able to choose unfortified types of flour. Similarly, the impact assessment will continue to be reviewed in light of the consultation responses and will detail the expected costs associated with fortification with folic acid.

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

Summary of responses

When asked about practical issues associated with the policy, there were 597 responses with 504 free-text responses.

One hundred and seventeen respondents stated that the policy would have a larger financial impact on smaller and traditional mills and would be a greater burden on space for them. Respondents noted that these mills make flour with traditional grind stones. They suggest that there are practical limitations of their properties (many of which are listed buildings) and that there could be a problem implementing the fortification in the confined environment that some of these businesses work in.

In addition 105 respondents stated that folic acid fortification would result in additional manufacturing and production time as well as further costs, 59 respondents referred to the need to update their labelling and packaging in order to reflect the addition of folic acid and 58 respondents referred to the practical implications of quality checks such as the ability to adequately mix the additional fortificant evenly into the flour.

UK Government and devolved administrations' response

We want to ensure that any negative impacts of the policy are minimised and this includes taking into account practical considerations for industry and businesses.

The current fortification requirements of the BFR and BFR NI apply to all flour millers. Following their Consultation on amending certain domestic food legislation in England, Defra have laid legislation (<https://www.legislation.gov.uk/ukxi/2021/616/made>) that removes European Economic Area (EEA)/EU exemptions to the rules and also allows millers in England to produce unfortified flour for products that will be exported to remain competitive. Devolved administrations are expected to take decisions on their respective legislation.

We intend to consider the policy alongside other wider changes that Defra and the devolved administrations are considering under their review of the BFR in order to support implementation. This will include proposing a suitable lead-time for when the policy will take effect so that industry have an appropriate amount of time to prepare and comply.

Currently the BFR and BFR NI require the fortification of non-wholemeal wheat flour with 4 nutrients. Therefore, the proposal would not be requiring businesses to fortify other types of flour or other non-wheat products which do not currently have to be fortified.

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

Summary of responses

Considerations on further trade implications for industry were received from 435 participants including 150 free-text responses.

38 respondents held the view that the policy will negatively affect small and traditional mills in particular as they fear that they some have to cease production due to additional expenses and space requirements, these concerns are noted in the UK Governments and devolved administrations consultation response to question 12 above and question 14 below.

28 respondents were concerned about the implications of the fortification policy on importing and exporting flour. These respondents questioned whether there would be issues with the importation of non-wholemeal wheat flour which is not fortified with folic acid. Additionally, the respondents queried whether certain countries that the UK exports flour to will not accept flour that is fortified with folic acid. The impact assessment (<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>) accompanying the consultation notes that current data suggest only around 5% of flour milled in the UK is exported with the remaining 95% used in the UK, some of which may be used in products that are then exported.

UK Government and devolved administrations' response

Recent changes to the BFR in England mean that an exemption for meeting the requirements of the BFR which was afforded to EEA countries has now been removed. Therefore, the EU can no longer export unfortified flour to the UK unless it is then exported or used in products that will be exported.

A transitional period up until end September 2022 applies but means from that date on all imported flour must meet the rules in England. To assist exporting business, an additional change was made at the same time to enable flour millers to produce unfortified flour providing it is exported or used solely in composite products destined for export. We expect this to extend to folic acid and as a consequence any further effects on exporters will be minimised. We will work in conjunction with Defra and the devolved administrations to consider the export implications and further information will be provided as part of that review process. In particular, Northern Ireland will have to consider the implications of the Northern Ireland Protocol.

Question 14. Are there are any effects on small businesses and medium businesses that need to be considered?

Summary of responses

Comments on effects of the requirement for additional fortification of flour on small and medium businesses were provided by 515 participants including 395 free-text responses.

Additional costs associated with the policy such as a potential need to purchase new equipment, training expenses and/or the employment of additional staff was raised by 220 responses. Similarly, 52 respondents noted that additional processing may be required such as the sifting and addition of a separate nutrient and 40 respondents commented on the limited space in a number of sites which would prevent the introduction of new equipment.

65 respondents viewed folic acid fortification as potentially resulting in reduced sales due to its presence in the flour.

UK Government and devolved administrations' response

After considering feedback to the consultation, the UK Government and devolved administrations, reached consensus to take forward fortification of non-wholemeal wheat flour.

As mentioned in the response to question 1, non-wholemeal wheat flour is already subject to fortification. Therefore the mandatory addition of a further fortificant exclusively to this form of flour will minimise the impact on industry as it will not widen the existing type of flour subject to fortification.

Next steps

The UK Government and devolved administrations are grateful for the number of responses provided to the consultation and have considered the responses carefully.

Following the consultation, the UK Government and devolved administrations have decided to proceed with the intention to make fortification of non-wholemeal wheat flour with folic acid (the baseline policy option) mandatory. The CMOs in England, Scotland, Wales and Northern Ireland all consider the proposed option as a suitable choice.

All policy options presented in the consultation had some (albeit variable) levels of support and no single policy option commanded majority support across all the respondents. The baseline policy option was considered able to deliver the policy aim of reducing the number of NTDs per year in the UK whilst resulting in the most minimal burden on industry.

The UK Government and devolved administrations will work together to take forward this policy and their intention to legislate on this basis. The UK Government and devolved administrations will work with stakeholders, including businesses across the bread and flour industry, to ensure that the policy and the timings of any resulting amendments to legislation can be delivered in a way to minimise the burdens and impact on industry.

Defra has responsibility for the BFR as it applies in England and will take forward any legislative changes needed on the BFR including folic acid. In Wales and Northern Ireland, the FSA has responsibility for the BFR and the BFR.NI respectively and will take forward any legislative changes as needed. In Scotland, FSS has responsibility for the BFR as it applies in Scotland.

Our aim is for the legislation to be laid in 2022 which will include a transitional period before the date of application. The UK Government and devolved administrations will announce further details on the timelines, at a later date.

As part of government standard practice, we will review and evaluate the policy 5 years following implementation.

Annex A:

Folate and folic acid supplementation education policies and programmes across the devolved administrations

School education is a devolved matter in the UK and each of the 4 UK countries have their own education system. A summary of folate and folic acid supplementation education policies and programmes across the devolved administrations are set out below.

The curriculum of health care professionals is governed by 3 regulatory bodies which all operate on a UK wide basis.

Folate and folic acid supplementation in the curriculum of health care professionals across the UK

The standard of training for health care professionals is the responsibility of the health care independent statutory regulatory bodies such as the General Medical Council (GMC), General Dental Council, the Nursing and Midwifery Council (NMC) and Health and Care Professions Council (HCPC) who set the outcome standards expected at undergraduate level and approve courses and Higher Education Institutions to write and teach the curricula content that enables their students to meet the regulators outcome standards. Whilst not all curricula may necessarily highlight a specific condition, they all nevertheless emphasise the skills and approaches a Health Care Practitioner must develop in order to ensure accurate and timely diagnoses and treatment plans for their patients, including for antenatal care.

The curricula for postgraduate specialty training are set by individual royal colleges and faculties, and the GMC approves curricula and assessments for each training programme. In the curricula for trainee GPs, which is set and maintained by the Royal College of General Practitioners, there is a topic guide for pregnancy (<https://www.rcgp.org.uk/training-exams/training/gp-curriculum-overview/life-stages-topic-guides.aspx>). This specifies that GPs must understand and be able to apply the 'principles and guidelines for routine antenatal care including recommended supplements, dietary and lifestyle advice, [and] immunisation in pregnancy'.

Antenatal care is also part of the curriculum for obstetrics and gynaecology (<https://www.rcog.org.uk/en/patients/patient-leaflets/healthy-eating-and-vitamin-supplements-in-pregnancy/>), and the Royal College of Obstetricians and Gynaecologists has a number of resources on the taking of folic acid in pregnancy.

Scotland

Education prior to conception and during pregnancy

In Scotland, the improving maternal and infant nutrition: a framework for action (2011) (<https://www.rcog.org.uk/en/patients/patient-leaflets/healthy-eating-and-vitamin-supplements-in-pregnancy/>) set out a recommendation for all women of childbearing age to be provided with relevant information on how to have a healthy pregnancy, including vitamin supplementation in the form of folic acid. As part of Scotland's 2018 Diet and Healthy Weight Delivery Plan (<https://www.gov.scot/publications/healthier-future-scotlands-diet-healthy-weight-delivery-plan/>), there was an action to consult on a preconception action plan to improve how services inform, engage and support women before they become pregnant to start at a healthy weight, and in good physical and nutritional health. This plan is currently in progress, with an intention to publish later in 2021 and includes the importance of folic acid intake pre and during pregnancy.

School Curriculum

Every child and young person in Scotland is entitled to a broad general education, which includes learning about food and health. This is a key part of Curriculum for Excellence and helps to ensure children and young people are provided with the skills, knowledge and experience they need to take responsibility for their own health and wellbeing as they grow and develop.

For example, through the experiences and outcomes approach, folic acid, along with other vitamins and minerals, would be included as part of lesson plans designed to support children and young people to explore the dietary needs – and how to meet those needs – of different people at various stage of life. This could also include the importance of folic acid during pregnancy, for example.

Wales

Education prior to conception and during pregnancy

In pregnancy, data on folic acid supplementation uptake is collated through the All Wales hand-held record and further information is provided through the 'Bump, Baby and Beyond' publication given to all women at their booking appointment.

School Curriculum

At the heart of the Curriculum for Wales framework there are 4 purposes which are central to every decision made about the new curriculum. One of the 4 purposes is to support children and young people to become 'healthy confident individuals'.

Central to the new curriculum will be a Health and Well-being Area of Learning and Experience (Area) that aims to ensure that learning and support around issues such as physical, mental and emotional health are provided to all young people in Wales. This Area can help learners to understand the factors that affect physical health and well-being. Schools will have the flexibility to select the content which best meets the needs of their learners in their specific context. Learners will have a range of needs and backgrounds, and the curriculum framework offers schools and practitioners the ability to choose the specific experiences, knowledge and skills, as well as the specific topics, activities and contexts that will best support learning. This includes health-promoting behaviours such as physical activity, including but not limited to sport; nutrition, the importance of a balanced diet; and personal care.

Relationships and Sexuality Education (RSE) also forms part of the Curriculum for Wales framework for this Area. The draft guidance has been published for consultation and it advises that the curriculum considers topics such as the 'knowledge and understanding of the causes, symptoms and impact of conditions and illnesses connected to sexual and reproductive health including fertility'. This means that schools will be able to teach issues such as the importance of folic acid during pregnancy within their curriculum, should they wish to do so.

England

Education prior to conception and during pregnancy

NHS England and NHS Improvement's Maternity Transformation Programme (<https://www.england.nhs.uk/mat-transformation/>) seeks to achieve the vision of the Better Births report (2016) (<https://www.england.nhs.uk/publication/better-births-improving-outcomes-of-maternity-services-in-england-a-five-year-forward-view-for-maternity-care/>) which is to improve maternity services across England. The Maternity Transformation programme includes work that aims to improve prevention and preconception health and as noted in the Public Health England (PHE) report making the case for preconception care (<https://www.gov.uk/government/publications/preconception-care-making-the-case>), this includes folate intake for women who could, or are planning to become pregnant.

The Maternity Transformation Programme strongly supports proposals to fortify flour and other cereal grain with folic acid whilst recognising that there is also an argument for more health education about the need to take folic acid when planning pregnancy as fortification alone will not be enough to provide the protective effect.

The 'Health and Wellbeing Fund: Starting Well' is a joint initiative run by [DHSC](#), [PHE](#) and NHS England and NHS Improvement ([NHSEI](#)) to support the reduction of health inequalities among new mothers and babies. It includes educational projects that aim to provide pre-conception advice. These projects include those run by the Bevan Healthcare CIC in Bradford.

School curriculum

The Department for Education ([DfE](#)) stated that whilst the importance of folate intake and folic acid supplementation during pregnancy is not specifically covered, the curriculum is intended to be a high-level overview and schools are able to teach beyond this. Therefore, content on folate intake and folic acid supplementation may be included in lessons or the specifications set by exam boards. Across the curriculum pupils are taught more generally about the importance of vitamins and minerals and the risk of health problems from a poor diet.

Since September 2020, Health Education became a statutory requirement in all state-funded schools. Within this subject, teachers may cover the importance of healthy eating during pregnancy and the specific need for increased folate intake and folic acid supplementation prior to conception and during the first 12 weeks of pregnancy.

Northern Ireland

Education prior to conception and during pregnancy

The Public Health Agency ([PHA](#)) is the major regional organisation in Northern Ireland for health protection and health and social wellbeing improvement. Their role also commits them to addressing the causes and associated inequalities of preventable ill-health and lack of wellbeing. To help raise awareness, a folic acid leaflet is available on the [PHA](#) website (<https://www.publichealth.hscni.net/publications/folic-acid-%E2%80%93-one-life%E2%80%99s-essentials-0>).

In 2017, Safefood (<https://www.safefood.net/research-reports/folate-status-pregnant-women>) (an Ireland body) conducted research and launched a folic acid social media campaign on the back of this research. The social media campaign aired both in Ireland and Northern Ireland.

NIDirect is the Northern Ireland Executive's one stop shop for information on government services and information. It includes information on health during pregnancy, including the need to take folic acid and other dietary information.

School curriculum

The flexibility in the curriculum in Northern Ireland means teachers can make decisions about the context in which this topic is explored.

The importance of healthy eating

The importance of healthy eating was addressed by several respondents through their free text responses, specifically the importance of increasing folate intake through diet. Some of these respondents were also of the view that natural folate is more beneficial than folic acid.

UK Government and devolved administrations' response

The importance of the population consuming a healthy and balanced diet is strongly supported by all governments of the UK.

The UK Government and devolved administrations' advice on a healthy, balanced diet is set out in the UK's national food guide, the Eatwell Guide (<https://www.gov.uk/government/publications/the-eatwell-guide>). The Eatwell Guide shows the proportions in which different types of foods are needed to have a well-balanced and healthy diet and is aimed at most people from the age of 5 years.

The Eatwell Guide includes advice to eat at least 5 portions of a variety of fruit and vegetables every day.

The RNI for adults is 200 micrograms per day. The UK Government and devolved administrations' advice is that women who could become pregnant or are planning to become pregnant, take a 400 micrograms folic acid supplement every day before conception and until the 12th week of pregnancy. This advice will remain once the policy to fortify flour with folic acid has been implemented.

Although folate is found naturally in foods such as green leafy vegetables, it is difficult to consume the amount recommended for preventing NTDs from food alone. Therefore, in the UK women who can become pregnant, or are planning to become pregnant, are advised to increase their consumption of folate containing foods as well as taking a folic acid supplement.

The fortification of non-wholemeal wheat flour with folic acid will improve blood folate concentrations in women who could become pregnant and therefore help in reducing the risk of NTDs.

Annex B: population groups and individuals affected

A number of participants noted there was a number of other population groups or individuals which may be affected by this policy, the UK Governments and devolved administrations' response to these concerns are addressed below.

Allergies

Some respondents raised concerns that individuals and the population would be impacted due to the possibility of folic acid resulting in the development of allergies.

Six respondents noted the need to provide appropriate product labelling for flour which would be fortified.

UK Government and devolved administrations' response

Some respondents raised concerns about folic acid and allergies. In accordance with the mandatory food information relating to substances causing allergies or intolerances required under retained Regulation (EU) No 1169/2011 (<https://www.legislation.gov.uk/eur/2011/1169/contents>) on the provision of food information to consumers, folic acid is not one of the 14 major allergens which must be declared and emphasised (that is, highlighted in bold, italics or underlined) when they are used in a food or an ingredient in food.

The Food Standards Agency (FSA) have evaluated the evidence and note that robust evidence on the influence of folic acid in maternal and infant diets on the development of allergies in general is inconclusive; one publication (<https://pubmed.ncbi.nlm.nih.gov/31252026/>) identified has shown an association of higher unmetabolised folic acid levels at birth was associated with the development of food allergy but this showed no association of levels in early childhood.

Conversely, another publication (<https://openres.ersjournals.com/content/6/1/00250-2019>) has shown maternal folic acid supplementation was not associated with risk for allergy symptoms or asthma. Any individuals who wish to avoid flour with added folic acid will be able to choose unfortified flour such as wholemeal and other non-wheat products and those that are 'gluten free'.

Additionally, in accordance with the mandatory food information requirements set out in retained Regulation (EU) No 1169/2011 (<https://www.legislation.gov.uk/eur/2011/1169/contents>) the presence of folic acid will be shown in the ingredients listing of non-wholemeal wheat flour alongside the other mandatory nutrients.

Those from low income backgrounds

It was noted by a number of participants that fortification of flour with folic acid could be beneficial to women from low income backgrounds who may be at an increased risk of NTD-affected pregnancies as they are less likely to take folic acid supplements in the time period prior to conception and up until the 12th week of pregnancy (the government advice is to take a 400 micrograms folic acid supplement every day during this period). The accompanying impact assessment to the consultation indicates that 10% of women in the most deprived decile report taking folic acid supplements in preparation for pregnancy in comparison to 26% of women who take folic acid supplements in the least deprived decile.

Additionally, intakes of folate significantly increase as income increases (<https://www.gov.uk/government/statistics/ndns-time-trend-and-income-analyses-for-years-1-to-9>). This could be due to limited access to folic acid supplements amongst those on lower incomes or because those on lower incomes are more likely to have diets that do not contain foods where folate is naturally found.

Some respondents specifically mentioned the Healthy Start Scheme (<https://www.healthystart.nhs.uk/getting-vitamins/>) where some pregnant women and breastfeeding women in England, Wales and Northern Ireland are eligible for vouchers for free Healthy Start vitamins including folic acid. The Healthy Start Scheme provides additional nutritional support to pregnant women and young children on low incomes. Whilst this scheme was mentioned by respondents, individuals are only eligible for the scheme once they are at least 10 weeks pregnant, and the purpose of vitamin supplements provided under the Healthy Start scheme is not to provide folic acid from pre-conception.

In Scotland, all pregnant women are provided with the Healthy Start Vitamins throughout their pregnancy irrespective of income. Additionally, in Scotland the Healthy Start Vouchers have been replaced by Best Start Foods and clients can apply for this support as soon as they realise that they are pregnant.

A small number of respondents also noted that introduction of the policy could have negative effects on those from poor and vulnerable backgrounds if it results in an increase in the price of goods if the costs of fortification are passed onto the consumers.

UK Government and devolved administrations' response

It is extremely important to find ways of increasing folate intakes and blood folate concentration amongst women who could or are planning to become pregnant, including those from more deprived socio-economic groups as NTDs are disproportionately more likely to occur amongst

deprived families. We hope that this fortification policy will have an additional benefit of raising awareness of the importance of folate in helping to prevent NTD-affected pregnancies.

Non-wholemeal wheat flour is commonly consumed by most women who could become pregnant, regardless of their income.

From an industry perspective, folic acid is a relatively inexpensive ingredient at approximately £60 per kilogram in bulk, which equates to less than £0.01 per 250 micrograms. The addition of folic acid to flour is an ongoing cost associated with the policy. However, many of the costs to industry associated with mandatory fortification are predominantly costs associated with changing the labelling and these are considered to be one-off costs.

We anticipate industry will likely use existing machinery to fortify non-wholemeal wheat flour, with folic acid which they use when fortifying with the other mandatory nutrients. Therefore, we do not expect the fortification of flour with folic acid to have a significant price burden on consumers.

Folic acid consumption and concern about potential increased disease risks

Increased risk of cancer

14 participants raised concerns of individuals/the population being at an increased cancer risk due to increased folic acid consumption. These concerns centred around a potential link between high doses of folic acid and an increased risk of lung, prostate, breast and/or colon cancer.

A small number of respondents were concerned about reports of an increase in cancer cases after the implementation of folic acid fortification in the US in 1998. These concerns are based on a paper published by Mason and others. (2007) (<https://pubmed.ncbi.nlm.nih.gov/17626997/>) reporting a temporal association between folic acid fortification and an increase in colorectal cancer incidence in the USA and Canada. Conversely, some respondents also noted the success of folic acid fortification policies in other countries where the prevalence of NTD incidences or NTD-affected pregnancies has decreased after fortification. As noted in the impact assessment accompanying the consultation, countries that have mandated folic acid fortification have seen falls in rates of NTDs of between 16% and 58%.

The UK Government and devolved administrations have previously considered these concerns on increased cancer risk when preparing the consultation proposal which references the 2017 SACN report (Update on folic acid) (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) (see section on 'Potential adverse effects of mandatory folic acid fortification' in the consultation proposal). This report considered the potential adverse effects of high folic acid intakes on cancer risk specifically in relation prostate, breast, colorectal and overall cancer risk (an average of the different types of cancers, which is dependent on the population and the prevalence of many cancer risk factors). The report concluded that the findings from the different types of studies were inconsistent but overall, the evidence was inconclusive in relation to prostate and colorectal cancer risk and did not suggest an adverse association with breast cancer or overall cancer risk. The risk of lung cancer was not considered in the 2017 report.

Additionally, the consultation proposal considered the concerns raised specifically regarding colorectal cancer. Colorectal tumours usually develop from adenomas over a period of 10 or more years (<https://gutscharity.org.uk/advice-and-information/conditions/bowel-cancer/>). The consultation proposal notes that in SACN's 2009 report to the CMO (Folic Acid and Colorectal cancer risk: Review of Recommendation for mandatory folic acid fortification) (<https://www.gov.uk/government/publications/sacn-report-to-cmo-on-folic-acid-and-colorectal-cancer-risk>), the committee specifically considered the paper

published by Mason and others. (2007). SACN considered the study in detail and concluded that there was no clear explanation for the observed increase in colorectal cancer incidence observed in the USA and Canada at around the same time as the introduction of folic acid fortification.

UK Government and devolved administrations' response

The success of folic acid fortification in reducing prevalence of NTDs in countries that have implemented mandatory folic acid fortification policies is a very positive step in helping to reduce NTDs and we are grateful to respondents for raising this.

We acknowledge that some respondents raised concerns that increased folic acid consumption could result in an increased risk of cognitive decline. These concerns were considered in the consultation proposal. Overall, the evidence in relation to cancer risk and cognitive impairment is inconclusive.

SACN considered the study by Mason and others (2007) in detail and concluded that there was no clear explanation for the observed increase in colorectal cancer incidence observed in the USA and Canada at around the same time as the introduction of folic acid fortification.

As part of government standard practice, we will review and evaluate the policy 5 years following implementation.

Increased risk of Alzheimer's disease

Some participants also raised concerns as to whether individuals/the population were negatively impacted due to an association between folic acid fortification and risk of developing Alzheimer's disease specifically cognitive decline. These concerns were examined in the consultation proposal which notes that SACN's position statement SACN Statement on Diet, Cognitive Impairment and Dementias (2018) (<https://www.gov.uk/government/publications/sacn-statement-on-diet-cognitive-impairment-and-dementia>) considers the potential risks of sustained high doses of folic acid and cognitive decline in older individuals.

SACN (2018), stated that there was insufficient evidence to draw any conclusions on the association between individual nutrients (including folic acid) and risk of cognitive decline or cognitive impairment.

SACN considered evidence on the benefits and risks of folic acid in 2006 and 2017 (Folate and Disease Prevention (<https://www.gov.uk/government/publications/sacn-folate-and-disease-prevention-report>) in 2006 and Update on Folic acid (<https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>) in 2017)). In 2006, SACN concluded that there were "indications of possible benefit, but overall, the evidence for either beneficial or deleterious effects of folic acid on cognitive function in older people" was "inconclusive". In 2017, SACN concluded that intervention studies showed no significant effect on cognitive decline in older individuals.

UK Government and devolved administrations' response

A small number of respondents raised concerns that increased folic acid consumption could result in an increased risk of cognitive decline. These concerns were considered in the consultation proposal. Overall, the evidence in relation to cancer risk and cognitive impairment is inconclusive.

There is strong evidence, however, that folic acid reduces NTD risk. Therefore, fortification of flour with folic acid would be beneficial in helping to reduce the risk of NTD-affected pregnancies in the UK.

As part of government standard practice, we will review and evaluate the policy 5 years following implementation.

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