

Title: Fortification of Flour with Folic Acid IA No: 13015 RPC Reference No: tbc Lead department or agency: Department of Health & Social Care Other departments or agencies: n/a	Impact Assessment (IA)			
	Date: tbc			
	Stage: Consultation			
	Source of intervention: Domestic			
	Type of measure: Other			
Contact for enquiries: folicacidfortification@dhsc.gov.uk				

Summary: Intervention and Options**RPC Opinion:** Awaiting scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value (£m)	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	One-In, Three-Out	Business Impact Target Status
Tbc	Tbc	Tbc	Tbc	Tbc

What is the problem under consideration? Why is government intervention necessary?

Around 1,000 pregnancies every year in the UK are affected by Neural Tube Defects (NTDs) in the womb, resulting in increased mortality and morbidity among unborn and newly born children. NTD risk is associated with low levels of blood folate among women who could become pregnant. Folate intake and blood count levels have been falling, a trend which could cause NTD risk to rise.

Attempts to raise folate levels through education and voluntary fortification have had limited effect. Government intervention is required to make further progress in reducing the number of NTD-affected pregnancies and the resultant impacts on families and the NHS. Fortification would have a distributional impact in reducing health inequalities, and help the wider population meet recommended folate intake levels.

What are the policy objectives and the intended effects?

- Reduce the incidence of NTDs, by increasing dietary intake of folic acid, and hence blood folate levels, in women who could become pregnant.
- Ensure there is no increase in the number of people exceeding tolerable upper levels for folic acid intake (this is likely to require some restriction on voluntary fortification or supplementation).
- Minimise the administrative burden and any competitive impact on business.
- Ensure any regulations or rules are proportionate, effective and properly enforced.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- Do nothing.
- Mandate the fortification with folic acid of UK-milled non-wholemeal wheat flour used for breadmaking.
- Mandate the fortification with folic acid of all UK-milled non-wholemeal wheat flour.

The two latter options include a range of further parameters, such as the amount of fortification, handling of imports/exports, handling of products containing flour etc. The legal definition of which specific flours are included or excluded under each option will also need to be confirmed in detail. These three options are designed to provide a range of views from not fortifying at all, through fortifying to a limited degree, to fortifying more widely. Additional policy options are reviewed briefly in the main text. They are not currently being pursued, but may be considered further, alongside the above, in the light of consultation responses.

Will the policy be reviewed? Yes. **If applicable, set review date:** tbc.

Does implementation go beyond minimum EU requirements?	N/A			
Are any of these organisations in scope?	Micro Tbc	Small tbc	Medium tbc	Large Tbc
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)	Traded: tbc		Non-traded: tbc	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: _____

Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2019	Time Period Years tbc	Net Benefit (Present Value (PV)) (£m)		
			Low: nil	High: nil	Best Estimate: nil

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
	Low			
High				
Best Estimate		nil	As now	As now

Description and scale of key monetised costs by 'main affected groups'

Option 1 represents the baseline "business as usual" scenario. It assumes that the current level of NTDs in foetuses (at least 1,000 per year), and all associated costs, will continue. Those costs include a health cost to children, treatment cost to the NHS, impact on families and a reduction in economic productivity. The missed opportunity to address these concerns means that these costs are highest under this scenario.

Most women who could become pregnant have below the recommended folate intake and blood folate levels, a trend which has worsened over time. If this trend continues, the risk of NTDs and the costs associated with option 1 will rise. Blood folate levels have also decreased in the general population over time in other age and gender groups. These increased risks will create costs for the NHS that could otherwise be reduced if other options were chosen. Actual case numbers are low, but the cost and quality of life impacts are significant as these are life-long conditions.

To facilitate comparison of options, the NPV of option 1 is conventionally presented as zero (no change) with other options assessed relative to that baseline. This makes it easier to see the net effect of intervention, compared to business as usual.

Other key non-monetised costs by 'main affected groups'

See above.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
	Low	nil		
High	nil		nil	nil
Best Estimate	nil		nil	nil

Description and scale of key monetised benefits by 'main affected groups'

By definition, option 1 represents no change from the status quo. Any costs or risks associated with other options will not be incurred.

Other key non-monetised benefits by 'main affected groups'

None.

Key assumptions/sensitivities/risks

None specific to this option.

Discount rate

3.5%

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: n/a
Costs: nil	Benefits: nil	Net: nil	

Summary: Analysis & Evidence

Policy Option 2

Description: Mandate the fortification of UK-milled non-wholemeal wheat flour used for breadmaking with folic acid

FULL ECONOMIC ASSESSMENT

Price Base Year: 2019	PV Base Year: 2019	Time Period Years: tbc	Net Benefit (Present Value (PV)) (£m)		
			Low: tbc	High: tbc	Best Estimate: tbc

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	-	tbc	-	tbc
High	-		-	tbc
Best Estimate	-		-	tbc

Description and scale of key monetised costs by 'main affected groups' Costs are largely unmonetised at this stage. Option 2 involves limited fortification of flour, which creates lower costs & benefits compared with option 3. Fortifying non-wholemeal flour used for breadmaking only may offer lower benefits because a significant proportion of women of child-bearing age consume only small quantities of bread.

Other key non-monetised costs by 'main affected groups'

In terms of size, the main costs are likely to fall between those of options 1 and 3. They will include:

- Costs to the supply chain (likely millers or bakers) in identifying which flour needs to be fortified (especially if different from existing micronutrient fortification), sourcing and adding folic acid to flour.
- Resultant labelling and quality assurance costs to industry, including auditing by the authorities.
- Possible changes being required to supply chains, particularly to import/export arrangements of both flour and flour-based products (although the policy intention is to minimise this).
- A possible impact on manufacturers of voluntarily-fortified products and/or supplements if restrictions are required to mitigate any risk of excess folic acid intake (or a potential health cost otherwise).
- Potential inconvenience to consumers who cannot or do not wish to consume added folic acid. One advantage of excluding wholemeal flour from fortification is that it provides an additional option for such people (indeed wholemeal flour has a higher level of natural folate than refined flour).

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	-	tbc	-	tbc
High	-		-	tbc
Best Estimate	-		-	tbc

Description and scale of key monetised benefits by 'main affected groups'

The benefits are largely unmonetised at this stage. The main benefit is expected to be a reduction in NTDs, possibly of the order of 5%-10%, equivalent to 50-100 NTDs prevented per year, or more if falling folate levels would otherwise have led to an increase. Preventing an NTD carries a lifetime benefit of up to £3m in health terms, depending on the severity of the condition.

Other key non-monetised benefits by 'main affected groups'

Reducing NTDs carries associated benefits in terms of reduced NHS treatment costs, improved wellbeing and better economic prospects for people who would otherwise have had NTDs and their families. Demand for folic acid by the industry is likely to rise, with a potential benefit to folic acid producers (although these may be overseas). There may be a reduction in inequalities, because the risk of NTDs is higher in less well-off families. The wider population meeting recommended intake levels may be beneficial in terms of anaemia.

Key assumptions/sensitivities/risks

Discount rate % 3.5

- Fortification can be funded within the industry with no significant pass through to consumers.
- Consumers will continue to eat what they do now and will not change in response to fortification.
- Any risk of an increase in the number of people who exceed the recommended tolerable upper level could be mitigated through restrictions on supplements.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: tbc
Costs: tbc	Benefits: tbc	Net: tbc	

Summary: Analysis & Evidence

Policy Option 3

Description: Mandate the fortification of all non-wholemeal wheat flour with folic acid

FULL ECONOMIC ASSESSMENT

Price Base Year: 2019	PV Base Year: 2019	Time Period Years: tbc	Net Benefit (Present Value (PV)) (£m)		
			Low: tbc	High: tbc	Best Estimate: tbc

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	-	tbc	-	tbc
High	-		-	tbc
Best Estimate	-		-	tbc

Description and scale of key monetised costs by 'main affected groups'

Costs are largely unmonetised at this stage. This option involves wider fortification of flour, which creates higher costs and benefits compared with option 2.

Other key non-monetised costs by 'main affected groups'

The main costs will be similar to those of option 2, but at generally higher levels:

- Costs to the supply chain (likely millers or bakers) in identifying which flour needs to be fortified (especially if different from existing micronutrient fortification), sourcing and adding folic acid to flour.
- Resultant labelling and quality assurance costs, including auditing by the authorities.
- Possible changes being required to supply chains, particularly to import/export arrangements of flour and flour-based products (although the policy intention is to minimise this).
- A possible impact on manufacturers of voluntarily-fortified products and/or supplements, if restrictions are required to mitigate any risk of excess folic acid intake (or a potential health cost otherwise).
- Potential inconvenience to any consumers who cannot or do not wish to consume added folic acid. As with option 2, one advantage of excluding wholemeal flour from fortification is that it provides an additional option for such people (indeed wholemeal flour has a higher level of natural folate).

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	-	tbc	-	tbc
High	-		-	tbc
Best Estimate	-		-	tbc

Description and scale of key monetised benefits by 'main affected groups'

The benefits are largely unmonetised at this stage. The main benefit is expected to be a significant reduction in NTDs, possibly of the order of 15%-20%, equivalent to 150-200 NTDs per year, or more if falling folate levels would otherwise have led to an increase. Preventing an NTD carries a lifetime benefit of up to £3m in health terms, depending on the severity of the condition.

Other key non-monetised benefits by 'main affected groups'

The reduction of NTDs carries associated benefits in terms of reduced NHS treatment costs, improved family wellbeing and better economic prospects for people who would otherwise have had NTDs. Demand for folic acid by the industry is likely to rise, with a potential benefit to folic acid producers (although these may be overseas). There may be a reduction in inequalities, because the risk of NTDs is higher in less well-off families. The wider population meeting recommended intake levels may be beneficial in terms of anaemia.

Key assumptions/sensitivities/risks

Discount rate

3.5

- Fortification can be funded within the industry.
- Consumers will continue to eat what they do now and will not change in response to fortification.
- Any risk of an increase in the number of people exceeding the recommended tolerable upper level, could be mitigated through restrictions on supplements.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: tbc
Costs: tbc	Benefits: tbc	Net: tbc	

Overview

1. The evidence base is structured as follows:
 - it sets out the problem at a high level;
 - it explains the issues the Government has identified and wishes to address;
 - it identifies options for change, setting out the associated rationale and evidence.
2. This document is a “consultation-stage” impact assessment, which means that the options identified and the preferred way forward are subject to change in the light of public consultation responses and further work. Costs and benefits may not be fully specified or quantified at this stage.
3. Except where stated, all discussion refers to the whole of the UK.
4. The main sources of evidence used are:
 - *Update on Folic Acid*. Scientific Advisory Committee on Nutrition (SACN). July 2017.¹ Latest advice and recommendations. Earlier SACN reports from 2006 and 2009 are also relevant and referenced in the 2017 report.
 - *Folic Acid - Statement on the Tolerable Upper Level*. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Feb-19.²
 - *Stochastic Modelling to estimate the potential impact of fortification of flour with folic acid in the UK*. Food Standards Scotland (FSS). July 2017.³
 - *National Diet and Nutrition Survey (NDNS)*. Public Health England (PHE). 2003-2019.⁴ Monitors the nation’s dietary habits. DHSC has completed limited analysis of recent NDNS data from 2015 and 2016, to support the FSS modelling (which used data up to 2014) and confirm it remains valid.
 - *NCARDRS congenital anomaly statistics*. PHE. 2016 (published Oct-18). Estimated prevalence of birth defects, incl. terminations.⁵ EUROCAT data is similar and is also used.⁶ Further work is ongoing to assess additional data from Wales.
 - *DHSC Abortion Statistics*. Number of abortions where NTDs are cited as a factor. 2017 (published Nov-18). England & Wales (plus non-residents).⁷

¹ <https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>

² <https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2019/cot-folic-acid-statement>

³ <https://www.foodstandards.gov.scot/publications-and-research/publications/stochastic-modelling-to-estimate-the-potential-impact-of-fortification-of-f>

⁴ <https://www.gov.uk/government/collections/national-diet-and-nutrition-survey>
<https://www.gov.uk/government/statistics/ndns-time-trend-and-income-analyses-for-years-1-to-9>

⁵ <https://www.gov.uk/government/publications/ncardrs-congenital-anomaly-annual-data>

⁶ <http://www.eurocat-network.eu/>

⁷ <https://www.gov.uk/government/collections/abortion-statistics-for-england-and-wales>

5. This impact assessment should be read alongside the consultation paper that it accompanies.

What is the problem under consideration?

6. Neural tube defects (NTDs) represent a group of congenital defects caused by incomplete closure of the neural tube (normally within 28 days of conception). The most common forms are:
 - **Anencephaly** – where a significant part of the brain or skull fails to develop.
 - **Encephalocele** – where part of the brain or associated structures forms outside the skull.
 - **Spina bifida** – where the spinal cord fails to close properly.
7. Around 1,000 pregnancies a year in the UK are diagnosed with a serious NTD, and the estimated incidence rate is 12.64 cases per 10,000 births.⁸ These may result in termination, miscarriage, neonatal death, or long-term disability to the baby of varying severity. The true number of affected pregnancies is probably higher because some women will miscarry before diagnosis, and some minor cases of spina bifida may remain undetected. Furthermore, levels of folate intake have been falling over time, a trend which would increase NTD risk if it continued unabated.
8. Evidence suggests that many of these NTDs could be prevented if women who could become pregnant had higher folate levels in their blood. Some folate occurs naturally in food, but Governments across the UK recommend that women who could become pregnant should take a daily supplement (tablet) of 400 micrograms of folic acid before conception and up until the 12th week of pregnancy. They are also advised to increase their daily intake of folate by eating more folate-rich foods and foods fortified with folic acid. Women who have had a previous NTD-affected pregnancy, or have a history of spina bifida or similar in their family (or that of the baby's father) are advised to take 5 milligrams⁹ of folic acid every day until the 12th week of pregnancy. In addition, women who have diabetes and those taking anti-epileptic medicines are advised to consult their doctor, as they may need to take a higher dose of folic acid.¹⁰ Folic acid is the synthetic equivalent of folate, although

⁸ Defined as the total number of diagnosed cases seen in live births, stillbirths, late miscarriage or termination (where the NTD was a causal factor in the decision to terminate the pregnancy), divided by the total number of births (live + stillbirth). The numbers are explained more fully in the annex.

⁹ Conversion: 1 milligram (mg) equals 1,000 micrograms (µg)

¹⁰ Full NHS advice is provided at <https://www.nhs.uk/conditions/vitamins-and-minerals/vitamin-b/>. The standard recommended intake level for folate for adults is 200µg per day.

there are differences in how they are metabolised. Essentially, folic acid increases folate levels in the blood, which then reduces the risk of NTDs.

9. However, supplements may not be taken early enough, particularly if the pregnancy is 'unplanned'¹¹. This increases the risk of an NTD-affected pregnancy. The problem is more prevalent amongst younger (teenage) women, less well-off families and in deprived areas.¹² This risk would be mitigated if folic acid intake were increased. If more women took the recommended amount of folic acid supplements when planning a pregnancy then the need for mandatory fortification would be reduced, but that has not happened sufficiently despite past attempts to publicise and encourage the behaviour. Even with mandatory folic acid fortification, it remains important for women who may become pregnant to continue to take additional folic acid supplements, as this would still be necessary to prevent the maximum number of NTDs. Supplements will therefore continue to have an important role in NTD prevention.

10. The status quo already allows food manufacturers to voluntarily add folic acid to food products if they wish, and some (such as many breakfast cereal manufacturers) already do. However, many women who could become pregnant continue to have lower than recommended folate levels. The need for supplementation (as detailed in para 8) will remain, even if flour is fortified.

Current folate intake among women of child-bearing age (16-49)

(DHSC analysis using National Diet & Nutrition Survey 2015-2016)

Total folate intake (µg per day, including normal diet and supplements)	% of women
<100	7
100 – 199	44
200 – 299	29
300 – 399	10
400 or more	10

11. Aside from women who could become pregnant, the rest of the population should be able to obtain sufficient folate through a normal healthy balanced diet (although the NDNS survey suggests that many may not achieve that aim).¹³

¹¹ A figure of “around half” is often quoted. One indicative survey for Great Britain in 2013 is available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898922/> and indicates that around 55% of pregnancies to be ‘planned’, and 45% to be ‘unplanned’ or ‘ambivalent’.

¹² For example, 10% of women in the most deprived decile take folic acid supplements compared to 26% in the least deprived. <https://www.gov.uk/government/publications/health-matters-reproductive-health-and-pregnancy-planning/health-matters-reproductive-health-and-pregnancy-planning#contents>

¹³ The proportion with low levels of red blood cell folate varies with age and gender, but is typically around 10%. See page 22 of: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/699241/NDNS_results_years_7_and_8.pdf

12. While only a proportion of these women will become pregnant, a clear majority would be at a heightened risk of NTD if they had an unplanned pregnancy, or if they did not take supplements at the appropriate time. The NDNS survey estimates that 91% of women of childbearing age have a red blood cell folate concentration indicative of elevated risk of NTDs, a level which has risen over time.¹⁴
13. Given that this situation has arisen despite both public health advice to take folic acid supplements, and with some foods being voluntarily fortified with folic acid, mandatory fortification is required to achieve a significant improvement.

What are the policy objectives and intended effects?

14. The main objective is to reduce the incidence of NTDs, by increasing dietary intake of folate (in the form of folic acid), and hence blood folate levels, in women who could become pregnant.
15. There is no formal target for the level of reduction, but analysis suggests that the number of NTDs could fall significantly if the policy is successful. Other countries (including the US, Australia and Canada) have implemented mandatory folic acid fortification policies for many years and have seen falls of between 16% and 58%¹⁵ albeit they may have had different diets, populations or fortification rules to those that might be expected in the UK. Modelling by Food Standards Scotland (FSS) in 2017 considered a range of scenarios and suggested a reduction of between 8% and 25% could be achieved in the UK without increasing the numbers of people who currently consume more than the tolerable upper level of folic acid, and with limits placed on the amount of folic acid in breakfast cereals, reduced-fat spreads and supplements.¹¹
16. While any increase in folic acid intake will reduce risk, the FSS work drew on earlier Food Standards Agency advice that raising intake levels by between 60µg and 100µg a day would be required to see significant benefits. This is in the context of current mean intake of around 239µg per day for women aged 16-49.¹⁶
17. It is important that any new UK regulations are safe, proportionate, effective and enforced. This creates additional objectives in support of the main policy:

¹⁴

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/699241/NDNS_results_years_7_and_8.pdf

¹⁵ <https://www.foodstandards.gov.scot/publications-and-research/publications/stochastic-modelling-to-estimate-the-potential-impact-of-fortification-of-f> Page 46 provides detailed references.

¹⁶ Source NDNS survey.

- Ensure intake levels do not exceed recommended upper levels, and that any risks are mitigated.
- Ensure that any particular groups who cannot or do not wish to consume added folic acid are properly catered for.
- Minimise the administrative and any financial burden on business.
- Minimise the impact on current trading agreements (both domestically and in international trade).

18. The proposed options (and any others identified during consultation) will be judged using the above criteria. Many other countries have introduced fortification policies successfully, but circumstances in the UK may not be the same, and so will require bespoke consideration.

What options are being considered?

19. There are many flexible parameters including which specific products should be fortified, what level of fortification is appropriate, whether steps should be taken to minimise any risk associated with excessive intake, who should be responsible for the fortification and so on. There are many permutations to be considered.

20. To provide perspective, and keep the number of options manageable, this IA considers three main options. These are not intended to fully specify all the various parameters in detail, but instead to provide some perspective on the likely scale of costs and benefits for differing levels of fortification. They are:

- Do nothing.
- Mandate the fortification of UK-milled non-wholemeal wheat flour used for breadmaking with folic acid.
- Mandate the fortification of all UK-milled non-wholemeal wheat flour with folic acid.

21. The three options are designed to provide a range of views from not fortifying at all, through fortifying a limited number of products, to fortifying more widely. The consultation document invites views more broadly. One issue is the practical definition of “flour used for breadmaking” since, even if defined as such at the milling stage, the subsequent use of that flour may extend to non-bread products. As suggested by FSS modelling, a narrow definition of “bread flour”¹⁷ would not be sufficient even at higher levels of fortification to achieve a 60-100µg increase in daily folic acid intake levels.

¹⁷ Because the FSS and other modelling refers to “bread flour” this IA preserves the use of that terminology. It is taken to mean “flour used for breadmaking”, although as noted precise definitions will need to be confirmed.

Alternative Options Considered

22. In addition to the three main options considered in this Impact Assessment, several other options to achieve the policy objective of reducing NTDs have been considered. These have not been quantified in detail but are presented for context and completeness. The Government will consider evidence from the consultation and assess whether any of these options (or others) should be revisited and assessed further.

Option	Consideration
1 Awareness campaigns	Encouraging women who could become pregnant to take folic acid supplements would partially address the problem of NTD risk. It could be done either directly (e.g. advertising) or through professionals (such as GPs or social services staff). However, past attempts to do this have had limited success, particularly amongst younger women and some socio-economic groups, and hence in reducing inequalities. The significant number of unplanned pregnancies in the UK also means that any advice given once a woman knows she is pregnant may be received too late.
2 Fortify flour, but on a voluntary basis	This option would involve further encouragement for manufacturers to add folic acid to flour or flour-based products. It could be done through a voluntary code of practice or co-regulation with government input. It would not require legislative change. Such an option could lead to uneven fortification, and/or inconsistency between similar products, and the precise impacts would be difficult to assess in advance, or monitor later. There may be limited uptake by industry and therefore less impact on reducing NTDs (indeed some past attempts have been unsuccessful). Any risk of excess folic acid intake would need to be tracked and it is possible that the government might need to intervene later.
3 Fortify a wider range of flours (not just non-wholemeal wheat flour)	Wholemeal and non-gluten (potato, rice etc.) flours could be fortified. However, it is considered that fortifying non-wholemeal wheat flour only would be sufficient to achieve the main policy aims (based on FSS modelling). Limiting the range of flours considered may be more consistent with current fortification processes for other micronutrients, while wholemeal

FINAL DRAFT

		flour has a higher natural folate level anyway, compared to white. ¹⁸ An argument in favour of wider flours being fortified is that certain ethnic or cultural groups may benefit. It is also important to ensure that anyone who is on a gluten-free diet is properly catered for (for example by encouraging manufacturers of gluten-free products to fortify them with folic acid).
4	Mandate fortification of other foods instead of (or as well as) flour	The primary advantage of flour is that it is so widely consumed. ¹⁹ Fortification of other foods is, generally speaking, less likely to have the same reach. It is also true that current flour regulations and industrial processes already facilitate the addition of several micronutrients. Other foodstuffs might require more in the way of legislative or industrial change – which could be more expensive.
5	Extend or encourage voluntary fortification of a wider range of foods	This could extend current fortification of some cereals, fruit juices and spreads, or potentially be extended to other foodstuffs. The considerations are essentially the same as those mentioned under voluntary fortification of flour, and mandatory fortification of other foods (options 2 and 4 in this table) combined. However, the aim of redistributing folic acid intakes towards those with the lowest intake levels, and hence highest risk of NTDs, would not be met. The aim of not increasing the numbers of people who currently exceed the tolerable upper level may also not be met. The health impact of any increased consumption of other foods may or may not be positive. Finally, such an option would not necessarily reach the women most in need.
6	Improve surgical outcomes in the womb	Medical capability is advancing in this area, and indeed announcements have been made recently about additional funding provision for such surgery. This is to be encouraged, but at the same time the number of NTDs that can be treated in this way is limited, and it is unlikely outcomes could be improved for large numbers of pregnancies with improved surgery alone. This type of surgery is relatively new in the UK (4 cases) although it has been used more widely in some other countries. There is a logical argument that prevention is better than a cure.
7	Fortify only foods or products that are	While it is true that some products may be marketed towards the relevant age group, that does not apply to

¹⁸ <https://www.fob.uk.com/wp-content/uploads/2016/12/FS11-folic-acid.pdf> See Q&A section.

¹⁹ www.nabim.org.uk reports that 99.8% of households buy bread. DHSC analysis of NDNS data (2015-2016) suggests that nearly everyone consumes flour to some degree. The proportion consuming non-wholemeal bread flour specifically was 92%.

<p>consumed by women who could become pregnant.</p>	<p>most foods, and it is not considered that a targeted approach would be practical or effective to implement in practice. It may also be more difficult to reduce inequalities in folic acid intake and NTD risk with a targeted approach. Targeting may also come at a higher retail price for consumers.</p>
---	---

23. The use of flour, and specifically non-wholemeal wheat flour, as a vehicle for folic acid fortification is relatively common, with many countries (including the US, Australia and Canada) adopting it. It is almost universally consumed in some form or another.¹² Fortifying flour is thus likely to improve folate levels for a large number of people (which helps lower NTD risk in women who may become pregnant, and improves the current low intake levels across the whole population).

24. Current regulations²⁰ already require non-wholemeal wheat flour to be fortified with a range of nutrients: calcium, iron, thiamine and niacin. The principle reason is to replace nutrients lost in the milling process, so the procedure is mostly restorative rather than additive. However, it means that existing regulations and business practices could potentially be easily adapted to include the addition of folic acid, rather than completely new rules and systems having to be introduced.

25. Within the “non-wholemeal wheat flour” category, exactly which types of flour could or should be fortified is flexible. There are several possible definitions:

- The 1998 Bread and Flour Regulations provide a definition of bread flour (although this is a relatively narrow definition that the FSS modelling suggests would not provide sufficient folic acid if fortified).
- The National Diet and Nutrition Survey definition of “bread flour”, which covers most uses of strong non-wholemeal bread flour.
- It is also possible to regard all non-wholemeal wheat flour as being in scope, including plain and other flours not used for bread. This is the broadest definition.

26. Other types of flour (wholemeal, gluten-free etc.) could in principle be fortified, although that is not currently a leading option. The consultation asks for views on the scope of fortification generally, and options may be further defined in the light of responses. The needs of those with gluten intolerance (and indeed anyone who doesn’t eat non-wholemeal wheat flour) will be considered separately.

27. Whichever definition, and whichever policy option is chosen, further decisions need to be taken on the scope of fortification. Considerations include:

²⁰ <http://www.legislation.gov.uk/uksi/1998/141/made>

- Whether flour is UK-produced or imported.
- Whether UK-produced flour is used in the domestic market or exported.
- Whether and which flour-based products are included.
- Whether the location of production facilities makes a difference.
- Whether certain products or producers (e.g. small businesses or specialist artisan producers) should be excluded.
- What level or levels of fortification are required?
- Who is responsible for the fortification (both process and cost)?
- Are there any knock-on effects (for example, would existing folic acid-enhanced foods need to be reformulated)?
- Other criteria may also be considered.

28. For the purposes of the three options considered here, the following assumptions are made:

- Do nothing – maintaining the status quo with no mandatory requirement to fortify flour.
- Mandate the fortification of UK-milled non-wholemeal wheat bread flour – use the NDNS definition (i.e. all strong non-wholemeal bread flour is in scope in principle). This covers flour produced in the UK for UK consumption only, but includes all products using such flour as an ingredient. The level of fortification is variable but would need to be at least 350 µg per 100g to increase folate intake levels by at least 60 µg (or more if voluntary fortification were restricted).²¹ These figures are illustrative and subject to review.
- Mandate the fortification of all UK-milled non-wholemeal wheat flour. Again, this covers flour produced in the UK for UK consumption only, but includes all products using such non-wholemeal wheat flour as an ingredient. The level of fortification is variable but would need to be around 200 µg per 100g to increase folate intake levels by at least 60 µg (or more if voluntary fortification were restricted)¹⁷. These figures are illustrative and subject to review.

29. Further analysis of the consistency with current regulations, and of the use of bread flour in non-bread products, is required to indicate which of the options (fortifying non-wholemeal bread wheat flour only or all non-wholemeal wheat flour), would be simpler and less burdensome to implement. Fortifying non-wholemeal bread flour only would offer a lower level of NTD reduction overall if the total amount of folic acid provided was lower and because a significant proportion of women of child bearing age consume only small quantities of bread.

²¹ Based on FSS analysis – stochastic modelling paper (footnote 2).

30. The consultation aims to explore the issues further. Further options and sub-options may be identified and assessed if the consultation or other evidence suggests they might have merit.

What are the expected benefits?

31. Fortifying flour with folic acid is expected to deliver the following direct benefits:

- The prevalence of low folate status, and hence NTD risk, will be reduced (this includes both preventing any increase which might otherwise have occurred, and reducing risk below its current level).
- The number of NTD-affected pregnancies will fall.
- The survival, health and life expectancy of affected babies will improve.
- The costs of treatment for NTD-affected babies will fall. This includes a range of costs including care, support and possible surgery before or after birth, and in the longer term,
- The consequential effects of NTDs on parents and families will reduce.
- There will be an economic benefit through reduced work absence (both through reduced requirements for care, and through the enhanced ability to work of those who might previously have had an NTD-related disability).
- Any reduction in the number of cases would allow both the NHS and third sector to provide more focused support to those that remain affected.
- Producers of folic acid (most of whom are overseas-based) will see increased sales.

32. It is not possible to quantify all these benefits precisely at this stage, and they will depend on the exact parameters chosen for the fortification option(s).

33. For the NTD risk reduction specifically, the FSS analysis presents the following results, and these have (on a limited basis) been corroborated by supplementary work within DHSC using more recent dietary data. Two scenarios are presented: one without any restrictions on voluntary fortification, and one with.²²

Indicative reductions in NTD risk, if flour is fortified (FSS analysis)²³

²² Specifically, the restrictions involved capping the level of voluntary fortification in breakfast cereals and spreads at 15% of RNI per 100g, and restricting supplements to 200µg per day, or 600µg per day for women of childbearing age. This is described as “capping all” in the FSS paper. The latter does assume that consumers follow the dosage instructions correctly. These restrictions are illustrative and not intended to pre-empt any final policy decision.

²³ See tables 21 and 22 in the FSS paper (pages 39-40). Option 2 in this context uses the NDNS survey definition of bread flour. The figures quoted refer to FSS Model C, which is relatively conservative, but does realistically reflect some women taking folic acid supplements. They are indicative.

FINAL DRAFT

(Assumes that voluntary fortification is **not** restricted, and thus may carry a risk of excess intake)

Level of fortification (µg per 100g)	Option 1 (do nothing)	Option 2 (non-wholemeal bread flour only)	Option 3 (all non-wholemeal flour)
100µg	0	4% - 7%	8% - 11%
200µg	0	8% - 12%	13% - 19%
250µg	0	9% - 14%	15% - 22%
300µg	0	11% - 16%	17% - 25%
350µg	0	12% - 18%	19% - 28%
450µg	0	14% - 21%	23% - 32%

Indicative reductions in NTD risk, if flour is fortified (FSS analysis)

(Assumes that voluntary fortification **is** restricted to avoid excess intake, as per SACN advice)

Level of fortification (µg per 100g)	Option 1 (do nothing)	Option 2 (non-wholemeal bread flour only)	Option 3 (all non-wholemeal flour)
100µg	0	Negative ²⁴	2% - 3%
200µg	0	2% - 3%	8% - 12%
250µg	0	4% - 6%	11% - 16%
300µg	0	6% - 8%	13% - 20%
350µg	0	7% - 11%	16% - 22%
450µg	0	10% - 14%	19% - 28%

34. The conclusion is essentially that the potential reduction in risk is roughly double, assuming the same level of fortification, if all flour is fortified, compared to fortifying bread flour only. That is to be expected as the quantities consumed of bread and non-bread flour are very similar.²⁵

35. The tables show that restrictions on voluntary fortification may reduce the benefit in terms of NTD risk, as well as avoiding any increase in the number exceeding the tolerable upper level. A balance needs to be struck. A further possibility is that restrictions could deliver a possible reduction in inequalities. This is because those with the lowest intake levels of folate (who may by implication be less likely to consume many voluntarily-fortified foods and/or supplements) will benefit from fortification, but not be affected by the restrictions. Conversely, any restrictions will have most impact on those who have high folate levels and thus are at reduced

²⁴ The analysis suggests that at this level, any widespread restrictions on voluntary fortification would outweigh the mandatory side, and increase NTD risk by 2-3%. In practice, one would probably adjust the level of restriction to avoid this.

²⁵ DHSC analysis of 2015-2016 NDNS data suggests women of childbearing age consume an average of 25g/day of bread flour, and 24g/day of non-bread flour (within the non-wholemeal category).

risk of NTD anyway. These assumptions will be reviewed further, alongside dietary data, in due course.

36. NDNS data indicate that nearly everyone in the general population who is likely to exceed the tolerable upper level will be consuming supplements (para 49 elaborates on this). The relatively low levels of folic acid currently in most fortified foods, or modelled in flour, are not sufficient to reach the tolerable upper level alone.

37. In terms of the babies protected, the risk percentages above should be applied to the current figure of around 1,000 diagnosed NTDs per year. For example:

- Option 2 – a central estimate of around 5-10% reduced risk, would protect 50-100 babies each year.
- Option 3 – a central estimate of around 15-20% reduced risk, would protect 150-200 babies each year.

38. These numbers are illustrative and actual figures will depend on the specific policy parameters chosen. Additionally, an unknown number of non-diagnosed NTDs may be avoided, typically NTD-affected pregnancies which miscarry early.

39. The value of a prevented NTD in health terms varies according to the severity. In the most severe cases, such as fatal cases of anencephaly, the health loss is equal to the full normal life expectancy of a healthy child. That is 70.6 quality-adjusted life years (QALYs) based on 2016 data, and 49.6 QALYs on a discounted basis.²⁶ Such QALYs are valued by society at £60,000 each, assuming (as in this case) that there is no opportunity cost of displacing NHS resources elsewhere to achieve them. That implies a direct health gain benefit of just under £3m per fatal NTD avoided.

40. Less severe NTDs, those which are not fatal but create disability or reduced life expectancy, will have a lower prevention value. For example, research on fortification in Australia²⁷ assumed that typical life expectancy for people with spina bifida was 43 years, and that their quality of life could be modelled by assuming it was 55% of the normal level. As a crude indication, that might imply a spina bifida patient could expect to see 14.4 discounted QALYs in their lifetime. That represents a loss of 35.2 QALYs compared with a healthy child, and such a loss would be valued at about £2m.²⁸

²⁶ This is taken from DHSC-produced QALY tables, which are in turn based on ONS life expectancy and Euroqol quality of life data. The assumed discount rate is 1.5%.

²⁷ <https://academic.oup.com/jn/article/143/1/59/4569794>

²⁸ Life expectancy of 43 relative to normal UK life expectancy of 81.5 is 53%. Multiplied by 0.55 to adjust for quality of life gives about 29%. $29\% \times 49.6 = 14.4$. The loss is therefore $35.2 \times 60,000 = £2.1m$. A similar answer is obtained by noting that the QALY tables also show that adults with a

41. Further NTDs may be less serious, or may be successfully treated in the womb or after birth. The health gain from preventing them will be lower (it is effectively a continuous scale up to the £3m maximum).
42. The modelling evidence available suggests that higher levels of folate reduce the risk (i.e. chance) of NTDs occurring, rather than necessarily reducing their severity when they do occur. This IA therefore assumes that the relative proportions of different types of NTD, and the severity of NTDs, will not be affected by fortification, but that the total number will be.
43. Some research has been carried out overseas and appraised by NICE, with tentative results suggesting that the cost per QALY generated by folic acid fortification is relatively low and cost-effective).²⁹
44. The value of improved health achieved from between 50 and 200 NTDs prevented per year (depending on the chosen option) is thus likely to be considerable, albeit not yet quantified precisely.
45. Savings to the NHS may also be significant, particularly for babies that currently survive an NTD with disabilities requiring long-term care. Further work is planned to better assess and quantify the likely impact on health and social care services.
46. 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. That in turn depends on the precise fortification options chosen.

What are the expected costs?

47. The main costs will also depend on the precise options and sub-options chosen, but in principle they include:

Costs to businesses

- One-off costs to business associated with becoming familiar with any rules, and setting up processes, equipment and supply chains to comply with them. It will be important to provide sufficient lead-in time prior to new rules taking effect, so businesses can prepare.

remaining life expectancy of 43 years, can expect around 29.9 discounted QALYs. Multiplying that by 0.55 gives 16.4, and an associated loss of $49.6 - 16.4 = 33.2$ years, worth £2m. Both these calculations are fairly crude and will be refined further as more evidence is assessed.

²⁹ <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-guidelines/healthy-start-cost-effectiveness-review.pdf> See page 25.

FINAL DRAFT

- The ongoing cost of folic acid fortification itself, comprising the cost of folic acid itself and the cost of physically adding it to flour when required. This may or may not require multiple production lines, cleaning and other adjustments. Folic acid on its own is relatively inexpensive (around £60 per kg in bulk) and as such is unlikely to significantly affect the price of fortified flour.
- It is unlikely that new machinery would be required because existing legal requirements already mandate the addition of similar micronutrients and by implication the use of appropriate machinery.
- Ongoing costs for labelling and quality control, both for fortification and for any products made with fortified flour. Such costs would be very dependent on the number of product lines and volumes handled by each business. Labelling would be required at all stages in the supply chain, from wholesale flour supplies to retail baked products, but should predominantly be a one-off cost of change (there may be some ongoing costs of machine adjustment if variant labelling is required depending on the destination of the goods).
- Any indirect costs (could also be a benefit) in terms of changes in consumer preferences, product positioning, marketing.
- If fortification of flour requires amendment to the current rules for voluntary fortification of other goods, like cereals, the affected businesses will need to respond, and may incur one-off costs to change processes. It is not expected that they would incur any significant long-term costs.
- Fortification may result in some reduced consumer demand for supplements, affecting sales in that market. Ideally, public health messaging would increase uptake of folic acid supplements in those likely to get pregnant. For other populations who don't need the additional folic acid, there would be a public health benefit in reducing the number exceeding the tolerable upper level.
- Retailers and caterers may see an increase in consumer queries and/or need to review their own labelling, menu information and so on.
- In principle, it is possible that fortification may encourage changes to current supply chains, particularly in respect of import and export practices. The policy intention is to minimise such effects, and it is hoped that the consultation may gather more evidence to inform the policy detail.

Costs to consumers

- The cost of fortification on a per loaf (or other food item) basis is expected to be very low, such that no significant change is expected in retail prices for flour and flour-based products. This will be reviewed following consultation, and as the range of products covered is clarified.
- Some consumers may not be able or wish to consume fortified products, and would need to seek alternatives (provision for such people will be considered fully as the policy is developed).
- Some consumers may object to the principle of the government deciding what they should eat (even if it is in fact likely to be beneficial to them).

- There is a potential risk³⁰ if, owing to fortification, a consumer's folic acid intake rises above the tolerable upper level of 1mg per day. Even without mitigation, this is expected to affect a very small number of people (less than 0.5%, based on DHSC modelling). In practice, the risk is likely to be mitigated as part of the policy objectives, for example by limiting voluntary fortification or perhaps by limiting or capping the use of supplements in some way. A balance is required, since if capping levels are too severe, and/or fortification levels low, it is possible that women may consume less folate than they do now, and hence see an increase in NTD risk.

Costs to government

- If anyone does take too much folic acid, then there is a chance that they could have consequential medical needs (e.g. if vitamin B12 deficiency were not detected). This risk is expected to be mitigated through policy design, and in any case, should be offset or outweighed in cost terms by the reduction in NTDs.
- One-off costs associated with producing guidance, and ongoing costs associated with monitoring folic acid intake and blood folate levels will also be incurred (albeit some of the latter is already incurred under the status quo). It is possible that existing guidance may need to be adjusted, as well as new guidance produced.
- Depending on the legislative mechanism chosen, local authorities may incur enforcement costs (both one-off familiarisation and ongoing), albeit mitigated if there are synergies with current enforcement practices for other micronutrients in flour.

Indirect longer-term consequences

- It is true that if babies who would otherwise die now survive, they may later suffer other illnesses or injuries requiring NHS treatment. However, because they could face any health issue totally unrelated to NTDs, such costs are out of scope and by convention, are not considered in impact assessments.

48. On the specific risk of consumers taking too much folic acid, this is relatively uncommon but could occur if someone takes folic acid supplements at a higher than required dose, or takes them unnecessarily (either directly, or perhaps as part of a multivitamin supplement where folic acid may be added but is not the primary vitamin being sought). Dietary folate alone, including at current levels in fortified foods, is unlikely to result in excess intake in those not consuming supplements. The FSS analysis considered the proportion of the population who might exceed the tolerable upper level because of fortification as shown below.

³⁰ This is explained more fully in para 49 onwards. The main risk is that high folate levels may make it more difficult to detect vitamin B12 deficiency, which can (if untreated) lead to health problems.

Potential % of people exceeding the tolerable upper level (FSS analysis)

Level of fortification (µg per 100g)	Without restrictions on voluntary fortification	With restrictions on voluntary fortification ³¹
Option 2 (non-wholemeal bread flour)³²		
0	0.417%	0.020%
100	0.422%	0.026%
200	0.473%	0.030%
250	0.482%	0.030%
300	0.515%	0.030%
350	0.571%	0.034%
450	0.755%	0.101%
Option 3 (all non-wholemeal flour)³³		
0	0.417%	0.020%
100	0.476%	0.034%
200	0.545%	0.059%
250	0.635%	0.071%
300	0.831%	0.102%
350	1.114%	0.195%
450	1.802%	0.539%

49. These results suggest:

- Around 0.4% of people already exceed the tolerable upper level, 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.
- Mandatory fortification on its own may increase this number, for example a level of 300µg per 100g would generate increases of around 0.1% of the population under option 2, and 0.4% of the population under option 3.
- Restrictions on voluntary fortification and/or supplements could mitigate any increase, and/or reduce the current level of excess intake, depending on the extent of such restrictions. The examples shown reflect the same restrictions as specified in footnote 18 above.

³¹ This includes restrictions on breakfast cereals, spreads and supplements as modelled by FSS. With zero fortification, restrictions are unlikely to be considered.

³² Using NDNS definition. See the overall population scenario in Table A12 (no restrictions) and Table A.15 (restrictions) in the FSS modelling paper.

³³ See the overall population scenario in Table A.13 (no restrictions) and Table A.16 (restrictions) in the FSS modelling paper.

50. For perspective, 0.1% of the population is 65,000 people, although only a subset of these would have conditions or circumstances that might be affected.
51. SACN has considered in depth the potential risks associated with sustained high doses of folic acid. The risks considered were: masking/exacerbation of low vitamin B12 status; cognitive decline in older individuals, cancer (prostate, breast, colorectal and overall risk); and the long-term effects of unmetabolized folic acid in the body.
52. SACN concluded that folic acid intakes up to 1mg per day are not associated with masking any anaemia associated with vitamin B12 deficiency, and found no effect of folic acid supplementation on cognitive decline in older individuals. SACN noted that the prevalence of B12 deficiency, with or without anaemia, did not increase after mandatory fortification was introduced in the US. Only a proportion of those exceeding the tolerable upper level will be at risk from B12 deficiency.³⁴
53. Evidence of a link between excess folic acid intake and cancer is inconsistent. SACN conclude that despite the inconsistencies and limitations in the data, the overall picture does not suggest a detrimental effect of folic acid on cancer risk.
54. A further potential concern is the appearance of unmetabolized folic acid in the systemic circulation. However, SACN concluded that there was no clear relationship between folic acid consumption and levels of unmetabolized folic acid in the systemic circulation, and the data are insufficient to assess whether unmetabolized folic acid in the systemic circulation is related to any adverse health outcomes.
55. A full assessment of these and similar factors is available in the SACN update on folic acid of July 2017.
56. SACN advice remains that mandatory fortification, alongside restrictions on voluntary fortification and clear guidance on the use of folic acid supplements, is an effective way of reducing NTD risk while avoiding excess intake. This advice is commensurate with the policy objective of guarding against any increase in the number of people exceeding the tolerable upper level. It implies that any change in health, resulting from excess intake, should be negligible. Full analysis will be completed post-consultation once detailed fortification parameters and restrictions are defined.

³⁴ The NDNS survey suggests around 5-7% of adults 65+ have a B12 level below 150pmol/L.

Further assessment of the potential impact on industry

57. The impacts on industry are primarily dependent on the scope and amount of mandatory fortification required, and whether any restrictions on current voluntary practice are introduced. Both factors are variable and will be determined by the joint objectives of reducing NTDs significantly, while avoiding any increase in people exceeding the tolerable upper level. Some business impacts may be fixed and others may depend on the policy parameters involved.
58. The government believes that folic acid should be added at whatever point in the supply chain is most convenient and efficient for the industry. It may be appropriate to add folic acid at the same time as other nutrients, such as niacin, are replaced. That is usually done at the mill, but could be done at a bakery or some other facility if more convenient to do so. Uniformity is not required, but may be preferable. Ease of monitoring and enforcement may also have an influence. Fortification would only be required for UK-destined flour, so the destination might need to be known (subject to any rules agreed on whether fortified flour or products could be exported or not).
59. **Wheat growers** – no significant impact is expected.
60. **Manufacturers of folic acid** – demand is expected to increase, from both existing and new customers. Production may need to be expanded accordingly. If current voluntary fortification is restricted, demand there may fall, but the net effect is expected to be a significant increase in usage. Most folic acid production is currently based overseas, and the default assumption is that this would continue.
61. **Millers** – there are around 30 milling companies operating in the UK³⁵, and over 50 flour mills. Annual production is around 5.5m tonnes of flour, of which around 84% is homegrown wheat and 16% imported. Mandatory fortification could apply to all UK-milled flour, or only homegrown flour – the rules will need to be defined. Around 45% of the total is white bread flour, over 30% is used to make starch and the remaining 25% comprises brown, wholemeal and white non-bread flours. 5% is exported and 95% used in the UK. If folic acid is added at the milling stage then millers will incur costs of purchase and processing. They may or may not elect to pass those costs on within their prices. The cost is expected to be low on a proportional basis, but not negligible as a total amount for the industry. Labelling will need to be updated, and there may be an impact on production costs (e.g. if machinery has to be cleaned).

³⁵ These and other figures in this section are sourced from NABIM, the National Association of British and Irish Flour Millers. www.nabim.org.uk

62. **Bakers and other food manufacturers** (e.g. confectioners, breaded products) – account for the majority of flour destined for human consumption (over 90%, with the rest exported or sold to consumers as raw flour). Some bakers may have their own milling subsidiaries (or vice versa) while others may be independent. If folic acid is added at the milling stage, then the impact on bakers may be limited to administrative costs (ensuring all rules on use and distribution of fortified flour are followed) and possibly the payment of a premium to the millers if costs are passed on. Bakers could of course pass that on further. If added outside the milling process, then manufacturers would incur the associated costs as detailed above. Again, labelling will need to be updated. There are an estimated 150 large, 350 medium and 4,500 small bakeries in the UK³⁶ (although this may not cover all manufacturers who use fortified flour). The figures also exclude in-store supermarket bakeries, although these (and indeed most bakeries) are expected to use pre-fortified flour rather than adding folic acid themselves,
63. Any business using fortified UK flour will need to comply with both UK and overseas rules. That may entail changes to where they source their flour and/or where they send products. The intention is to use the consultation to explore further the issues and clarify the impact of different rule options. The intention is to cause minimum disruption to existing supply chains, while preserving the benefits associated with fortification.
64. **Retailers** – are not expected to see any major change in either costs or demand for their products. Consumer queries may arise, particularly in the short term, which might entail some need for staff training.
65. **Manufacturers of goods which are currently voluntarily fortified with folic acid** – typically breakfast cereals, some spreads, multivitamin juices and some other products. If restrictions are introduced on voluntary fortification then clearly manufacturers will need to familiarise themselves and adapt as necessary. In practice, processes, labelling and marketing may be affected. At the same time, businesses may save money through not requiring as much folic acid. It is not anticipated that demand for products would fall if folic acid levels were reduced, unless the fortification was a large part of a product's appeal. For products to claim they are a "source of folic acid" the level of fortification must be at least 15% of RNI per portion or per 100g/100ml (whichever is smaller). It is possible that any restrictions might still allow fortification up to that amount so that the claim may be preserved. Depending on the precise circumstances, some labelling changes may be required.
66. **Manufacturers and retailers of folic acid supplements** – Current advice for pregnant women to take a supplement will not change, such that core existing

³⁶ <http://www.craftbakersassociation.co.uk/bakery-info.php>

demand for folic acid supplements should remain. Instead it is perhaps multivitamin tablets which may currently contain folic acid, but not be marketed at or used by pregnant women specifically, where restrictions might have more of an impact. It is possible that restrictions might require such products to be reformulated and/or re-labelled. No decision has been taken yet.

67. The bottom line with all the above is that impacts are heavily dependent on policy choices, and those choices will be informed by views and evidence received during consultation. The aim remains to minimise any costs or burdens on business, and to facilitate the fortification process, while delivering the benefits sought.

How do the main options compare?

68. Options cannot be fully assessed until all sub-option parameters are considered and defined, but in general terms:

69. Option 1 (do nothing) – will see no changes to current practice and no changes to the current level of NTDs (around 1,000 affected pregnancies a year).

70. Option 2 (fortify non-wholemeal wheat bread flour) – this is the more limited fortification option. It would offer a lower level of NTD reduction overall, compared to option 3, if the total amount of folic acid provided was lower and because a significant proportion of women of child-bearing age consume only small quantities of bread.

71. Option 3 (fortify all non-wholemeal wheat flour) – this is the wider fortification option. Because the range of products covered is wider, it can be expected (for a similar level of fortification per 100g) to have a larger positive impact in reducing NTDs than option 2. It would maximise the gross benefits of the policy.

72. Further analysis of the consistency with current regulations, and of the use of bread flour in non-bread products, is required to indicate how simple or burdensome each option would be to implement. The presence of economies of scale, or otherwise, is also unclear at this stage. The comparative costs of options 2 and 3 may be informed by consultation responses.

73. As explained, these three options provide examples of zero, limited and wider fortification. Other options exist along that continuum.

Risks and assumptions

74. An overriding assumption is that consumer dietary habits will not change in response to folic acid fortification. This is unproven but may be informed by responses to the consultation.
75. The evidence behind folic acid providing a significant health benefit in terms of reduced birth defects is strong, and supported by evidence from many countries around the world. In the UK, SACN continues to recommend fortification on that basis, provided steps are taken to mitigate any risk of excessive intake.
76. It is assumed as a practical constraint, that fortification cannot be targeted only on women who are likely to become pregnant, and therefore that fortified foods will be eaten by everyone over time.
77. The costs of fortification may not be especially high as a proportion of total flour production costs, although they may be non-negligible in aggregate terms.
78. Any decisions on policy design and associated parameters will be taken in the light of the consultation and other evidence. No decision has been taken yet.

Wider Impacts and Specific Impact Tests

Small and Micro Business Assessment

79. The precise scope of any new regulations is not yet defined and will be informed by the consultation. The existing regulations for fortification of flour with other additives apply to all businesses, and a similar arrangement is possible for folic acid. However, it is also possible that certain criteria (such as business size) might be applied to determine whether the rules for folic acid specifically should be varied in any way. The aim would be to achieve an appropriate balance between public health, fairness, proportionality and trade facilitation. No decision has been taken.
80. Although the milling, and to a lesser extent baking, industries are dominated by large firms, there are a significant number of small artisan businesses that might be affected in some way (4,500 small bakeries for example). In addition, retailers of all sizes may need to be familiar with rules on labelling and be able to deal with consumer queries.
81. The types of cost incurred will be similar to those mentioned for businesses in general. However, there may be some circumstances unique to small firms. Examples may include:

- Higher operating costs (e.g. lack of economies of scale for buying folic acid);
- Different use of machinery (e.g. traditional grinding stones rather than modern equipment) and hence differing levels of wastage, ability to achieve uniform fortification and maintenance costs; and
- Differing numbers of products, customers, suppliers and other parameters which might affect costs.
- This list is not exhaustive and the consultation seeks further evidence.

82. The business costs associated with folic acid fortification are expected to be relatively small, albeit non-negligible. This remains true for small and micro businesses, not least because existing legislation already requires fortification processes and appropriate labelling to be in place, albeit with other micronutrients. The impact will be reviewed in the light of consultation as decisions are taken.

Societal impacts

83. The main impacts are likely to be:

- A significant benefit to families who would otherwise be affected by NTDs, with consequent reductions in care needs and health costs, together with improved prospects.
- A potential improvement in inequalities, because there is evidence that NTDs are disproportionately more likely to occur amongst deprived families.
- Some disproportionate impacts on sub-populations – for example cultural groups that eat less flour (e.g. those for whom rice is the staple) may be less positively affected.
- Anyone with gluten intolerance or other restrictions on flour intake, may also be less affected.

84. A fuller assessment of societal impacts will be completed in due course.

Equality and Family Test issues

85. All policy decisions will be considered alongside a full equality assessment. That will assess whether any individuals or groups with protected characteristics might be disadvantaged. The issues to be considered will include, but are not limited to:

- The effect of fortification on all protected characteristics.
- The effect of fortification on families generally and specifically on those with different levels of income, and in more deprived areas.
- The effect on people who cannot (or choose not to) eat fortified flour or products made with it.

FINAL DRAFT

- The effect on people who are unable or choose not to consume folic acid.
- The effect on people in particular at-risk groups (such as those at risk of B12 deficiency, those with allergies or those taking other medication).
- The effect on people with special diets, whether for medical, cultural, religious, personal or other reasons.

Proportionality

86. Our aim will be to ensure that any intervention is proportionate. As the costs and benefits are updated and quantified in the light of consultation, the test will be whether the costs, and particularly any costs to businesses, are justified given the likely range of benefits achieved.

Competition

87. The effect on competition is unclear at this time, and will be assessed in the light of consultation. It is possible that rules for larger and smaller businesses may differ, as might rules for import/exporters and domestic firms. What the agreed rules may be is not yet known, but the effects will be assessed and used to inform final policy decisions in due course. The policy intention is to minimise any such effects.

Next Steps

88. The options and evidence set out in this impact assessment are provisional. They will be reviewed and updated where possible in the light of responses to the consultation, with updated advice being provided to ministers accordingly. This will inform further policy decisions on how the Government wishes to proceed. Any subsequent legislative proposals may be subject to further consultation and may be accompanied by an updated impact assessment. Timescales will be confirmed in due course.

Annex: Further evidence and analysis

Neural tube defects

89. Neural tube defects represent a group of congenital defects caused by incomplete closure of the neural tube within 28 days of conception. The most common forms are:

- **Anencephaly** – characterised by a significant part of the brain or skull failing to develop. The condition is almost always fatal either before or shortly after birth.
- **Encephalocele** – characterised by part of the brain or associated structures forming outside the skull. Reparative surgery in infancy is possible, but long-term disability is common.
- **Spina bifida** – characterised by the spinal cord not closing properly. Lesser defects (*spina bifida occulta*) can be asymptomatic and remain undetected, but more severe types (*myelomeningocele* and *meningocele*) can cause long-term disability. Corrective surgery is sometimes possible but may not remove all symptoms.

90. It is not possible to measure the true number of NTDs accurately because some affected pregnancies will miscarry before diagnosis, or (in minor cases of spina bifida) may remain undetected.

91. The Scientific Advisory Committee on Nutrition (SACN) produced an estimate of 700-900 NTD-affected pregnancies per year in the UK in 2006, based on data from 2003.³⁷ This estimate was based on a series of assumptions about the accuracy of reporting systems at the time. It was the best available estimate and has remained in use since.

92. More recent data suggest that the current number of NTDs may be higher than the range estimated by SACN in 2006, since the total number of births has been higher in recent years.³⁸

93. Estimates of the prevalence rate are also helpful, defined as the total number of diagnosed cases seen in live births, stillbirths, late miscarriage or termination (where the NTD was a causal factor in the decision to terminate the pregnancy) divided by the total number of births (live + stillbirth).

³⁷ <https://www.gov.uk/government/publications/sacn-folate-and-disease-prevention-report>. Para 171.

³⁸ <https://www.ons.gov.uk>. Total births (live + stillbirth) were 758,000 in 2017 and 780,000 between 2013 and 2016, compared with 700,000 in 2003. ONS forecast 7.7m births over the next 10 years or 770,000 per year.

Estimated prevalence of NTDs

	Central estimate	Indicative range
Estimated cases per 10,000 births ³⁹	12.64	11.96 – 13.34
Implied number of annual UK cases ⁴⁰	1,000	950 – 1,050

94. Based on the above, a rounded estimate of 1,000 is suggested for modelling purposes. The breakdown by condition is roughly 50% spina bifida, 40% anencephaly and 10% encephalocele, based on EUROCAT data.

What is the link between folic acid and NTD risk?

95. The Scientific Advisory Committee on Nutrition provided an update on folic acid in July 2017.⁴¹ It summarised previous evidence of the link with NTD risk by noting:

- “conclusive evidence from randomised controlled trials has shown that folic acid supplementation during the early stages of pregnancy can reduce the risk of the foetus developing neural tube defects”; and
- “significant reductions in the prevalence of NTDs among live births have been reported in countries with mandatory folic acid fortification policies”.

96. The precise nature of the relationship between folate intake and NTD risk has also been researched. The FSS report sets out evidence attempting to quantify the effect. There is considerable uncertainty, reflected in the use of a range of different models.

Current folate intake

97. The FSS analysis assessed folate intake levels (the sum of natural folate intake plus any added folic acid under the status quo). They considered women aged 14-49 years, and estimated the average intake to range from 109 µg/day (lowest

³⁹ Based on the average prevalence rate between 2012 and 2016 as published by <http://www.eurocat-network.eu/>. These data cover part of the UK only, but are assumed for IA modelling purposes to be representative. Similar data are also collated by the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) and published by PHE, although the time series is shorter. The tabulated numbers measure the total number of NTDs per 10,000 total births (live births plus stillbirths).

⁴⁰ Assumes 770,000 total births per year in the UK, which is the current ONS forecast for the next ten years. $770,000 \times 12.64 / 10000 = 973$ rounded to 1,000. Births and cases in any single year may be higher or lower. Assumes that the prevalence rate estimate is a reasonable approximation for the UK. FSS modelling produced a slightly higher figure (1,110) although this was based on earlier 2010-14 data, which included a slightly higher birth rate, and a slightly higher prevalence estimate. This IA uses more recent figures.

⁴¹ <https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations>

quintile by intake) to 472 µg/day (highest quintile) with an overall average of 251 µg/day. More recent DHSC analysis, of women aged 16-49 years, has an average intake of 239 µg/day, which is similar.

98. In terms of the longer-term trend, the NDNS shows a decline in folate levels over time, both in folate intake and in blood status. Over 90% of women of child-bearing age are not achieving recommended levels. There may be a number of reasons for this trend, but one factor is changes in voluntary fortification, and in consumption of those foods. For example, FSS modelling shows that the intake of folic acid from spreads is much lower than it was in 2006 (9-10ug compared to 21-22ug). Consumption of such spreads has fallen slightly, but from engagement with industry it is clear that some manufacturers have removed folic acid from their spreads as well.
99. The question is whether the trend will continue. This is less certain, but protection against any further rise is an additional reason for intervention. While it is true that the proportion of women of child-bearing age not meeting recommended levels is already very high (over 90%), the degree of shortfall for those women could worsen. There is a time delay before both dietary analysis and actual NTD incidence figures become available, and continued monitoring will help clarify the direction of travel.

Effect of fortification on folate intake

100. Most analysis of the effects of fortification assumes that current dietary habits will continue unchanged, and that approach is repeated in this impact assessment. In practice, people may change their preferences in direct response to folic acid being added to certain foods. It is difficult to predict whether this would occur, but the consultation may provide an indication.
101. On the assumption that eating habits do not change significantly, the FSS analysis suggested that each 100 µg/100g of folic acid added to bread flour would increase folate intake in the total population by around 20 µg/day. The equivalent figure for fortifying all flour was 40 µg / day (reflecting the near 50-50 split of intake between bread and non-bread flour).
102. This calculation assumed that there would be a 25% production loss between fortification and consumption, and further that only 88.7% of flour would be fortified (on the basis that fortification would only apply to UK-produced flour, and that 11.3% of flour consumption might be imported).
103. Repeating these assumptions with the more recent 2015/16 data produces the same result of 20 µg / day higher intake of folic acid, for every 100 µg/100g added

to bread flour, and a similar amount if added to non-bread flour. Again, this covers non-wholemeal wheat flour only.

Effect of folate intake on the risk of NTDs

104. The FSS analysis considers the relationship between folate intake and blood folate levels, and then the relationship between blood folate levels and NTD risk. Both relationships are uncertain but have been modelled using statistical regression methods. The FSS work drew on a range of models and research, and concluded that for women who could become pregnant the following were reasonable:

For converting folate intake (total µg per day) to blood folate levels (nmol / litre):

$$\text{Blood folate level} = \exp (0.41316 \times \text{Ln} (\text{intake}) + 4.03577)$$
 (or equivalently)
$$\text{Blood folate level} = 56.586 \times (\text{intake} ^{0.41316})$$

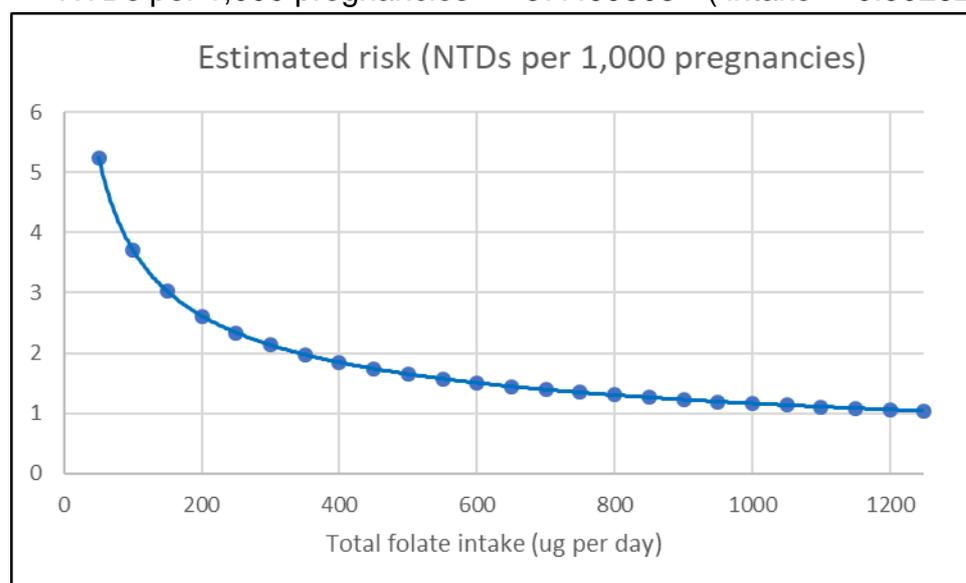
For converting blood folate level (nmol per litre) to probability of NTD occurring, p:

$$\text{Ln} (p / (1-p)) = A - B \text{Ln} (\text{blood folate level})$$
 Where either $A=1.6463, B=1.2193$ or $A=4.57, B=1.7$

105. The two options represent, respectively, modelling for an Irish population (arguably similar to the UK) and a Chinese population (less similar, but based on more recent data). The differences and further details are fully explained on page 17 of the FSS paper. FSS preferred the former (Irish) version, which is also the more conservative.

106. Combining the various equations produces a relationship between total folate intake and the probability of incurring an NTD. This looks like this:

$$\text{NTDs per 1,000 pregnancies} = 37.499808 * (\text{intake} ^{-0.502627})$$



107. The greatest benefit occurs in women who currently have low folate levels, and diminishes for women further up the scale. Once intake reaches 600 µg or so, the benefits of additional intake are relatively small. This is completely consistent with the advice for pregnant women to take a supplement of 400 µg a day, in addition to normal dietary intake.

108. The results demonstrate:

- Fortification of flour with folic acid will reduce NTD risk.
- The size of the reduction will depend on the scope and level of fortification. A broader definition of flour, and a higher level of fortification, will produce the greatest reduction in NTD risk, although other considerations should be considered as discussed below.

Potential risks attached to excess intake of folic acid

109. The question of whether there is a safe tolerable upper level for folic acid intake was considered by the Expert Group on Vitamins and Minerals in 2003⁴² and an update was recently published by the Committee on Toxicity⁴³. Current guidance is that an additional folic acid dose of up to 1mg per day would not be expected to have any adverse effects.⁴⁴

110. The Scientific Advisory Committee on Nutrition (SACN) recognises that mandatory folic acid fortification in addition to current levels of voluntary fortification, could lead some individuals to exceed the current tolerable upper level. Accordingly, SACN recommends that mandatory fortification should only be introduced alongside restrictions on voluntary dietary fortification, to ensure no increase in the numbers of people with intakes above the tolerable upper level.

111. The following points may add perspective:

- There is unlikely to be any risk for intakes below the tolerable upper level.
- The risk of exceeding tolerable upper levels could be mitigated by restricting voluntary fortification, or by reducing the scope/level of mandatory fortification. It could also to some extent be mitigated by nutritional advice and guidance, including in relation to the use of supplements.
- Any restrictions on voluntary fortification would most likely involve setting a limit, either in terms of the range of foods that can be voluntarily fortified, or the

⁴² <https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf>

⁴³ <https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2019/cot-folic-acid-statement>

⁴⁴ A significant exception is that higher doses may be appropriate where pregnant women have a history of NTDs. They are advised to take 5mg a day until the 12th week of pregnancy. This level of supplementation would typically be made on prescription, with appropriate medical advice.

level of fortification for such foods. It may also involve restriction or advice on the use by consumers of folic acid supplements.

- Introducing limits of any kind may imply a reduction in current levels of voluntary fortification, or it might imply that current levels should not increase.
- Women who could become pregnant, but who cannot or choose not to consume flour, will continue to benefit from voluntary fortification, as will all those with increased intakes that remain within the recommended range.
- Any restrictions may also reduce the benefit of reduced NTD risk to pregnant women, and will need to be assessed in that wider context.

112. Under current rules⁴⁵, food manufacturers can choose to add folic acid voluntarily to their products. This is common, for example, with some breakfast cereals and multi-vitamin juices. At least one baker fortifies one of its varieties of bread.

113. Current levels of fortification vary. To claim on labelling that a product is a “source of folic acid”, a manufacturer must ensure that at least 15% of the recommended nutrient reference value (NRV) is present in 100g/100ml, or in a typical portion if smaller. Cereals, for example, may suggest a portion is 30g. The NRV for folic acid is 200 µg per day, meaning that at least 30 µg should be present in a portion to make the claim. Manufacturers may add more than this if they choose, and some do.

114. Given that one way of reducing any risk of exceeding tolerable upper levels is to limit voluntary fortification, the FSS also analysed scenarios of capping (i.e. placing an upper limit) on levels of folic acid added to breakfast cereals, spreads and/or dietary supplements. The results show that:

- Capping some or all voluntary fortification reduces folic acid intake.
- That reduces the risk of exceeding the upper tolerable level, but it also reduces the benefits of NTD reduction.
- If capping levels are severe, and fortification levels low, it is possible that women may consume less folate than they do now, and hence see an increase in NTD risk. This is most likely if a narrow definition of flour is used for fortification.
- Capping folic acid supplements could have a significant effect. Although relatively few people (9%) use them, their contribution to overall mean intake of folic acid in the population is higher than for voluntarily fortified foods).⁴⁶

⁴⁵ <https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling>

⁴⁶ Those taking folic acid supplements specifically may well be pregnant and advised to do so. It is other users of high-dose multivitamin tablets (containing more than the population recommended intake levels of 200µg folate per day) who are most likely to exceed the tolerable upper level. Currently this is around 1 in 200 people. Even so, it might be prudent to place limits on voluntary fortification anyway, as levels could change in future.

- Capping folic acid in breakfast cereals, particularly if combined with limits on spreads, tends to reduce intake significantly and hence lower both the risk of excess intake, but also the NTD benefit for the majority.

115. With all the above, two overarching assumptions are made:

- That people will continue to eat the same foods they do now, even if folic acid levels change; and
- That it is not possible to limit either fortification or capping to certain groups of the population. Although there may be exceptions, most foods (and certainly flour) are eaten by all sorts of people. Fortifying flour for pregnant women only, and capping foods for people at risk of excess intake only, are not realistic solutions in practice.

What are the current intake levels of flour?

116. FSS have published flour consumption estimates based on the National Diet and Nutrition Survey (NDNS), using UK-wide data from 2008/09 to 2013/14. This includes the following:

Average consumption of non-wholemeal wheat flour (g/day) – 2008/09 to 13/14

Category	Bread flour	Non-bread flour	Total
Total population (male & female)	31	28	59
14-18 females specifically	29	29	58
19-34 females specifically	30	26	56
35-49 females specifically	26	22	48

117. DHSC has also analysed more recent NDNS survey data for 2015/16 with the following results:

Average consumption of non-wholemeal wheat flour (g/day) – 2015/16

Category	Bread flour	Non-bread flour	Total
Total population (male & female)	30	25	55
16-49 females specifically	25	24	49

118. These figures are provisional, and based on a smaller sample size than the earlier analysis. The overall picture is similar.

119. Focusing on the 16-49 female group (“women of childbearing age”) the more recent data can be broken down further:

Women of childbearing age (16-49) - average consumption of non-wholemeal wheat flour (g/day) – 2015/16

Category	<10g per day	10g-50g per day	>50g per day
Bread flour	29%	59%	12%
Non-bread flour	21%	71%	7%
Total flour	6%	50%	44%

The three levels of consumption in the table are somewhat arbitrary, but suggest that:

- 29% of women aged 16-49 don't eat much bread flour, and 21% don't eat much non-bread flour, so those women would be unlikely to be significantly affected if fortification applied to one type or other only.
- This proportion falls to 6% if both types of flour were fortified.
- In other words, option 2 might not provide much benefit for 29% of women, while that proportion would fall to 6% under option 3.
- This analysis covers non-wholemeal wheat flour. Wholemeal and non-wheat flours are not included.

Further analysis

120. All the analysis in this impact assessment will be reviewed and updated where possible in the light of the consultation, and as further research becomes available. All results remain provisional at this time.

Index

Summary: Intervention and Options	1
Summary: Analysis & Evidence Policy Option 1	2
Summary: Analysis & Evidence Policy Option 2	3
Summary: Analysis & Evidence Policy Option 3	4
Overview	5
What is the problem under consideration?	6
What are the policy objectives and intended effects?	8
What options are being considered?	9
What are the expected benefits?	14
What are the expected costs?	17
Further assessment of the potential impact on industry.....	22
How do the main options compare?	24
Risks and assumptions.....	25
Wider Impacts and Specific Impact Tests.....	25
Next Steps	27
Annex: Further evidence and analysis	28
Neural tube defects.....	28
What is the link between folic acid and NTD risk?	29
What are the current intake levels of flour?	34
Further analysis	35