

Title: Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 IA No: RPC Reference No: Lead department or agency: Department for Environment, Food and Rural Affairs (DEFRA) Other departments or agencies: Department of Health and Social Care (DHSC), Food Standards Agency (FSA), Food Standards Scotland (FSS)	Impact Assessment (IA)
	Date: 20/05/2022
	Stage: Development/Options
	Source of intervention: Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Maria Prokopiou
Summary: Intervention and Options	
RPC Opinion: Awaiting Scrutiny	

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status Qualifying provision
TBC	TBC	TBC	TBC

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

The Bread and Flour Regulations (BFR) 1998 require all wheat flour other than wholemeal to be fortified with four nutrients, namely calcium, iron, thiamin and niacin to replace what is lost in the milling process and to supplement diets in the case of calcium. Such requirements date back to early post war times and food rationing and were aimed at improving public health.

The BFRs have been kept largely unchanged since they came into force in 1998, but improvements are now needed. Following the UK's exit from the EU, disparities between the BFRs and wider food legislation have arisen, meaning there is ambiguity over how the regulations are legally interpreted by businesses and enforcement authorities. Secondly, stakeholders such as small-scale flour millers have raised concerns that the regulations may fall disproportionately on certain businesses. Government intervention is necessary to address these issues and as the matter concerns adapting specific parts of regulation it is the best placed to carry out these improvements.

For folic acid, please see the associated impact assessment¹ and consultation exercise².

What are the policy objectives of the action or intervention and the intended effects?

The objectives are to improve the BFRs by:

- Resolving the interpretation issues regarding how the BFR's interact with overlapping food regulations and ensuring that the understanding of the regulations is consistent throughout industry and enforcement. Thus, removing any legal ambiguities and ensuring that the interpretation of regulations is clear for businesses and enforcement authorities.
- To ensure that the regulations are not disproportionately burdensome on businesses by introducing exemptions which do not compromise the public health outcomes which the regulations are designed to uphold.

For the folic acid intervention, the objectives are:

- To reduce the incidence of neural tube defects by increasing the dietary intake of folic acid, and therefore blood folate levels in women of childbearing age.

¹"Folic acid pre-consultation impact assessment" - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/808698/folic-acid-impact-assessment.pdf
² "Proposal to add folic acid to flour. consultation document", DHSC, September 2021 - <https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document?msclkid=1ad34e6ecfa711ec8b65a9a50cbbdb72#consultation-questions>

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

Short-listed options (see evidence base for long-list)

- 1) **Option 1 – Do nothing** - Do not amend the Bread and Flour Regulations 1998. Measures looking to improve regulatory clarity, exemptions based on industry feedback and mandatory fortification of flour with folic acid would not be introduced into the BFRs.
- 2) **Option 2 – Introduce folic acid fortification of flour (as the only amendment to the BFR)** - This option would entail amending the BFR to allow the fortification of flour with folic acid. No further amendments to the BFRs would be made. This measure has already been subject to a pre-consultation IA.
- 3) **Option 3 – As per Option 2 plus look to address BFR’s interactions with wider food regulations (see below)** - This option would build on option 2 above but also involves two additional measures to address inconsistencies between the Bread and Flour Regulations and the other overlapping food regulations, as per the below:
 - a) Amend BFRs to raise required fortificant levels to the 15% level required by overlapping legislation on the addition of vitamins and minerals to food generally - This option would involve raising the minimum levels of nutrients so that they are all level with or higher than the 15% NRV threshold specified in Regulation 1925/2006. By aligning BFRs with the horizontal rules & wider nutritional legislation (Regulation 1925/2006 & Regulation 1169/2011) on the fortification of food, industry will get clarification on UK fortification requirements.
 - b) Amend BFR’s to remove existing calcium carbonate criteria, requiring millers to comply with specification in Regulation 231/2012 instead – this option would remove misalignment with the overlapping legislation on additives.
- 4) **Option 4 – As per Option 3 and clarify the scope of the regulations with respect to fortification requirements for wheat flour (see below)** - This option would build on option 3 above but also involves an additional measure to provide clarity on the type(s) of wheat flour the regulations apply to, as per the below:
 - a) Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to “common wheat” Triticum aestivum only - this option would provide legal clarity on the type of wheat that falls within the scope of the BFR’s, removing ambiguity for industry and enforcement authorities in terms of what flour requires fortification.
- 5) **Option 5 (preferred option) - As per Option 4 and introduce specific exemptions from the regulations to reflect industry feedback (see below)** - This option would build on option 4 above but also involves two additional measures to introduce specific flour fortification exemptions, as per the below:
 - a) Introduce exemptions from all fortification requirements for small-scale millers – this option would mean any type of mill producing at least 500t per year would not be exempt from the requirement to fortify.
 - b) Exempting lower flour content foods where flour makes up <10% of the final product - this option would involve an exemption for millers, removing the requirement to fortify flour when it is destined for sale to manufacturers intending to incorporate it in products where the flour forms less than 10% of the total product.

Option 5 is our preferred option as it best meets the policy objectives of the intervention.

Alternatives to Regulation

Non regulatory options would not effectively meet the policy objectives of this intervention and have not been assessed in fine detail in this document. We have provided an explanation alongside further analysis in Section 4.1 and Annex A.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 5 years after					
Is this measure likely to impact on international trade and investment?			Yes / No		
Are any of these organisations in scope?		Micro Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:	Non-traded:	

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: Introduce folic acid fortification of flour (as the only amendment to the BFR)

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 375	High: 581	Best Estimate: 492

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	23	0.5	27
High	28	1	37
Best Estimate	27	27	34

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

The main costs arising from the mandatory fortification will be the cost of relabelling all products that contain UK-milled non-wholemeal wheat flour, so that folic acid is listed amongst the other fortificants. We estimate the relabelling costs will come to £27m over the 10-year appraisal period.

There will also be costs involved in industry becoming familiar with the new regulations, which are derived from employee time, we estimate this to come to £4.6k over the same period. Government will also incur familiarisation costs as enforcement staff will also need to understand the change to regulations, estimated to cost £19k.

The annual costs of the required additional fortification are estimated to be £0.75m.

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

A small number of people may exceed the recommended intake level for folic acid as a result of the fortification of non-wholemeal wheat flour. This may have adverse health impacts such as potentially masking the diagnosis of pernicious anaemia, failing to prevent the neurological effects associated with the condition.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	412
High	Optional	Optional	608
Best Estimate			526

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

The main benefit of the policy is the prevention of NTDs – estimated to be around 190 every year. This is estimated to result in monetised health benefits of approximately £455m in total over the 10-year appraisal period. There are also economic benefits such as an increase in labour participation for would-be parents of NTD patients, as well as NHS treatment cost savings, estimated to be £46m and £25m respectively, over the appraisal period.

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

Producers of folic acid will see an increase in sales; however, the majority of folic acid is imported into the UK, and as such this benefit has not been quantified.

Increased folic acid intake across the entire population may lead to reduced levels of B9 anaemia (folate).

Reduced social care costs for people that would otherwise have had an NTD.

Key assumptions/sensitivities/risks	Discount rate (%) ¹	3.5/1.5
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- (1) The average life-expectancy of a healthy new-born remains constant over the assessment period.
- (2) Where an individual is born without an NTD, they are born in perfect health.
- (3) The baseline risk of NTD occurrence remains constant over the assessment period.
- (4) All NTD cases are reported medically.

¹ For all of the proposed options, we have used 2 discount rates, as per Green Book guidance. 1.5% is to be used for the health-related benefits and costs whereas 3.5% will be used for all other benefits and costs.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:19.3
Costs: 3.9	Benefits: 0	Net: 3.9	

Summary: Analysis & Evidence

Policy Option 2

Description: As per Option 2 plus look to address BFR's interactions with wider food regulations

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

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

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

Costs are largely unmonetised at this stage, further monetisation of key costs will take place in the final assessment following fortification. Consultation responses will help to firm up finalised costs and benefits, as will subsequent discussions with stakeholders.

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

All the costs of option 2 plus:

- Familiarisation costs for businesses and enforcement authorities
- Increase in fortification cost for millers who were not already fortifying flour to the levels required in Regulation 1925/2006.

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

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

All of the benefits of option 2 owing to the mandatory fortification of flour with folic acid. Other benefits are largely unmonetised at this stage, further monetisation of key benefits will take place in the final assessment following consultation. Consultation responses will help to firm up finalised costs and benefits, as will subsequent discussions with stakeholders.

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

All the benefits of option 2 plus:

- Legal clarity provided to businesses and enforcement authorities.

Key assumptions/sensitivities/risks	Discount rate	3.5/1.5
<ul style="list-style-type: none"> • Raising the minimum levels of nutrients required in flour poses no risks to consumers. • Increasing the fortification levels would result in higher costs for millers. • The majority if not all millers are fortifying to the levels required by Regulation 1925/2006 and are using E170 specification calcium to do so. 		

BUSINESS ASSESSMENT (Option 2)

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

Summary: Analysis & Evidence

Policy Option 3

Description: As per Option 3 and clarify the scope of the regulations with respect to fortification requirements for wheat flour.

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate					
Description and scale of key monetised costs by 'main affected groups'					
Costs are largely unmonetised at this stage, further monetisation of key costs will take place in the final assessment following consultation. Consultation responses will help to firm up finalised costs and benefits, as will subsequent discussions with stakeholders.					
Other key non-monetised costs by 'main affected groups'					
All the costs of option 3 plus: <ul style="list-style-type: none"> Familiarisation costs 					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate					
Description and scale of key monetised benefits by 'main affected groups'					
Benefits are largely unmonetised at this stage, further monetisation of key benefits will take place in the final assessment following consultation. Consultation responses will help to firm up finalised costs and benefits, as will subsequent discussions with stakeholders.					
Other key non-monetised benefits by 'main affected groups'					
All the benefits of option 3 plus: <ul style="list-style-type: none"> Clarity on Bread and Flour Regulations fortification requirements for different types of flour. 					
Key assumptions/sensitivities/risks				Discount rate	3.5/1.5
All of the risks/assumptions of option 3 plus: <ul style="list-style-type: none"> Different types of wheat can be clearly distinguished from one another during the enforcement process. 					

BUSINESS ASSESSMENT (Option 3)

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

Summary: Analysis & Evidence

Policy Option 4 (Preferred)

Description: As per Option 4 and introduce specific exemptions from the regulations to reflect industry feedback (preferred option).

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

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

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

Costs are largely unmonetised at this stage, further monetisation of key costs will take place in the final assessment following consultation. Consultation responses will help to firm up finalised costs and benefits, as will subsequent discussions with stakeholders.

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

All the costs of option 4 plus:

- Familiarisation costs
- Additional production costs
- Labelling costs.
- Marginal decreases in consumer intakes of nutrients currently added to non-wholemeal flour. Monitoring and enforcement costs.

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

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

Benefits are largely unmonetised at this stage, further monetisation of key benefits will take place in the final assessment following consultation. Consultation responses will help to firm up finalised costs and benefits, as will subsequent discussions with stakeholders.

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

All the benefits of option 4 plus:

- Increased competitiveness of food businesses in European markets.
- Reduction in fortificant costs for exempt millers.
- More choice for consumers when buying unfortified flour-based products.

Key assumptions/sensitivities/risks	Discount rate	3.5/1.5
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All of the risks and assumptions of option 4 plus:

- Unfortified flour will be readily available, either via imports or through domestic production.
- All millers producing less than 500t of eligible flour per year are producing solely for the domestic market.
- Export markets will continue to act unfavourably towards mandatory fortification and that this negatively affects the desirability of products that contain very little, albeit fortified, flour.
- Removing the fortificants from products which contain less than 10% flour will not pose a risk to consumers.

BUSINESS ASSESSMENT (Option 4)

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

Costs:	Benefits:	Net:	
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1 Introduction

1. This impact assessment covers five proposed measures relating to the Bread and Flour Regulations. These regulations lay down specific labelling and compositional rules for bread and flour in the United Kingdom. Under these rules white and brown non wholemeal wheat flour is required to have added to it specified quantities of calcium carbonate, iron, thiamine and niacin. The regulations also lay down chemical specifications for those added nutrients.
2. The fortification of flour – by which we mean the addition of the nutrients listed above into flour in order to support public health objectives – is one small part of the flour production process, that in itself fits into a wider flour milling industry linked to the markets for both milling wheat and bakery products. An overview of this wider context is set out below.

UK Flour Market Overview

Wheat is the primary grain that is used to make flour in the UK according to the UK flour milling production and usage survey, undertaken at AHDB on behalf of Defra¹. Each year the UK produces around 5 million tonnes of flour from both wheat that is grown in the UK as well as imported grain. The flour that is produced is used to make a number of different products from loaves of bread to starch, with over half of flour produced used for bread making.

The wheat that is used in flour production

Wheat is the main arable crop that farmers grow in the UK. Over the past five years (2017-2021) the UK has grown between 9.7 million tonnes and 16.2 million tonnes of wheat each year, according to the results of the Defra cereal and oilseed rape production survey². There are a number of agronomic, environmental and economic factors that influence the amount of wheat that is grown and produced domestically year by year.

Not all of the wheat that is grown can be used to mill into flour, different varieties are planted and grown depending on the intended end use – whether that is for flour milling or animal feed. Wheat varieties that are grown in the UK for flour milling are approved through a testing scheme and included on the National List. The trade association, UK Flour Millers, classify the varieties on the national list as per their end use. Figure 1 below outlines these classifications, qualities and uses.

Figure 1: UK Flour Millers wheat classifications

Classification	Qualities and uses
UK Flour Group 1	Bread-making varieties with consistent milling and baking performance. They will achieve a premium if they achieve specified requirements of 13% protein, 250s Hagberg Falling Number and 76kg/hl specific weight.
UK Flour Group 2	Varieties with bread-making potential but not suited to all grists because of variability in performance or some undesirable traits.
UK Flour Group 3	Soft varieties used for biscuits, cakes etc. They are lower in protein (11.0 - 11.5%), have good extraction rates and extensible but not elastic gluten.
UK Flour Group 4	These are both hard and soft wheats used mainly for animal feed. Millers may use some varieties in general purpose grists.

¹ [UK flour milling production and usage survey](#)

² [Defra cereal and oilseed rape production survey](#)

Source: UK Flour Millers

Each year, around 6 million tonnes of wheat is used by the milling industry in the UK. In a typical year around 85% of the total wheat used to produce flour is grown domestically. To ensure continuity in the quality of the flour that is produced, around 15% of the total wheat used is imported from North America (mainly Canada) and Europe (mainly France and Germany)³. The imported wheat typically has higher protein levels than what is grown domestically, due to differences in climate and soil.

UK flour production

When the wheat arrives at the mill it will be cleaned and then milled, where the three main components of the grain will be separated. These three components are the bran, wheat germ and endosperm.

The flour produced is used for a number of products from bread to biscuits, to ready meals to confectionary. Similar to the point that not all wheat grown is of the same variety, not all flour produced is to the same specification. The properties of the wheat used to make the flour determine the end use of the flour. For example, bread flour needs to have high protein levels to aid with gluten formation. However, flour used to make cake and biscuits needs to have less gluten to allow for the correct texture.

On average, each year, flour millers in the UK produce around 5 million tonnes of flour, with over half of that flour intended for bread making (AHDB/Defra UK Flour Millers Survey)¹. There are three types of bread flour, white, brown and wholemeal. Other flours are categorised by their end use, such as cake flour, food ingredient flour and biscuit flour. The different flours will be subject to mandatory fortification – the introduction of specific nutrients to support public health objectives – where they fall “in-scope” of the Bread and Flour Regulations and it is that fortification which forms the focus of the Impact Assessment which follows in this document.

To fortify the flour the four nutrients required are added to the flour stream by way of a premix late in the milling process. This premix is supplied either as a complete blend of all 4 nutrients together or a blend of three of the nutrients (iron, thiamin and niacin) with calcium being added separately as Calcium Carbonate.

As well as wheat, a small proportion of flour produced in the UK is made from other grains and pulses such as rye and rice.

What is flour used for?

The majority of the flour produced in the UK is for domestic use, with approximately 6% of total flour production exported each year, according to HMRC trade data⁴. The largest importer of UK flour is Ireland, which accounts for an average of 80% of all UK flour exports. Other smaller volume destinations include France, Poland and Thailand amongst others.

In terms of usage in the UK, around 60% of all flour produced in the UK is bread flour, while the flour that we see on the shelves in the supermarkets (household flour), accounts for approximately 2% of production (Defra/AHDB UK Flour Millers Survey)¹.

Figure 2 below shows the different flour categories that are collected by AHDB in partnership with Defra under the UK flour millers survey, as well as the proportion of each of total production. It is

³ [UK Flour Millers](#)

⁴ [HMRC](#)

important to note that the 'Other flour' category includes production by the bioethanol and industrial starch industries and is not used for food production.

Figure 2: Proportion of each flour category of total production

Category	Proportion of total production*
Total bread flour	56%
Biscuit flour	9%
Cake flour	2%
Household flour	2%
Food ingredients flour	8%
Other flour**	23%

Source: AHDB, Defra

*Proportions are based off the previous five-year average (2017-2021).

**Includes output from bioethanol and industrial starch industries.

UK bakery market

In 2019/20 on average over half a kilogram of bread was bought per person per week according to the Defra Family food statistics⁵. Over the course of a year, this equates to around 26kg loaves of bread being purchased per person each year. It is estimated that 11 million loaves of bread are sold every single day in the UK, according to the Federation of Bakers (FOB)⁶.

Wrapped and sliced bread accounts for around 85% of UK bread production, while in-store bakeries produce approximately 12%, with the remainder being made up of high street/craft bakeries, according to FOB⁷.

1.1 Justification of analytical approach in the IA

3. In this pre-consultation IA, other than for the mandatory fortification of folic acid, we have focused on the qualitative costs and benefits of the shortlisted options identified. This is because there are some key questions around the monetary value of costs and benefits that we are looking for feedback on as part of the consultation. Monetised costs and benefits will be presented as part of future assessments that will be completed post-consultation. We believe the joint impact of measures investigated will be less than £5m per annum, however we are still carrying out a full impact assessment. This is to provide a more thorough analysis and to show that the proposed measures have been supported with robust evidence. Furthermore, DHSC has already committed to providing full costings for the folic acid aspects of the policy within the final post-consultation impact assessment. We also recognise that the impact of individual measures, particularly for specific devolved administrations, will be lower than that threshold. Some specific points relating to the approach taken in the impact assessment to follow are set out below.

1.1.1 UK approach

4. This assessment covers the whole of the UK. The scope of it was agreed following discussions within the two related Government departments – Defra and DHSC - and the devolved administrations and in line with the commitments set out under common framework agreements and the Food Compositional Standards and Labelling (FCSL) Framework. The FCSL sets out non legislative arrangements for cooperation between

⁵ [UK flour milling production and usage survey](#)

⁶ [Federation of Bakers \(FOB\)](#)

⁷ [Federation of Bakers \(FOB\)](#)

officials in the Department for Environment, Food and Rural Affairs (Defra, Food Standards Scotland (FSS), the Food Standards Agency (FSA) in Wales and the Food Standards Agency in Northern Ireland about FCSL Policy. The UK wide scope reflects the fact that much of the relevant data on the milling industry is collected on a UK-wide basis and separate datasets for each devolved administration often do not exist.

5. However, it is recognised that each devolved administration will need to form their own judgement on the impacts which potential amendments to the existing BFRs. To support this, every effort has been made to separate out data for England, Scotland, Wales, and Northern Ireland where relevant by the UK-wide economist team working on the assessment. Much of the data presented is for context to facilitate responses to the questions in this assessment and the accompanying consultation.
6. Where separate data does not exist for a particular devolved administration, sensible assumptions will be made in subsequent assessments to assess the impact of the proposed measures on a devolved administration level. In addition, all responses and feedback which reflect impact at the devolved administration level will be utilised in subsequent assessments and will be greatly appreciated.

1.1.2 Assessment structure

7. Where possible the impact of measures covered in this assessment has been broken down for England, Scotland, Wales and Northern Ireland. It has been necessary to demonstrate impact on both a measure-by-measure basis and within groups of different measures (with similar policy objectives), which form the options formally assessed in this document. This is important so that the number of options considered stays manageable whilst providing sufficient detail on the costs of benefits of each specific potential intervention in turn.
8. For this reason, the sections that follow in this assessment will often provide comment on overall impact or the impact of a group of intervention measures before digging down further on a case-by-case basis.

1.1.3 Folic acid consultation and Impact Assessment

9. Introduction of the requirement to add folic acid to non-wholemeal wheat flour is part of the group of measures being considered in this assessment. That intervention – unlike all other measures included in this assessment - has already been subject to a consultation exercise⁸ and is included in this latest consultation to establish the level of fortification.
10. Since the consultation process concluded, DHSC have been conducting a large amount of analysis, focusing on the level of fortification with folic acid that is to be proposed. This analysis can be found in Annex B at the end of the document along with the associated policy context.
11. Further assessments of the group of measures within scope of this document will include how the costs and benefits related to the introduction of folic acid into flour will interact with other measures and how that affects overall impact – e.g. economies of scale relating to making a number of labelling changes simultaneously.

⁸ [DHSC Consultation Exercise](#)

1.1.4 Improvement notices

12. A move to a new more proportionate approach to enforcement is also being proposed in line with other food legislation. This involves moving away from criminal sanctions as the only enforcement measure for breaches of the BFR regulations to introducing the use of improvement notices as a frontline enforcement option but with a backstop criminal sanction for failure to comply with the improvement notice.
13. Non-compliance with the BFR fortification requirements is currently a criminal offence. If a business does not meet the requirements in the regulation, it is breaking the law and can be fined. This approach is seen to be inconsistent with modern enforcement measures in place in other food standards legislation - for instance, the Food Information Regulations, the Honey Regulations and the Fruit Juices & Fruit Nectars Regulations. In addition, continuing to classify all breaches of fortification requirements as a criminal offence would retain costly court cases as the only way of addressing non-compliance when compliance could be achieved via use of simpler, more proportionate, and less costly enforcement option. Government policy is to avoid the use of criminal sanctions and minimise the use of the courts' time when bringing in new legislation. The continued use of criminal sanction as a frontline enforcement approach would need to be justified and is likely to be viewed unfavourably by the Ministry of Justice (MoJ) during a Justice Impact Test, particularly given the offences would relate to a non-food safety breach.
14. Although this change in enforcement arrangements is not covered in detail in the assessment that follows, it will be analysed within future assessments, where the detailed costs and benefits will be assessed and quantified where possible. This approach has been taken both because it is the enforcement of the regulations rather than the regulations that are changing in this respect and also to recognise the differing starting positions of the devolved administrations⁹ and manner of providing for improvement notices under existing legislative frameworks (given this is a pre-consultation IA covering all of the UK). The FCSL common framework recognises that enforcement provisions are a matter for individual devolved administrations and outside its scope.
15. The introduction of improvement notices as an enforcement option is also covered within the accompanying consultation document and all feedback provided to the relevant question(s) will be utilised and greatly appreciated.

1.2 Key regulation references

Food is a devolved policy area, any legislative changes following consultation will be implemented through four separate statutory instruments for England, Scotland, Wales and Northern Ireland to give effect to the same legislative outcome across the whole UK.

The following list provides an overview of legislation that is referred to throughout this document. There are currently some differences in how food legislation is applied across the UK. To avoid repeating these distinctions throughout this document the abbreviations highlighted in bold will be used to encompass how the rules are applied across the UK. Where necessary, distinctions between how the rules apply across the UK will be explained.

16.

- i. **The Bread and Flour Regulations (BFR)** – The Bread and Flour Regulations 1998 and The Bread and Flour Regulations (Northern Ireland) 1998 which lay down

⁹ Currently, improvement notices are not used enforcement of food standards regulations in Scotland. However, Scotland intends to take a similar approach with the introduction of compliance notices but for all food standards requirements at the same time rather than as individual regulations are reviewed. [A separate consultation was held on the introduction of compliance notices for food standards requirements in Scotland](#). Hence, the proposal applies to potential changes to the BFRs in England, Wales and Northern Ireland only.

specific rules on the labelling and compositional standards of bread and flour in Great Britain and Northern Ireland respectively.

- ii. **Regulation 1925/2006:** This lays down rules for the addition of vitamins and minerals and of other substances to food. In Great Britain, this Regulation has been retained in domestic law under the European (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- iii. **Regulation 1333/2008:** This lays down the rules on food additives: definitions, conditions of use, labelling and procedures. In Great Britain, this Regulation has been retained in domestic law under the European (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- iv. **Regulation 231/2012:** This lays down specifications for food additives. In Great Britain, this Regulation has been retained in domestic law under the European (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- v. **Regulation 1169/2011:** This lays down rules on the provision of food information to consumers. In Great Britain, this Regulation has been retained in domestic law under the European (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.

Food Information Regulations 2014 – Food Information (England) Regulations 2014; Food Information (Scotland) Regulations 2014; Food Information (Wales) Regulations 2014; Food Information (Northern Ireland) Regulations 2014 provide enforcement provisions for rules on the provision of food information to consumers in England, Scotland, Wales and Northern Ireland respectively.

2 Problem under consideration

Key points

- There are disparities between the Bread and Flour Regulations and wider food legislation that have arisen following EU exit.
- UK government and devolved administrations have also committed to reviewing other issues which have been raised by stakeholders.
- The BFRs have been kept largely unchanged since their establishment in 1998.

2.1 Issue to be addressed

17. There are multiple areas in which it has been suggested that the current Bread and Flour regulations (BFR) could be improved so that they are more favourable to industry, resolve ambiguity in legislation, and more clearly interact with wider food policy. Ultimately, if these aims are fulfilled, then we should further achieve wider policy objectives, such as supporting the productivity and resilience of the bread and flour industry (and the wider

food industry) through updated legislative arrangements & achieving public health outcomes set out in the associated folic acid analysis contained within this impact assessment.

18. More specifically, ambiguity is seen to exist in the legislative arrangements covering the fortification criteria of nutrients, calcium carbonate and the definition of wheat. The regulations are also seen to be potentially disproportionately burdensome for small scale millers or those manufacturers who use a very small amount of flour in food products. Consequently, the suggestion is that there needs to be a number of amendments to the BFR in order to reduce the burden to businesses, confusion in enforcement criteria, and disproportionate challenge to small scale millers and other businesses. In addition, the introduction of folic acid into flour is seen to bring further benefits for businesses, consumers, HMG and the public as a whole.
19. More details on the problems under consideration for each potential measure covered within this assessment can be found below. In each case, a summary paragraph is included before a sub-section containing additional detail.

2.1.1 Mandatory Fortification of UK-milled Non-wholemeal Wheat flour with Folic Acid

20. The previous consultation on the proposal to add folic acid to flour to help prevent NTDs provided detail on why folic acid is important during pregnancy. Current Government advice is for women who could become pregnant to take a daily folic acid supplement of 400 micrograms before conception and up until the 12th week of pregnancy; with some women, for example those with a family history of NTDs and those with certain conditions or taking some medications, advised to take a daily supplement of 5 milligrams until the 12th week of pregnancy.
21. Around half of pregnancies in the UK are unplanned. Those planning a pregnancy can follow Government advice regarding folic acid supplementation, to reduce the risk of NTDs, However, for unplanned pregnancies, these messages may not have reached the women in time to increase their folate intake before conception, hence the call for intervention to achieve a reduction in NTD-affected pregnancies, and the resulting impact on families and the NHS. NTDs are often serious in nature and can significantly affect both the life expectancy and quality of life in those affected by the conditions. By fortifying non-wholemeal wheat flour with folic acid, the blood folate levels of women who could become pregnant across the population should increase through dietary consumption, therefore reducing the number of NTD affected pregnancies.

Further Details

22. The three main NTDs included in the analysis in respective order of frequency are Spina Bifida, Anencephaly and Encephalocele. Current data suggests there are around 1.2 to 1.3 NTD affected pregnancies per 1,000 births in the UK. Given the relative severity of NTDs, even a small number of cases carry a large cost to the NHS and the wider economy due to reductions in labour productivity.
23. Given the existing inclusion of four fortificants in non-wholemeal wheat flour (Niacin, thiamine, iron and calcium), the addition of folic acid into the same kind of flour is the most convenient and cost-effective way for industry to enact the changes to regulations.
24. Data from 2015-16 shows that only 10% of women who could become pregnant had a total folate intake above the recommended level of 400ug a day, and whilst only a proportion of these women will become pregnant, there will be a heightened risk of NTD affected pregnancies that could be reduced with mandatory fortification.

2.1.2 Minimum Level of Nutrients Added to Flour

25. There is an opportunity to improve the regulatory framework governing flour fortification requirements for UK businesses by providing clarity on the interaction of overlapping legislation. The BFR sets minimums for the addition of calcium, iron, niacin and thiamine in flour produced in the UK with some at lower levels than 15% of their NRVs. There are also minimums that would apply to these nutrients when they are added to food controlled by Regulation 1925/2006 on the addition of vitamins and minerals to foodstuffs.

26. Article 6(6) of Regulation No 1925/2006 requires that where nutrients are added to food, it must be at a significant amount - defined in Regulation 1169/2011 as 15% of the nutrient reference values (NRVs). As the two minimum levels differ in some cases, there may be ambiguity around which takes precedent resulting in confusion in terms of compliance. The minimum fortificant requirements of the BFR compared with NRVs is illustrated in table 1 below.

Table 1: Minimum fortificant requirements of the BFR compared with NRVs

Nutrient	Current Minimum Levels Amount per 100g Flour in BFR's	NRV per 100g, as outlined within Annex XIII of 1169/2011	15% of the respective NRV per 100g	Is 15% an increase on the existing BFR?
Calcium²	235-390mg (calcium carbonate) 94-156mg (calcium) ³ As percentage of NRV (per 100g): 11.75%-19.5%	2000mg (calcium carbonate) 800 mg (calcium)	300mg (calcium carbonate) 120mg (calcium)	Stricter but calcium carbonate is generally added at the mid-range and thus is well above the 15% minimum amount.
Iron	≥1.65mg As percentage of NRV (per 100g): 12%	14 mg	2.1mg	Stricter
Thiamin⁴	≥ 0.24mg (thiamine hydrochloride) 0.21mg (thiamine) As percentage of NRV (per 100g): 19%	1.26mg (thiamine hydrochloride – rounded to 2 dp) 1.1 mg (thiamine)	0.19mg (thimaine hydrochloride) 0.165mg (thiamin)	Looser
Niacin	≥ 1.60mg As percentage of NRV (per 100g): 10%	16 mg	2.4 mg	Stricter

2.1.3 Calcium Carbonate Specification

27. There is also an opportunity to provide further clarity and improve the regulatory framework governing flour fortification requirements by UK businesses by ensuring consistency with overlapping legislation covering specifications of food additives. In relation to calcium purity, the misalignment relates to the additive specification applied by regulation 6 on purity criteria for calcium (in Regulation 231/2012, applied by Regulation 1925/2006) and the current requirements of the BFR. As Regulation 1925/2006 Article 5 states that purity criteria for vitamins and minerals “for other purposes than those covered by this Regulation” apply, this would indicate that Regulation No 231/2012 (which lays down specifications for food additives listed in Annexes II and III of Regulation 1333/2008) also

applies. This contains a criterion for calcium which is stricter in some instances than that currently prescribed in the BFR, creating challenges in terms of compliance and enforcement.

28. Previously, the supply of calcium used in UK flour fortification was sourced from a single quarry in England. It met the BFR specification (pharmacopeia) but exceeded the purity criteria in Regulation 231/2012 (E170) for two variables (acid insoluble matter and fluoride).

Table 2:

	Acid insoluble	Fluoride
E170 Regulation 231/2012	0.2%	50 mg/kg
Steeple Morden Source	0.25%	100 mg/kg

29. Calcium carbonate composition is determined by the natural geological makeup and is therefore unvarying and very difficult to change. Where the E170 criteria have needed to have been met, (e.g. for exports to the EU) industry has moved to using calcium imported from France instead. This enables them to meet the requirements in both the BFR and Regulation 231/2012 to supply both the domestic market and export to the EU without using different calcium carbonate sources for different markets. Given that the quarry producing the calcium carbonate in the UK is no longer producing calcium carbonate for human consumption, industry is now entirely using the imported source of calcium, compliant with the specification in Regulation 231/2012.

2.1.4 Scope of the Regulations

30. The BFR currently refers to the need to fortify “flour derived from wheat.” The meaning of wheat in this context may need to be defined to provide clarity on which type(s) of wheat must comply with the fortification requirements in the BFR. The scientific taxonomy for “common wheat” is ‘*Triticum aestivum*’ but there are several more subspecies of the *Triticum* genus including spelt and other ancient grains which are gaining more use in milling processes, and all are derived from “wheat”. There is hence an opportunity to provide greater clarity to facilitate compliance and consistency in enforcement approaches.
31. The scientific taxonomy for “common wheat” is ‘*Triticum aestivum*’ but there are several more subspecies which are gaining more use in milling processes, and all are derived from “wheat”. Currently, the levels of consumption of wheat flour made with grains other than “common wheat” are comparably very low. In the UK approximately, 5 million tonnes of wheat are milled each year for human consumption¹⁰. Alternative grains to “common wheat” account for around 1.8% of this¹¹.
32. Whilst industry have been taking the view that BFR fortification requirements apply only to ‘common wheat’ or ‘bread wheat’ (and this was believed to be the original policy intention), some local enforcement officers/trading standards have previously considered that spelt flour could be captured by the regulations given they only specify “wheat”. Therefore, there is an interpretation issue and a need to provide clarity for businesses to facilitate compliance and consistency in enforcement approaches.

2.1.5 Exemptions - Treatment of small-scale mills within existing Bread and Flour Regulations

Summary

¹⁰ Facts and Figures (ukflourmillers.org)

¹¹ Estimate based on approximate figures from industry contact.

33. Flour is sometimes milled in relatively small volumes – often when small-scale, traditional milling businesses are involved rather than industrial-scale milling of grain. Traditional milling tends to focus on producing stoneground flours using horizontal millstones, where wind or water is the primary source of power. Industry stakeholders have argued that, due to the nature of these small-scale milling producers, the requirement to fortify flour endangers their future viability by forcing them to get involved in an activity which is not operationally practical and places a proportionally more significant burden on them, compared to larger, industrial-scale businesses. There is hence a need to examine whether an exemption to the existing BFRs should be granted for these types of businesses.

Further detail

34. Traditional and small mills are often charitable bodies, where the sale of flour for commercial purposes (normally to local/regional markets) is a significant aspect of the enterprise. Industry estimates indicate that there are around 35 small mills producing flour commercially and 150 producing flour in very low volumes to demonstrate the traditional milling process and raise funds for upkeep.

35. The percentage of milled flour that small-scale mills (defined here as producing less than 500t of flour per year) contribute to overall UK flour production is very low. In the year 2019-2020 the Traditional Cornmillers Guild (TCMG) estimate output of traditional mills was less than 0.02% of the nation's flour production¹². Defra have received requests for these small-scale mills to be exempt from the fortification requirements from industry stakeholders. Defra had intended to provide this exemption in the BFR when first raised in 2013 – as part of a wider review of the regulations – but a ministerial decision was made not to update the legislation at that time.

36. The BFR burden placed on small-scale millers would also potentially increase further with other measures proposed for the BFR – i.e. introduction of folic acid fortification to flour and increased levels of other fortificants required. Stakeholders also argue that the impact on human health (or loss of potential benefit when considering potential fortification of flour with folic acid) from introducing this exemption would be very small, given that output accounts for such a small proportion of UK flour production. The reasoning for fortification being seen to be impractical and more burdensome for small-scale millers is set out below:

- The technology used in small scale mills – often flour mills powered by wind or water energy - means it is not possible to dose flour accurately with fortificants in consistent amounts, especially the small proportions required by the BFR. Some of the technology in these mills originated in the 19th century and hence was not designed for the precise distribution of fortificants required by the regulations.
- To install the machinery required is impractical given the Listing restrictions in the buildings that many traditional mills are housed in (Grade 2*, Grade 1, Scheduled Ancient Monuments). The costs involved with purchasing and installation are also viewed to be prohibitive when compared to the revenue of most small-scale mills.
- Small-scale mills typically have restricted space for storage of grain meaning that millers purchase small tonnages at any one time. The requirements of the BFR entail that each “parcel” of flour would need to be tested for calcium, thiamine, niacin etc to ensure that the fortificants have been sufficiently mixed in and demonstrate that the flour has been fortified to the required levels. Small-scale mills argue that they cannot afford the additional cost overhead of testing every parcel of flour once

¹² Pre-assessment information request from Traditional Cornmillers Guild (TCMG)

produced. The argument is hence that there would be a much lower per-unit cost of testing (using dedicated technology) in larger, industrial-scale mills where throughput is much more significant.

- Income derived from selling non-wholemeal flour is seen to be a vital part of the turnover of all working mills, in turn safeguarding the future of the listed buildings they operate from and the tradition of small-scale milling. Should new requirements for increasing the levels of existing fortificants and additionally fortifying flour with folic acid lead small-scale millers to conclude that they should focus their output on unfortified flour (e.g. wholemeal), it is expected that their future income could be severely restricted given consumer preference for non-wholemeal flours.

2.1.6 Exemptions - Treatment of flour used in final products containing only a small amount of flour

Summary

37. Flour is sometimes used in small amounts in final food products. It has been suggested that the health benefits from fortifying the flour going into these final products are not significant enough to justify the costs involved with retaining the fortification requirement and associated logistical challenges for such products. There is hence a need to examine whether an exemption to the existing BFRs should be granted for the flour that goes into these types of products.

Further detail

38. The idea that flour destined for products which contain only a small amount of flour could be exempted from BFR fortification requirements is not new. A threshold of 5% and 10% was previously consulted on under the Red Tape Challenge exercise in 2012 but industry was generally not supportive at that time because it was seen to be logistically too challenging.

39. However, the landscape has changed and when new food information rules came into force, producers were required to label all of the mandatory fortificants on the ingredients list of products. This new labelling requirement could put UK producers at a competitive disadvantage when competing for business and marketing in the EU, as some member states have an unfavourable view of mandatory food fortification. Therefore, opportunities to export to the EU could be compromised, as food businesses may choose an unfortified over a fortified product.

This issue is being re-addressed now, because:

- a) Firstly, there is no longer the capacity to source unfortified flour for the domestic market from EU member states. While the UK was an EU member state it was necessary and appropriate to recognise products from other EU and EEA member states that did not meet the fortification requirements in the BFR to ensure free movement of goods within the EU Single Market. Since leaving the EU and in order to stay compliant with WTO rules, the mutual recognition arrangement with EU member states was removed, with the change coming into effect in October 2022 in Great Britain.
- b) Secondly, producers of products that contain less than 10% of flour will likely need to maintain two separate production lines if looking to serve the domestic and export markets – with the former producing food containing fortified flour (compliant with BFR) and the latter producing food containing unfortified flour (to meet the consumer

preferences of the EU market). This may cause significant logistical and financial impacts for those businesses. As the amount of flour that goes into the products for the domestic market is very low, the health benefits from the fortificants involved are seen to be less than the logistical and financial costs identified from having the two separate production lines.

40. As the quantity of flour that goes into the products in question is very low and by extension, the amount of fortificants consumed are marginal, it is hoped that this consultation may gather more evidence on the severity of these issues, the strength of consumer preferences of the EU market in relation to products containing very little flour, the number of producers that may be likely to adopt a dual production process to serve both the domestic and export markets; and the costs associated with doing so.

41. An exemption on fortifying flour used in products which contain less than 10% flour has been proposed as products under this threshold are not deemed to be the key vehicles which contribute to the dietary intakes of these added nutrients. It is therefore expected that exempting these products would have negligible impact on the effectiveness of the policy as a public health measure. This assumption is consistent with previous modelling exercises carried out by the Scientific Advisory Committee on Nutrition (SACN) which excluded contribution of flour intakes of products estimated to contain less than 10% flour. FSS modelling on the impacts of folic acid fortification exempted products containing less than 4% non-wholemeal wheat flour, this implies that the modelled impact of folic acid fortification could be achieved if products containing less than 4% non-wholemeal wheat flour are exempt.¹³ Analysis of data from 2016-19 of the UK-wide National Diet and Nutrition Survey suggests that the contribution of products which contain 4-9% non-wholemeal wheat flour (bringing total exemption to less than 10%), to overall intakes of non-wholemeal wheat flour is less than 5g/day. Therefore, intake of folic acid from products containing 4-9% non-wholemeal wheat flour is likely to be small.

42. In Northern Ireland, the mutual recognition arrangements with the EU still apply, meaning that unfortified flour can be sold for use in the manufacture of products for both the domestic and EU export markets. Under EU law, it is necessary to recognise products from the EEA that do not meet the fortification requirements (as long as they are legally sold and in free circulation in the member state from which they are imported), to ensure the free movement of goods on the EU single market. This means that the policy options discussed below are likely to have a negligible, if any, impact on non-milling businesses in Northern Ireland. However, potentially resulting changes to legislation would bring Northern Ireland further into alignment with the rest of the UK, whilst giving Northern Irish millers the opportunity to produce unfortified flour for the NI market as well as the GB market for use in exempt products.

2.2 Rationale for Government Intervention

43. At the top level (considering all the measures under consideration), government intervention is required to improve existing legislation in the following respects:

- **Interaction with wider food regulations** - To address the inconsistencies between the Bread and Flour Regulations and other overlapping food regulations. This will mitigate some of the ambiguity over how legislation is applied.
- **Scope of the regulations** - To clarify potential differing interpretations over the scope of fortification requirements for wheat flour. This will allow consistent understanding

¹³ FSS modelling on the impact of fortifying flour with folic acid.

across the flour supply chain and local enforcement of what types of flour are subject to these fortification requirements.

- **Exemptions** – To address regulatory burdens disproportionately affecting some businesses where public health outcomes of the policy are not compromised to the same extent.

44. The scope to consider non-regulatory measures to address the individual challenges as well as the wider group of problems this assessment looks to examine is investigated in section 3, which follows on from this section.

45. A short description of the rationale for intervention on a measure-by-measure basis is also included below.

2.2.1 Minimum Level of Nutrients Added to Flour

46. Government intervention is required to improve existing legislation to make it clearer for businesses and enforcement authorities. The objective of the intervention would be to update and align BFR legislation covering fortificant levels with the principle of fortification set out in Regulation 1925/2006 and the addition of vitamins and minerals to food at a significant level. This will help in providing greater clarity for all and making it easier for industry to be compliant, as well as ensuring consistent enforcement. The result would be to improve the BFR legislation by addressing issues of ambiguity in the regulations to provide clarity for businesses.

2.2.2 Calcium Carbonate Specification

47. Government intervention is required to improve existing legislation to make it clearer for businesses and enforcement authorities. The objective of the intervention would be to ensure coverage of calcium carbonate purity in the BFR legislation is not at odds with wider food additive rules. As well as providing greater clarity and thereby making it easier for industry to be compliant (& help enforcement authorities to be consistent). The result would be to improve the BFR legislation by addressing issues regarding alignment of the regulations with wider food rules to provide clarification for businesses.

2.2.3 Scope of the Regulations

48. Government intervention is required to remove the potential for confusion amongst businesses and enforcement officers in relation to the definition of “wheat.” This would clarify whether the use of ancient grains, such as spelt, is out of scope of the BFR in terms of fortification requirements. The result of the intervention would hence be to improve the BFR legislation by reducing the risk of confusion in relation to compliance and enforcement processes.

2.2.4 Exemptions - Treatment of small-scale mills within existing Bread and Flour Regulations

49. Government intervention is required to ensure the future viability of small-scale mills by addressing potentially significant challenges presented by existing and proposed fortification requirements due to the practical and technological limitations of small-scale operations. The result of the intervention would be to improve the BFR legislation by providing a measure that tackles the risks set out above.

2.2.5 Exemptions - Treatment of producers of final products containing only a small amount of flour

50. Government intervention is required to reduce regulatory burden for industry where nutritional benefits are expected to be lower than the associated logistical and financial challenges involved with maintaining two separate production lines for producers of products containing very little flour wishing to supply both UK and export markets. It has been suggested that the health benefits from fortifying flour that makes up less than 10% of final products are not significant enough to justify retaining the fortification requirement and associated logistical challenges for such products. The result of the proposed intervention would hence be to improve the BFR legislation by reducing the number of instances where the challenges associated with fortification for producers of these products exceed the potential gains from associated health benefits.

3 The Policy Objectives and Intended Outcomes

51. Our primary objective of this intervention is to improve the existing legislation within the BFR's, to ensure that they remain fit for purpose and continue to support UK industry whilst protecting consumers. In order to address the areas of the legislation where improvements may be required, we have included secondary objectives for each area below:

*i. **Interaction with wider food regulations***

To resolve the interpretation issues regarding how the BFR's interact with overlapping food regulations.

*ii. **Scope of the regulations***

To ensure that the understanding of the regulations is consistent throughout industry and enforcement. Thus, ensuring that the interpretation of the rules is clear for industry and enforcement authorities.

*iii. **Exemptions***

To ensure that the regulations do not disproportionately affect certain businesses or types of businesses without compromising the targeted outcomes.

*iv. **Folic acid***

- 1) To minimise the number of people who exceed the Guidance Level of folic acid intake.
- 2) To ensure groups that cannot or do not want to consume folic acid in flour are properly catered for.
- 3) To minimise the administrative and financial burden on business.
- 4) To minimise the impact on current trading agreements, both domestic and international.

52. On a measure-by-measure basis, the policy objectives are seen to be as follows:

*i. **Mandatory Fortification of Non-Wholemeal Wheat flour with Folic acid***

The main objective is to reduce the incidence of NTD affected pregnancies by increasing the dietary intake of folic acid, and as a result blood folate level, in women of childbearing age. This will lead to significant social and economic benefits.

*ii. **Minimum Level of Nutrients Added to Flour***

The main objective is to resolve the interpretation issues regarding how the BFR's interact with overlapping regulations (Regulation 1925/2006 & Regulation 1169/2011) on the flour fortification requirements and thus provide legal clarity for industry and enforcement authorities. This will make it easier for industry to be compliant and remove ambiguity in respect to the application of enforcement measures by enforcement authorities.

iii. **Calcium Carbonate Specification**

The main objective is to resolve the interpretation issues regarding how the BFR's interact with overlapping regulations (Regulation 231/2012) on the specifications of calcium carbonate used in fortification and thus provide legal clarity for industry and enforcement authorities. This will make it easier for industry to be compliant and enforcement authorities to be consistent.

iv. **Scope of the Regulations**

The main objective is to ensure that the understanding of the regulations (what type of wheat falls within the scope of the fortification requirements) is consistent throughout industry and enforcement. Thus, ensuring that the interpretation of the rules is clear for industry and enforcement authorities.

v. **Exemptions - Treatment of small-scale mills within existing Bread and Flour Regulations**

The main objective is to mitigate the burden of the BFR's on small scale millers. Secondly it is to ensure their future viability by addressing the significant challenges that exist with fortification due to the practical and technological limitations of small-scale operations. Finally, it is to achieve this without compromising the policy goals of wider health objectives.

vi. **Exemptions - Treatment of flour used in products containing only a small amount of flour**

The intervention intends to reduce regulatory burden for industry where nutritional benefits are expected to be lower than the costs associated with meeting the regulations. As a result of the intervention, flour that makes up less than 10% of final products will not need to be fortified, which will lead to the preservation of export markets and UK producers' competitiveness within them.

4 Options Appraisal

4.1 Options considered

53. There are a number of individual potential measures within the remit of this assessment, and these would have impacts across the UK. Although that means that there are a large number of possible permutations¹⁴ that could be progressed, we have investigated five main options in detail within this IA in order to keep the number of options manageable. However, in the detail further down this assessment, there is also consideration of different options on a per-measure basis to demonstrate the groundwork that has been performed when considering which measures should be "grouped up" into the options set out below.

54. The options have been developed looking at different levels of additionality in terms of the scale of government intervention that could take place. The grouping of measures chosen for individual options are designed to reflect the similarities in terms of policy objectives and consultation structure. Feedback from the consultation will be used to inform both the groups of measures and the individual interventions themselves – and different

¹⁴ Over a hundred once alternative options relating to individual measures are taken into account.

combination of measures could be considered in future assessments should feedback suggests that needs to be the case. The options are:

- Option 1 – Do nothing (Do not amend the Bread and Flour Regulations 1998)
- Option 2 – Introduce folic acid fortification of flour (as the only amendment to the BFR)
- Option 3 – As per Option 2 plus look to address BFR’s interactions with wider food regulations (see below)
- Option 4 – As per Option 3 and clarify the scope of the regulations with respect to fortification requirements for wheat flour (see below)
- Option 5 (preferred option) - As per Option 4 and introduce specific exemptions from the regulations to reflect industry feedback (see below)

55. The proposal to introduce a requirement to add folic acid into flour has already been subject to a pre-consultation exercise and hence there will be regular references to the detail in the accompanying assessment¹⁵ in the detailed sections found later in this IA. The individual measures proposed – described in more detail later – which sit under the categories specified in Option 3, 4 and 5 above are:

i. Interaction with wider food regulations

- Amend BFRs to raise required fortificant levels to the 15% NRV level required by overlapping legislation on the addition of vitamins and minerals to food.
- Amend BFRs to remove existing calcium carbonate criteria, requiring millers to comply with the specification in Regulation 231/2012 instead.

ii. Clarifying scope of the regulations with respect to fortification requirements for wheat flour

- Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to “common wheat” *Triticum aestivum* only.

iii. Introduce specific exemptions to reflect industry feedback

- Introduce exemptions from all fortification requirements for small-scale millers.
- Exempting lower flour content foods from all fortification requirements where flour makes up less than 10% of the final product ingredients.

56. Option 5 is our preferred option as it best meets the policy objectives of the intervention. It will:

- a. Improve public health outcomes via the fortification of flour with folic acid.
- b. Align the BFRs with wider food rules and provide clarity to businesses and enforcement authorities
- c. Make the policy intervention more deliverable by including exemptions for businesses who are disproportionately affected by the regulations.

Implementing this option also means that these changes will happen at the same time which makes familiarising with these changes simpler for businesses and enforcement authorities.

¹⁵ Fortification of Flour with Folic acid Impact Assessment

4.1.1 Non-regulatory Options

57. Given that this assessment formally analyses groups of potential measures together to produce the options set out in section 4.1, strong consideration was given to non-regulatory options in a grouped context – leading to the non-regulatory option listed in Table 3 below and relating to all proposed non-folic acid measures (see below for more on folic acid). We have not focused on this option or other possible non-regulatory options in detail in this document as they were not seen to be sufficiently effective at addressing our rationale for intervention.
58. A large part of the reason for that assessment is a group of quite differentiated measures are being considered and hence finding a non-regulatory option that is relevant and achieves the policy objectives & rationale for intervention of all of the proposed interventions is extremely difficult. For instance, it might be possible for government to produce marketing material to encourage industry to produce flour as per the requirements of EU legislation relating to fortification – but this would not tackle issues with the BFR being seen to be disproportionately burdensome for some businesses. The differentiated nature of the various proposed measures hence means that any non-regulatory options that were designed to try to apply to all of them would need to be suitably generic – which in turn limits the effectiveness of those options to the various specific policy objectives of each proposed measure individually¹⁶. However, we welcome views during the consultation whether the non-regulatory option considered in Table 3 below or other possible non-regulatory options should be recommended for further analysis in future assessments and remain fully open to considering those options in much more detail in the next stage of analysis.
59. For folic acid, non-regulatory options were considered as part of the pre-consultation impact assessment carried out in 2019¹⁷ which included conducting folic acid supplement awareness campaigns and encouraging voluntary fortification of flour with folic acid. These options were not quantified in detail as they were not seen as being effective at addressing the problem of Neural Tube Defects. Please see the folic acid pre-consultation impact assessment for further details.

4.2 Alternative options considered

60. A set of “long list” options was considered on a per-measure basis and these – along with details of how they were whittled down into a per-measure shortlist – are presented in the detail set out later within this IA. In relation to the four “grouped” options above, other options designed to achieve the policy objectives have been considered and are set out below. These have not been quantified or considered in detail but are presented for context and completeness.

Table 3: Consideration of alternative options

Option	Consideration
Other combinations of measures under the categories of “improving regulatory clarity” and “introduce specific exemptions to reflect industry feedback.”	For the purpose of managing the analysis within this assessment and reflecting the structure of the accompanying consultation, individual measures with a broadly similar policy objective have been

¹⁶ Also note that non-regulatory options were also considered for each individual measure relating to the existing BFRs (i.e. all but Folic acid) on a measure-by-measure basis. Those measure-by-measure non-regulatory options and the initial assessment of those can be found in Annex A.

¹⁷ [Fortification of Flour with Folic acid Impact Assessment](#)

	grouped up in the shortlisted options. This will be reviewed upon receipt of consultation feedback.
Introduce all potential changes via guidance accompanying the Bread/Flour legislation rather than amendments to the legislation itself. (Non-regulatory option)	A significant focus on many of the policy objectives is around regulatory clarity and this will not be improved if amendments to legislation are not made – it is the differences in overlapping legislation itself that leads to the lack of clarity many of the proposed legislative measures are designed to address. Accompanying guidance would also not give the industry the level of flexibility which could be achieved by implementing the measures covering potential exemptions and hence tackling the disproportionate burden of the regulations on some businesses. Encouraging the voluntary fortification of flour with folic acid was considered as part of the pre-consultation impact assessment produced previously ¹⁸ .
Introduction of all/some of the measures on a phased basis – for instance, splitting the implementation of Option 4 above into three phases to reflect the order of option 1 to 3.	Whilst the implementation of measures around the introduction of exemptions could potentially be delayed, it is felt that delaying the implementation of the policy to require fortification of flour with folic acid or measures around improving regulatory clarity would be problematic. The proposal to require fortification with folic acid has already been subject to a consultation process and has considerable support from a wider public health perspective. Measures relating to improving clarity are looking to protect industry members from legal challenge which could result from different interpretation of requirements in overlapping regulations, and it is felt clarity is needed in that area as soon as possible. Consultation feedback relating to the timing of implementation of the various measures will be considered in final assessments.

4.3 Shortlisted options

61. Following on from the discussion above, the remaining options are described in more detail below.

i. Option 1 – Do Nothing

As the name suggests, this option would involve making no changes to the existing BFRs at all. Measures looking to improve regulatory clarity, exemptions on the basis of industry feedback and mandatory fortification of flour with folic acid would not be introduced into the BFRs. It is possible that the latter could still be introduced via other legislation covering food manufacturers (such as millers) but that would not be “in scope” for this assessment, which purely considers potential changes to the BFRs.

ii. Option 2 - Introduce folic acid fortification of flour only

¹⁸ Fortification of Flour with Folic Acid Impact Assessment

This option would entail amending the BFR to allow the fortification of flour with folic acid. No further amendments to the BFRs would be made. This measure has already been subject to a pre-consultation IA¹⁹.

Since the pre-consultation IA and subsequent feedback, the level of folic acid that could be introduced into flour has been considered, using the FSS modelling. A summary of that analysis and the associated policy context can be found in Annex B.

iii. Option 3 – As per Option 2 plus look to address BFR’s interactions with wider food regulations

This option would build on option 2 above but also involves two additional measures to address inconsistencies between the Bread and Flour Regulations and the other overlapping food regulations, as per the below:

- Amend BFRs to raise required fortificant levels to 15% of the NRV in line with overlapping legislation on the fortification of foods generally - This option would involve raising the minimum levels of calcium, iron, and niacin so that they are all level with the 15% NRV threshold specified in Regulation 1925/2006. By aligning BFRs with the horizontal rules & wider nutritional legislation (Regulation 1925/2006 & Regulation 1169/2011) on the fortification of food, industry will get clarification on UK fortification requirements.
- Amend BFR’s to remove existing calcium carbonate criteria, requiring millers to comply with specification in 231/2012 instead – this option would remove misalignment with the overlapping regulations on additives.
- No further amendments to the BFRs would be made beyond the above.

iv. Option 4 - As per Option 3 and clarify the scope of regulations with respect to fortification requirements for wheat flour

This option would build on option 3 above but also involves an additional measure to provide clarity on the type(s) of wheat flour the regulations apply to, as per the below:

- Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to “common wheat” *Triticum aestivum* only - this option would provide legal clarity on the type of wheat that falls within the scope of the BFR’s, removing ambiguity for industry and enforcement authorities in terms of what flour requires fortification.
- No further amendments to the BFRs would be made beyond the above.

v. Option 5 – As per Option 4 and introduce specific exemptions from the regulations to reflect industry feedback (Preferred)

This option would build on option 4 above but also involves two additional measures to introduce specific flour fortification exemptions, as per the below:

- Introduce exemptions from all fortification requirements for small-scale millers – this option would mean any type of mill producing at least 500t per year would not be exempt from the requirement to fortify.
- Exempting lower flour content foods where flour makes up <10% of the final product - this option would involve an exemption for millers, removing the

¹⁹ Fortification of Flour with Folic Acid Impact Assessment

requirement to fortify flour when it is destined for sale to manufacturers intending to incorporate it in products where the flour forms less than 10% of the total product.

- No further amendments to the BFRs would be made beyond the above.

4.4 Cost and Benefits of option 2 – Introduce folic acid fortification of flour only

62. This option would entail amending the BFRs to require the fortification of flour with folic acid. No further amendments to the BFRs would be made.

63. Since the pre-consultation IA and subsequent feedback, DHSC have been conducting further analysis on the level of folic acid that could be introduced into flour. A summary of that analysis is included below. A more detailed breakdown of the analysis and the associated policy context can be found in Annex B.

4.4.1 Costs – option 2

4.4.1.1 Costs to businesses

4.4.1.1.1 Relabelling

64. Manufacturers of products containing non-wholemeal wheat flour will need to relabel their products as soon as they begin to include flour that has been reformulated by millers according to the new legislation. This will involve updating the ingredients list to include folic acid amongst the other fortificants, which is considered a minor change and would cost approximately £2,100 (2019 prices) per Stock Keeping Unit (SKU) according to data from research conducted by Campden BRI²⁰.

65. When multiplied by the total number of SKUs containing non-wholemeal wheat flour, which is estimated to be 13,000, the total relabelling cost to industry is estimated at £27.3m.

4.4.1.1.2 Fortification

66. Flour millers will incur a cost in order to reformulate their non-wholemeal wheat flour with folic acid as a result of purchasing the ingredient. An estimate from the UK Flour Millers (UKFM) industry body was that the annual cost of fortifying across industry would be between £0.5m and £1m²¹ – we use the middle value of £0.75k as the central estimate in the analysis. Across the 10-year appraisal period for the policy, the discounted total cost to industry is estimated at £6.5m.

4.4.1.1.3 Familiarisation

67. Relevant employees in businesses affected by the measure will need to become familiar and learn the ways in which the new legislation will impact the processes in their organisations. In the analysis we have assumed that a research and development manager will familiarise themselves with the legislation, before relaying the information to

²⁰ 2010 Campden BRI study “Developing a framework for assessing the costs of labelling changes in the UK”

²¹ Pre-assessment information request from UKFM

two corporate managers or directors²² – salaries for both roles were taken from ONS data²³.

68. We assume that the research and development manager will take 2 hours to understand the new legislation, and an hour to explain the changes to the corporate managers and directors²⁴. The total wage cost of this process is estimated to be £4.6k after accounting for non-wage uplifts, with further detail provided in the annex.

4.4.1.2 Costs to government

69. The Government will face familiarisation costs for enforcement staff. We assume that enforcement staff will also require two hours to become familiar with the measure²⁵. The cost of employing an enforcement officer is drawn from National Careers Service data, from which we use the middle value of £34.5k annually, which equates to an hourly employment cost of £23.26 once non-wage costs are accounted for.

70. It is assumed that one enforcement officer in each of the 408 UK local authorities will become familiar with the measure²⁶, equating to a total cost of £19k.

4.4.1.3 Total monetised costs

Total Cost	
Impact	Cost (£m, 2019)
Relabelling (Transitory)	£27.3
Fortification (Annual, 10y total shown)	£6.5
Industry Familiarisation (Transitory)	£0.005
Enforcement Familiarisation (Transitory)	£0.02
Total	£33.8

4.4.1.4 Non monetised costs

71. There are also costs that have not been monetised as part of the analysis, listed below. Further details on each are provided in the annex.

- a. Potential for small proportion of the population to exceed Guidance Level folic acid intake and the associated potential risk to their health, and higher costs to the NHS, Social Care and the wider economy in lost productivity.
- b. Technical costs for millers associated with reformulating flour
- c. Potential for loss of profits due to consumers choosing to reduce or stop purchases of products including non-wholemeal wheat flour
- d. Reduced choice for consumers who may not want to purchase flour fortified with folic acid
- e. Internal quality assurance costs to millers

4.4.2 Benefits to wider society

4.4.2.1 Health benefits

72. Society will see large health benefits owing to the reduction in total NTD affected pregnancies that will occur as a result of an increase in folate intake across the population of women who could become pregnant.

²² We have limited evidence on which to base this assumption, but in order to calculate the cost we have used our best estimate. We would welcome views/evidence on this in the consultation.

²³ Source: ONS (2020) Annual Survey of Hours and Earnings , Table 14.5
<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>
 (last accessed 30/11/2020)

²⁴ We have limited evidence on which to base this assumption, but in order to calculate the cost we have used our best estimate. We would welcome views/evidence on this in the consultation.

²⁵ As above.

²⁶ As above.

73. Based on modelling conducted by Food Standards Scotland (FSS), and data from Eurocat on the split of NTD cases in the UK by the type of NTD, we estimated the reduction in the number of cases for each of the three main NTDs given a level of fortification.
74. Drawing on FSS modelling figures, we estimate a reduction in NTD of 19% at the proposed fortification level of 250ug/100g of flour. Using Quality Adjusted Life Years (QALYs), a measure of life lived in good health, we could measure the total health benefits owing to the reduction in NTD cases based on data regarding how each type of NTD affected an individual's QALYs throughout life in comparison to a baby born in perfect health.
75. The difference in QALYs for an individual with an NTD and one without were then monetised using the standard HMT Green Book value of £70,000 for 1 QALY. This was then multiplied by the number of cases that would be expected to be prevented as a result of the measure to give a total monetised health benefit. This was repeated for each year of the 10-year appraisal period, with the same reduction in cases seen each year, to give the total health benefit. This figure was estimated as being £455m. Further detail on the methodology can be found in the annex.

4.4.2.2 Labour Productivity

76. Due to the complexities and severity of some NTD cases, the parents of children affected by them often have to provide additional care meaning they need to work less hours than they otherwise would. Evidence drawn from a literature review stated a 21%-27% reduction in labour participation in parents of children affected by Spina Bifida. We use the middle value of 24% in the analysis.
77. Data from the Office for National Statistics (ONS) shows a labour participation rate for people aged 18-49 of 0.76, and an average annual income of £29k. We estimate an annual reduction of 95 Spina Bifida cases, meaning that 190 parents would be affected by a reduction in labour participation. The aggregated annual income of an average 190 people aged 18-49 is £4.3m, and for parents of children with Spina Bifida this is £3.3m with the reduction in labour participation accounted for.
78. This implies a loss to the economy of approximately £1m each year due to reduced labour participation, which when repeated for 95 new cases of Spina Bifida each year over the appraisal period totals to a prevented loss of £46m.

4.4.2.3 NHS Treatment Cost Savings

79. The NHS will save money on the treatment of NTDs due to the reduced number of cases.
80. Finished Consultancy Episode (FCE) data accounts for unique hospital episodes for different conditions – in the year ending March 2021 there were 898 FCEs related to NTDs. We expect this to fall to 727 each year assuming that the 19% reduction in NTD cases applies to FCEs as well.
81. NHS annual spend on congenital conditions in the year ending March 2020 was £256.5m, with NTDs accounting for 1.2% of congenital FCEs. Assuming different conditions have the same treatment cost, this would equate to a spend on NTDs of around £3m. After a 19% reduction, we would expect 727 FCEs relating to NTDs, meaning a new NHS annual spend of £2.4m, representing a saving of £0.6m.
82. When this is repeated annually over the 10-year appraisal period, this represents a total benefit of £25.3m.

4.4.2.4 Total monetised benefits

Impact	Benefit (£m, 2019, 10 yr total)
Health Benefits	£455
Labour Productivity	£46
NHS Treatment Cost Savings	£25.3

Total	£526
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4.4.2.5 Non monetised benefits

83. There are also benefits that we have not monetised at this stage of analysis. These are listed below, with further detail provided in the annex:

- a. Increase in folic acid intake across the wider population
- b. Social care savings

4.4.3 Cost and benefits summary table

84. The below table summarises the discounted costs and benefits for the measure and provide a net-present value, including a lower and upper estimate generated through sensitivity analysis, which can be found in the complete write-up in the annex.

Summary of Discounted Costs and Illustrative Benefits – Option 2 (£m, 10-year appraisal period)				
Group affected	Impact	Low estimate	Central estimate	High estimate
Manufacturers	Transition – Familiarisation	-0.003	-0.004	-0.005
	Transition – Relabelling	-22.5	-27.3	-28.3
	Fortification	-4.3	-6.5	-8.6
Total manufacturer impact		-26.9	-33.8	-36.9
Government	NHS Cost savings	12.6	25.3	29.6
	Transition - Enforcement Familiarisation	-0.02	-0.02	-0.02
Total Government impact		12.6	25.2	29.5
Wider society	Health benefits	359	455	526
	Economic benefits (Parent labour participation)	40	46	52
Total wider societal impact		399	501	578
NPV		375	492	581

4.5 Cost and Benefits of option 3 – As per Option 2 plus look to address BFR’s interactions with wider food regulations

85. This option would include all the costs and benefits of Option 2 in addition to the costs and benefits included below.

4.5.1 Costs – option 3

4.5.1.1 Costs to businesses

Direct

4.5.1.1.1 Familiarisation Costs:

86. This option will impose a familiarisation cost on businesses as a result of the changing regulations. Certain employees at flour milling businesses will need to read and become familiar with the requirements of the revised regulations, seeking external advice where necessary. They will then need to distribute this information to relevant parties within the organisation.

87. We assume that it would take one hour for an employee to become familiar with and understand the policy, and then an additional hour to explain the changes to two directors or managers invested in the manufacturing process. These timeframes are arbitrary assumptions; however salary estimates have been tested as part of sensitivity analysis in which higher and lower costs can be interpreted as also being due to differences in time taken. This would then be a total of 8 working hours spent familiarising with the policy at each miller and other flour manufacturers.

88. Data from The Office for National Statistics’ (ONS) Annual Survey of Hourly Earnings (ASHE) has been used to estimate the hourly wage of employees involved in the familiarisation process. A non-wage cost uplift of 22% has been applied to the figures to account non-wage employment on-costs such as national insurance contributions.²⁷ The median wage for a research and development manager in 2020 was £24.11, and £22.73 for corporate managers and directors.²⁸ Applying the non-wage uplift increases these figures to £29.41 and £27.73 respectively.

89. We assume that the familiarisation process requires 3 hours of a research and development manager’s time, and 1 hour each from 2 corporate managers and directors. Across the 32 milling businesses in the UK the central estimate for the total familiarisation cost is £4.6k.²⁹ For this calculation, we have assumed that these milling businesses operate more than one mill, but that only one official per milling business would need to familiarise themselves with the revised regulations. We acknowledge the uncertainty around the wages of the employees involved, therefore sensitivity analysis has been conducted with 25th and 75th percentile earnings from the ASHE data. A summary of the industry-wide familiarisation costs can be seen in the below table:

90. Industry-Wide Familiarisation Cost

	Industry-Wide R&D Manager Cost, 2 hours, £	Industry-Wide Corporate Manager + Director Cost, 2 hours, £	Industry-Wide Total Familiarisation Cost, £

²⁷ A 22% non wage is added to the overall hourly wage costs, as per RPC guidance.

²⁸ Annual Survey of Hours and Earnings (ASHE). Taken from “Table 14.5a “Hourly pay – Gross (£) – 2020 <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14> (last accessed 30/11/2020)

²⁹ Number of UKFM Milling Members. UKFM members produce approximately 99% of all flour produced in the UK.

Lower	£2,200	£1,200	£3,400
Central	£2,800	£1,800	£4,600
Upper	£3,700	£2,800	£6,500

91.

4.5.1.1.2 Fortification costs

92. There are a number of millers that are currently fortifying to the minimum levels required by the BFRs as opposed to the levels required by Regulation 1925/2006. We estimate that this number is small, given that 91% of the premix sales in the UK are compliant with the minimum levels required by Regulation 1925/2006. Due to the proposed increase in the minimum fortificant levels, these millers could face an increase in their production costs as greater quantities of fortificants would need to be used to fortify their flour. The indicative costings of using a premix which is compliant with the higher levels is compared to the premix compliant with the minimum levels of nutrients as stated in the Bread and Flour Regulations in Table 4 below. Full estimates of the cost of moving from the minimum fortification levels to those required in Regulation 1925/2006 will be included in future assessments post consultation.

Table 4: Indicative costs of added nutrients to flour (per tonne of flour)³⁰

Cost of premix compliant with the levels specified in the Bread and Flour Regulations (per tonne of flour)	Cost of premix with calcium, iron and niacin levels raised to 15% NRV (per tonne of flour)
£1.20	£1.30-£1.36

93. Since July 2021, UK produced food grade calcium carbonate is no longer available in significant amounts³¹, therefore we assume that all millers are using E170 grade calcium carbonate to fortify their flour. Consequently, the proposed removal of the existing calcium carbonate criteria is not expected to result in any changes to miller's fortification costs.

Indirect

94. This option could make it difficult for UK based calcium manufacturers to provide food grade calcium for fortification purposes in future. Since Regulation 231/2012 would now apply, UK supplied calcium would not be able to meet these standards unless the composition was changed, which is very difficult to do. However, it is important to note that, since July 2021, there are currently no UK based manufacturers of food grade calcium carbonate. This will be an unmonetised indirect cost in future assessments post consultation.

4.5.1.2 Costs to consumers

Indirect

³⁰ Pre assessment information request from UKFM.

³¹ The quarry producing the calcium carbonate in the England stopped producing calcium carbonate for human consumption after this date.

95. The small proportion of millers that would face increased fortification costs as a result of the increased minimum fortification requirements could pass these onto consumers in the form of price rises. However, given that the cost of the additional fortification is expected to be very low, such that no significant change is expected in retail prices for flour and flour-based products.

4.5.1.3 Costs to government

Direct

4.5.1.3.1 Familiarisation Costs

96. This option will impose familiarisation costs on compliance and enforcement authorities as a result of the changing regulations. These authorities will need to read and become familiar with the revised regulations.

97. According to the National Careers Service for England, a TSO works around 38 to 40 hours per week and earns between £19k and £50k a year³². Using the midpoint of this range we estimate an hourly salary assuming a 38.5-hour working week, 5 weeks holiday and 8 days of bank holidays. Uplifting this hourly wage by 22% for non-wage uplift implies the hourly cost of employing a trading standards officer is £23.26. Assuming familiarisation and dissemination of information to other TSOs for the regulation will take a total of two hours per Local Authority, and that only one officer familiarises with the legislation in the first instance, we estimate that familiarisation costs for all 408³³ Local Authorities in the UK would be around £19k.

98. Further estimates of the familiarisation costings will be included in future assessments post consultation.

4.5.2 Benefits – Option 3

4.5.2.1 Benefits to businesses

Direct

99. This option offers legal clarity by making it easier for businesses to be compliant with the calcium criteria rules as it removes the possibility of ambiguity or confusion between the two overlapping regulations in the BFR's and Regulation 231/2012. This means that businesses would be less likely to have to spend time and money in order to defend themselves during the adjudication process due to unexpected BFR enforcement. This is an unmonetised benefit due to the difficulty of placing a monetary value on legal clarity.

4.5.2.2 Benefits to consumers

100. There are not expected to be any direct benefits to consumers from this option.

4.5.2.3 Benefits to government

Direct

101. Like the impact on businesses this option also offers legal clarity to enforcement authorities as it makes it easier for them to enforce the calcium criteria rules. This would mean HMG would be less likely to have to spend as much resource on the prosecution of

³² National Careers Service (ND) Trading standards officer, <https://nationalcareersservice.direct.gov.uk/job-profiles/trading-standards-officer> (accessed 16/12/20)

³³ [Local government | The Institute for Government](#)

businesses who are not in breach of the law. Therefore, a cost-saving would ensue. This is an unmonetised benefit due to the difficulty of placing a monetary value on legal clarity.

Table 3: Costs and Benefits Summary – Option 3

OPTION 3	Benefits	Costs
Business	<ul style="list-style-type: none"> Provision of legal clarity for milling businesses. D. 	<ul style="list-style-type: none"> Familiarisation costs for millers as a result of the changing regulations. D Minor increased in fortification costs for millers who were not already fortifying flour to the levels required in Regulation 1925/2006. D No additional production costs as all millers are already using E170 standard calcium. D. Makes it difficult for UK calcium producers to provide calcium carbonate for fortification in the future. I.
Consumer	<ul style="list-style-type: none"> No benefits identified. 	<ul style="list-style-type: none"> Potential price increases for flour and flour related products if increased fortification costs are passed onto consumers. No significant change expected, however. I
Government	<ul style="list-style-type: none"> Legal clarity provided to law enforcement authorities. D. 	<ul style="list-style-type: none"> Familiarisation costs for enforcement and compliance authorities because of the changing regulations. D.

Direct Costs/Benefits = D, Indirect Costs/Benefits = I

4.6 Costs and benefits of option 4 - As per Option 3 and clarify the scope of regulations with respect to fortification requirements for wheat flour

102. This option would include all the costs and benefits of Option 3 in addition to the costs and benefits included below.

4.6.1 Costs – Option 4

4.6.1.1 Costs to businesses

Direct

103. This option would impose familiarisation costs on millers who would need to spend time reviewing and understanding the amended regulations. Like options 2 and 3, we estimate that familiarisation costs for the sector to be approximately £4,600 across the entire sector. Please see section 4.5.1.1 for further details. Further estimates of the familiarisation costings will be included in future assessments post consultation.

104. It is our understanding that currently flour made from grains other than ‘common wheat’ are not being fortified in the UK³⁴. Hence, this option is not expected to result in any millers changing which types of grains they fortify and thus their cost of fortification.

4.6.1.2 Costs to consumers

105. There are not expected to be any significant costs to consumers from this option.

³⁴ Pre-assessment information request from UKFM

4.6.1.3 Costs to government

Direct

106. This option will impose familiarisation costs on compliance and enforcement authorities as a result of the changing regulations. These authorities will need to read and become familiar with the revised regulations.
107. According to the National Careers Service for England, a TSO works around 38 to 40 hours per week and earns between £19k and £50k a year³⁵. Using the midpoint of this range we estimate an hourly salary assuming a 38.5-hour working week, 5 weeks holiday and 8 days of bank holidays. Uplifting this hourly wage by 22% for non-wage uplift implies the hourly cost of employing a trading standards officer is £23.26. Assuming familiarisation and dissemination of information to other TSOs for the regulation will take a total of two hours per Local Authority, and that only one officer familiarises with the legislation in the first instance, we estimate that familiarisation costs for all 408³⁶ Local Authorities in the UK would be around £19k.

4.6.2 Benefits – Option 4

4.6.2.1 Benefits to businesses

Direct

108. This option would provide legal clarity to businesses and resolve the current ambiguity over what grains they are expected to fortify. This will ensure a consistent understanding of the regulations across the industry. This is an unmonetised benefit due to the difficulty of placing a monetary value on legal clarity.

4.6.2.2 Benefits to consumers

109. The following indirect benefits to consumers would be expected to accrue from the implementation of this option if pursued. This option would improve consumer choice by providing unfortified alternative options alongside non-wheat-based flour. This should be taken into consideration for those with particular dietary requirements where avoiding fortificants like calcium and iron is sometimes advised. This is an unmonetised benefit due to the difficulty of placing a monetary value on consumer choice.

4.6.2.3 Benefits to government

Direct

110. This option would provide greater clarity to the industry and enforcement authorities and resolve the ambiguities over which grains are required to be fortified. This is an unmonetised benefit due to the difficulty of placing a monetary value on legal clarity.

Table 4: Costs and Benefits Summary – Option 4

OPTION 4	Benefits	Costs
Businesses	<ul style="list-style-type: none">Clarity on fortification requirements for different types of flour D.	<ul style="list-style-type: none">Familiarisation costs D.
Consumer	<ul style="list-style-type: none">Greater choice of flour for consumers with dietary requirements. I.	<ul style="list-style-type: none">No significant costs.

³⁵ National Careers Service (ND) Trading standards officer, <https://nationalcareersservice.direct.gov.uk/job-profiles/trading-standards-officer> (accessed 16/12/20)

³⁶ Local government | The Institute for Government

Government	<ul style="list-style-type: none"> Clarity on fortification requirements for different types of flour D. 	<ul style="list-style-type: none"> Familiarisation costs D.
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Direct Costs/Benefits = D, Indirect Costs/Benefits = I

4.7 Costs and benefits of option 5 – As per option 4 and introduce specific exemptions from the regulations to reflect industry feedback

111. This option would include all of the costs and benefits of Option 3 in addition to the costs and benefits included below. Where a cost or benefit is specific to a particular exemption it has been labelled as such.

4.7.1 Costs – Option 5

Direct

4.7.1.1 Costs to businesses

112. The following direct costs to businesses would be expected to accrue from the implementation of this option if pursued. This option would impose familiarisation costs on millers and food businesses as they would need to spend time reading and understanding the revised regulations. For the small-scale millers exemption this option would affect a small number of mills, totalling around 53 (45 in England, 3 in Wales, 5 in Scotland and none in Northern Ireland).³⁷ Whereas the products with low flour content exemption will affect millers and food businesses alike. For the small millers exemption, we use the assumption that it would take the same total of 5 hours for the business to familiarise with the new regulations. However, to reflect the small scale nature of these mills, we assume that only one production manager per mill would be reading these amended regulations³⁸. As a result we estimate, using the median wage for a research and development manager in 2020 (£24.11)³⁹ as a proxy for a production manager’s wage, that the total familiarisation cost for the 53 millers above would be around £7,800. However, we do not currently have the data on how many businesses the low flour content exemption will affect, so this familiarisation cost currently remains unmonetised. We welcome input from consultation respondents on where we can potentially find this data and we plan to be discussing with industry stakeholders before future assessments take place either way. Full estimates of the familiarisation costs will be included in future assessments post consultation.

4.7.1.1.1 Small-scale millers exemption

113. Food products manufactured using flour produced by millers who would qualify for the exemption would need new labelling if they had previously covered the addition of fortificants. It is not currently clear how many food products are affected but the number is expected to be small given that the quantity of flour is also small. Full estimates of labelling costs will be included in future assessments post consultation.

4.7.1.1.2 Products with low flour content exemption

³⁷ The 53 mills figure here is the maximum possible numbers of mills that could face a familiarisation cost. We recognise that some of these mills could be part of the same milling businesses, hence this familiarisation cost should be viewed as the maximum estimate. We will look to estimate a more precise amount in the final assessments.

³⁸ We have limited evidence on which to base this assumption, but in order to calculate the cost we have used our best estimate. We would welcome views/evidence on this in the consultation.

³⁹ Annual Survey of Hours and Earnings (ASHE). Taken from “Table 14.5a “Hourly pay – Gross (£) – 2020

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14> (last accessed 30/11/2020)

114. Food businesses are likely to face increased compliance costs, as they will need to have a mechanism in place to ensure that the flour content of final products is at or below the threshold set. Full estimates will be included in future assessments post consultation. UK millers may face additional production costs associated with producing both fortified and unfortified flour if they do not already do so. Full estimates will be included in future assessments post consultation.

Indirect

4.7.1.1.3 Small-scale miller exemption:

115. If qualifying millers are not required to fortify, this will result in a reduction of pre-mixer sales to those millers. The monetised value of these sales will be considered in future assessments. Some millers who produce marginally more than 500t per year of eligible flour may choose to reduce output if the saved fortification costs exceed the profits received from production above the threshold limit. Full estimates will be included in future assessments post consultation.

116.

4.7.1.2 Costs to consumers

117. Consumers may experience a marginal decrease in fortificant intake as a result of the exempted products they consume no longer containing fortified flour. However, the impact on health outcomes is expected to be negligible given the small amounts of flour no longer being fortified.

4.7.1.3 Costs to government

Direct

118. This option will impose familiarisation costs on compliance and enforcement authorities as a result of the changing regulations. These authorities will need to read and become familiar with the revised regulations.

119. According to the National Careers Service for England, a TSO works around 38 to 40 hours per week and earns between £19k and £50k a year⁴⁰. Using the midpoint of this range we estimate an hourly salary assuming a 38.5-hour working week, 5 weeks holiday and 8 days of bank holidays. Uplifting this hourly wage by 22% for non-wage uplift implies the hourly cost of employing a trading standards officer is £23.26. Assuming familiarisation and dissemination of information to other TSOs for the regulation will take a total of two hours per Local Authority, and that only one officer familiarises with the legislation in the first instance, we estimate that familiarisation costs for all 408⁴¹ Local Authorities in the UK would be around £19k.

4.7.1.3.1 Small-scale miller exemption

120. There would be an additional compliance need to check/monitor small scale millers captured by the exemption and thus who are not fortifying continue to produce less than 500t per year. It is expected that this additional need can be absorbed into the existing general compliance monitoring process.

4.7.1.3.2 Products with low flour content exemption

⁴⁰ National Careers Service (ND) Trading standards officer, <https://nationalcareersservice.direct.gov.uk/job-profiles/trading-standards-officer> (accessed 16/12/20)

⁴¹ [Local government | The Institute for Government](#)

121. Government will need to put in place a mechanism to monitor the percentage of unfortified flour used in final products and enforce the regulations in cases of non-compliance.

4.7.2 Benefits – Option 5

4.7.2.1 Benefits to business

Direct

4.7.2.1.1 Small-scale miller exemption

122. Qualifying millers would not have to accrue fortification costs. The monetised value of these sales will be considered in future assessments. Note, this does not take account of any costs associated with modifying premises or purchasing additional equipment.

4.7.2.1.2 Products with low flour content exemption

123. Food businesses would be able to increase their competitiveness in European markets where mandatory fortification is viewed unfavourably. As they will be able to sell qualifying products which contain unfortified flour without the need to run dual production processes, thus reducing their production costs.

Indirect

4.7.2.1.3 Small-scale miller exemption

124. The viability of small-scale millers would be supported given the removal of the need to fortify considering practical, legal and technological limitations facing them.

4.7.2.1.4 Products with low flour content exemption

125. This option could reduce production costs for millers and food manufacturers alike if the removal of the need to fortify reduces the production costs of the flour.

4.7.2.2 Benefits to consumers

Direct

126. This option would offer consumers more choice when buying unfortified flour-based products. This should be taken into consideration for those with particular dietary requirements, where avoiding significant intakes of nutrients like calcium and iron is sometimes advised.

4.7.2.2.1 Small-scale miller exemption

127. The preservation of the viability of existing traditional mills is seen to also preserve the tourism and local society benefits of their existence. Local communities place a value on these types of mills, and they can attract tourists interested to see how their historical technology operates.

4.7.2.3 Benefits to government

Direct

4.7.2.3.1 Products with low flour content exemption

128. Compared to the business-as-usual scenario and assuming that the requirement to use fortified flour will have a negative effect on trade, government will benefit from increased tax revenues compared to what would have otherwise been the case.

Maintaining competitiveness and trade between UK food businesses and Europe will maintain profits and any associated tax revenue.

129. Reduced risk of businesses relocating abroad. If businesses' export trade was affected badly enough, they may consider moving abroad under the business-as-usual option. This would have both political and economic ramifications.

Indirect

4.7.2.3.2 Small-scale miller exemption

130. Where a milling business is meeting the definition of a traditional miller, there will no longer be a need for compliance and enforcement authorities to check if fortificant levels are reaching required standards, potentially saving some resource.

131. For those areas of the UK where there are currently zero or very few millers fitting into the exemption criteria, the measure will provide "future proofing" such that should more of those types of mills be established, an existing policy framework will be in place to cover them. This is an unmonetised benefit.

Table 5: Costs and Benefits Summary – Option 5

Option 5	Benefits	Costs
Business	<p><i>Products with low flour content exemption</i></p> <ul style="list-style-type: none"> Trade: increase competitiveness in European markets where mandatory fortification is viewed unfavourably. D. Potential for reduced input costs, if unfortified flour is less costly to produce. I. <p><i>Small-scale miller exemption</i></p> <ul style="list-style-type: none"> Reduction in fortification costs for millers who qualify for the exemption. D. Viability of small-scale millers would be supported. I. 	<ul style="list-style-type: none"> Familiarisation costs. D. <p><i>Products with low flour content exemption</i></p> <ul style="list-style-type: none"> Potential for additional production costs, if mills produce both fortified and unfortified flour. D. Compliance costs. D. <p><i>Small-scale miller exemption</i></p> <ul style="list-style-type: none"> Labelling costs. D. Potential reduction in pre mixer sales. I. Potential reduction in flour output at millers producing marginally over 500t per year. I.
Consumer	<ul style="list-style-type: none"> More choice for consumers when buying unfortified flour-based products. D. <p><i>Small-scale miller exemption</i></p> <ul style="list-style-type: none"> Consumers place a value on these small-scale mills and will continue to benefit from them. I. 	<ul style="list-style-type: none"> Marginal decrease in fortificant intake for some consumers. D.

Government	<p><i>Products with low flour content exemption</i></p> <ul style="list-style-type: none"> • Exchequer benefits: increased tax revenue due to increased trade compared to BAU. D. • Reduced risk of businesses relocated abroad. D. <p><i>Small-scale miller exemption</i></p> <ul style="list-style-type: none"> • Savings related to enforcement authorities no longer having to enforce regulations. I. • 'Future proofing' for areas where there are zero or very few 'small scale' millers. I. 	<ul style="list-style-type: none"> • Familiarisation costs. D. <p><i>Products with low flour content exemption</i></p> <ul style="list-style-type: none"> • The cost of monitoring and enforcing the exemption. D. <p><i>Small-scale miller exemption</i></p> <ul style="list-style-type: none"> • The cost of monitoring and enforcing the exemption. D.
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Direct Costs/Benefits = D, Indirect Costs/Benefits = I

5 Risks and assumptions

As per earlier sections of this IA, we have separated out this section to cover risks and assumptions at both the total and measure-specific level.

5.1 Overall risks and assumptions

132. In terms of risks at the overall level, it is recognised that introducing multiple interventions at the same time could lead to a greater period of adaptation than normal for some businesses who are affected by many of them. Although this has been considered and inclusion of a phase-in period would be expected, views are welcomed on whether the timescales set out in the consultation are sufficient.

133. In addition, it is recognised that the complexities introduced by bringing in multiple measures at the same time may lead to some cost savings that may not be recognised if considering the impact of individual measures separately. For instance, there may be a saving in both familiarisation and labelling costs from those estimated above if multiple changes are introduced at the same time, given it's likely to be the same processes involved and the potential for economies of scale. The intention is for these cost savings to be considered in subsequent assessments once feedback from this pre-consultation assessment is received.

134. We have throughout made standard assumptions on how market participants will react as policy interventions are introduced. For instance, we assume throughout that the main objectives of businesses is to maximise profits. There may be some cases where this could be challenged – e.g. in terms of the health impacts of fortification or the consumer benefits from maintaining the viability of traditional millers – but every effort has been made to recognise those in the discussions of costs and benefits. Furthermore, another assumption underpinning the analysis is that consumer demand of flour-based products will not significantly change over time.

135. In addition, a key assumption is made throughout that other prevailing market conditions are unchanged when policy interventions are introduced. This assumption will come under particular focus now with food supply chains facing a sustained period of cost pressures and the impact of the Russia and Ukraine conflict being felt by those potentially impacted by these measures – e.g., via volatility in global grain markets. Continuation of the current levels of volatility and uncertainty will mean this assumption becomes more and more challengeable.

5.2 Measure-specific risks and assumptions

5.2.1 Option 3 – As per option 2, plus address interactions with wider food regulations

5.2.1.1 Amend BFR by removing calcium carbonate criteria (millers would instead apply the calcium specification in Reg 231/2012).

5.2.1.1.1 Assumptions

- Assumes all millers are already using E170 specification calcium when they fortify their flour.
- Assumes that the removal of the existing calcium carbonate criteria within BFR creates legal clarity for businesses and enforcement authorities.
- Assumes that the chemical composition of calcium carbonate is related to natural geographical makeup and is therefore difficult to change.

5.2.1.2 Amend BFR to raise required fortificant minimum levels to the 15% NRV level required Regulation 1925/2006 on the addition of vitamins and minerals to foods

5.2.1.2.1 Assumptions

- It is assumed that increased levels of fortification would result in higher costs for millers. However, as these fortification costs may not be especially high as a proportion of total flour costs, a relatively small increase in the fortification levels would not be a significant change in costs.
- It is assumed that the majority of UK flour millers are already fortifying to the levels required by Regulation 1925/2006. This is supported by the fact that approximately 91% of premix sales consist of premixes that meet the minimum levels required by Regulation 1925/2006. Therefore, increased fortification costs for the industry as a whole are expected to be small as only a small proportion of millers will have to adapt their fortification levels to comply with the updated BFR.
- Raising the minimum levels of nutrients required in flour poses no risks to consumers. Modelling work is being conducted by DHSC to capture the impact that this measure will have on health outcomes. Further analysis will be included in future assessments post consultation.

5.2.2 Option 4 – As per option 3, plus clarify scope of regulations

5.2.2.1 Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to flour derived from “common wheat” Triticum aestivum only.

5.2.2.1.1 Assumptions

- Different types of wheat can be clearly distinguished from one another during the enforcement process.

5.2.3 Option 5 – As per option 4, plus introduce specific exemptions

5.2.3.1 Exempt products that contain less than 10% flour from fortification.

5.2.3.1.1 Assumptions

- Export markets will continue to act unfavourably towards mandatory fortification and that this negatively affects the desirability of products that contain very little, albeit fortified, flour.
- Businesses are not already preparing to run a separate production line for products destined for the export market and would otherwise be unwilling or unable to export to certain European markets using fortified flour.
- Unfortified flour will be readily available, either via imports or through domestic production.
- No suitable alternative markets could be found and any potential loss of export revenue could not be absorbed by the domestic market.
- Removing the fortificants from products which contain less than 10% flour will not pose a risk to consumers. Modelling work is being conducted by DHSC to capture the impact that this measure will have on health outcomes. Further analysis will be included in future assessments post consultation.

5.2.3.1.2 Risks

- Setting a threshold may encourage producers to alter recipes so that products other than those originally intended meet the threshold for unfortified flour usage.

5.2.3.2 Introduce exemptions from all fortification requirements for small-scale millers. Any type of mill producing at least 500t per year would not be exempt from the requirement to fortify.

5.2.3.2.1 Assumptions

- All millers looked to maximise profits.
- All millers producing less than 500t of eligible flour per year are producing solely for the domestic market.

6 Wider Impacts and Specific Impact Tests

6.1 Equality and Family Test Issues

136. There are not expected to be any equality or family-related impacts of the illustrated options beyond those set out in the analysis above.

6.2 Proportionality

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

6.3 Competition

138. The effect on competition is unclear at this time and will be assessed in the light of consultation responses. It is possible that the impact on larger and smaller businesses may differ, as might be the case for import/exporters and domestic firms. The policy intention is to minimise any negative impacts on competition.

6.4 Potential trade implications

139. The potential impact on trade will be tested at consultation and considered as part of future assessments. It is not expected that there will be significant implications for UK

trade at the aggregate level given that only 6% of flour produced domestically is exported (circa 270,000 tonnes) according to HMRC trade data⁴². However, we welcome views on this expectation during the consultation process.

7 Small and Micro Business Assessment (SaMBa)

7.1 Scope

140. This IA is focussed on amending the BFR to ensure the regulations are fit for purpose. This SaMBa, however, will focus on exempting Small and Micro Businesses (SMBs) from the BFR requirements altogether, rather than only the amendments to the BFR proposed here.

141. If SMBs were exempt only from the amendments rather than the regulations in their entirety, they would still be required to fortify, but at different levels to larger businesses. This has the potential to cause confusion amongst businesses and enforcement agencies. This also represents an additional burden on those SMBs who currently produce unfortified flour under mutual recognition rules, which will no longer be in place from October 2022.

7.2 Number and definition of SMBs

142. SMBs are traditionally defined as businesses that employ between one and forty-nine full-time equivalent employees. This definition also includes community and voluntary bodies.

143. Milling is not a labour-intensive business and according to insight from UK Flour Millers, approximately half a dozen of their member millers in the UK employ less than 50 people. Given the nature of these businesses, exempting all micro businesses from the exemption based on employee numbers could undermine the health benefits of the intervention. This is because milling businesses could easily restructure their operations in order to qualify for the exemption, plus potentially leading to insignificant amounts of flour being unfortified.

144. In addition, as described below, a subset of millers within the SMB category have fundamentally different production processes which lead to a disproportional burden on them which could be more appropriate to recognise via an exemption. Hence an alternative approach could be to exempt milling businesses based on the amount of flour they produce in order to capture these type of millers – who produce a smaller quantity of flour.

7.3 Output-based exemption

145. Small-scale milling businesses tend to focus on producing stoneground flours using horizontal millstones, where wind or water is the primary source of power. They are often charitable bodies, where the sale of flour for commercial purposes (normally to local/regional markets) is a significant aspect of the enterprise. There are around 35 small mills producing flour commercially in the UK and 150 producing flour in very low volumes to demonstrate the traditional milling process and raise funds for upkeep⁴³.

⁴² [HMRC](#)

⁴³ Figures taken from 2013 submission by TCMG.

146. Such small-scale milling enterprises tend to produce less than 500 tonnes of flour individually per year⁴⁴. Their contribution to overall UK flour production is very low. For example, in the year 2020-2021 the Traditional Cornmillers Guild (TCMG) estimated that output of traditional mills was less than 0.05% of the nation's flour production.

147. Industry stakeholders⁴⁵ argue that due to the nature of these small-scale milling producers, the requirement to fortify flour endangers their future viability, as fortification is not operationally practical and places a more significant burden on them, compared to larger producers using modern machinery. That burden could potentially increase further with other measures proposed for the BFR – such as the introduction of folic acid fortification to flour.

148. Fortification is seen as impractical and more burdensome for small-scale millers because:

- The technology used in small scale mills – often flour mills powered by wind or water energy - means it is not possible to dose flour with additives in consistent amounts, especially the small proportions required by the BFR. Some of the technology in these mills originated in the 19th century and hence is not designed for the precise distribution of fortificants.
- To install the machinery required is impractical given the Listing restrictions in the buildings that many traditional mills are housed in (Grade 2*, Grade 1, Scheduled Ancient Monuments). The costs involved with purchasing and installation are also prohibitive when compared to the revenue of most small-scale mills.
- Small-scale mills typically have restricted space for storage of grain, meaning that millers purchase small tonnages at any one time. The requirements of the BFR would hence mean that each “parcel” of flour would need to be tested for fortificants to ensure that they have been sufficiently mixed in and demonstrate that the flour has been fortified to the required levels. The cost burden would be more significant for small-scale mills, compared to larger, industrial-scale mills, where throughput is much more significant and dedicated technology is used.
- Income derived from selling flour is seen to be a vital part of safeguarding the future of the listed buildings small-scale mills operate in and the tradition of small-scale milling. Should the fortification requirements lead small-scale millers to conclude that they should focus their output on unfortified flour (e.g. wholemeal), it is expected that their future income could be severely restricted given consumer preference for dressed flours.

149. Exempting small-scale mills (defined as those producing less than 500 tonnes of flour per year), many of which produce flour almost exclusively for local/regional markets, is not expected to result in a significant loss of the health benefits from fortification, due to their small overall market share. Furthermore, meeting the fortification requirements is likely to be particularly burdensome for small-scale mills, in the ways described above. Many small-scale mills offer additional benefits to society in terms of their cultural and historical significance, which could potentially be lost if they were to become no longer viable. As a result, the costs to society of enforcing fortification requirements on small-scale mills is expected to outweigh the benefits to society as a result of fortification of these businesses in particular.

⁴⁴ Only one mill of this kind is seen to produce more than 500t per year from TCMG insight.

⁴⁵ For instance, the Traditional Corn millers Guild and the Society for Protection of Ancient Buildings

7.4 Anticipated costs and benefits from exemption

150. Should small-scale millers be exempted from fortification, the following costs and benefits are anticipated.

7.4.1 Costs to businesses

151. If qualifying millers are not required to fortify, this will result in a loss of pre-mixer sales to those millers. The monetised value of these sales will be considered in future assessments.

152. Food products produced using flour from qualifying millers would need new labelling if labels had previously covered the addition of fortificants. It is not currently clear how many food products are affected but the number is expected to be small given that the quantity of flour involved is also small.

153. There would be familiarisation costs involved with millers reviewing and understanding the new exemption. For the small-scale millers exemption this option would affect a small number of mills, totalling around 53 (45 in England, 3 in Wales, 5 in Scotland and none in Northern Ireland).⁴⁶ Whereas the products with low flour content exemption will affect millers and food businesses alike. We also use the assumption that it would take the same total of 5 hours for the business to familiarise with the new regulations. However, to reflect the small scale nature of these mills, we assume that only one production manager per mill would be reading these amended regulations⁴⁷. As a result, we estimate, using the median wage for a research and development manager in 2020 (£24.11)⁴⁸ as a proxy for a production manager's wage, that the total familiarisation cost for the 53 millers above would be around £7,800. Full estimations of familiarisation timings and costs will be included in future assessments post consultation.

7.4.2 Costs to consumers

154. There will be a minor reduction in health benefits relating to a small amount of flour now being unfortified and consumed domestically.

7.4.3 Costs to government

155. There will be an additional compliance need to check/monitor those small millers captured by the exemption continue to produce less than 500 tonnes per year. It is expected that this additional need can be absorbed into the existing general compliance monitoring process.

156. There are expected to be familiarisation costs associated with compliance and enforcement authorities reviewing and understanding the new exemption if introduced. There are believed to be 215 authorities who may fall under the requirements of the exemption, of which 150 are in England, 32 are in Scotland, 22 are in Wales and 11 are in

Northern Ireland, according to the FSA⁴⁶/FSS⁴⁷ websites. Estimations of familiarisation timings and costs will be included in future assessments post consultation.

7.4.4 Benefits to businesses

157. Qualifying millers would not have to accrue fortification costs. The monetised value of these sales will be considered in future assessments. Note, this does not take account of any costs associated with modifying premises or purchasing additional equipment given that they may be affected by regulations related to listed buildings.

7.4.5 Benefits to consumers

158. The preservation of traditional mills is often of cultural and historical significance. Local communities place a value on these types of mills, which can attract tourists interested to see how their historical technology operates.

• Benefits to government

159. Where a milling business is producing less than 500 tonnes of eligible flour per year, there will no longer be a need for compliance and enforcement authorities to check if fortificant levels are reaching required standards, potentially saving some resource. For those areas of the UK where there are currently zero or very few millers fitting into the exemption criteria, the measure will provide “future proofing” such that should more/some of those types of mills be established, an existing policy framework will be in place to cover them.

7.5 Risks and assumptions

7.5.1 Risks

160. Some millers who produce marginally more than 500 tonnes of flour per year may choose to reduce output if the fortification costs saved exceed the profits received from production above the threshold limit. There is believed to be only 1 miller in the UK within 100 tonnes of the exemption threshold and hence which this argument could possibly apply to.

7.5.2 Assumptions

161. The key assumptions made when considering the impact of the exemption are:

- All millers look to maximise profits.
- Most small-scale millers under the threshold use traditional or heritage production processes. UK Flour Millers – who tend to represent commercial milling businesses in the UK – indicate that none of their members produce less than the threshold amount indicated.

8 Monitoring and Evaluation

⁴⁶ [England, Wales and Northern Ireland food safety local authorities](#)

⁴⁷ [FSS website reference to local authorities](#)

162. This monitoring and evaluation section covers the all the proposed changes to the BFRs excluding the folic acid measure, for information on folic acid please see the previous consultation⁴⁸.
163. A programme for post implementation monitoring and review is being developed to collect information about the effects in practice of proposed new policy and amendments to existing rules and determine whether policy objectives have been met.
164. Our primary objective of this intervention is to improve the existing legislation within the BFR's, to ensure that they remain fit for purpose and continue to support UK industry whilst protecting consumers. To address the areas of the legislation where improvements may be required, we have included secondary objectives for each area below:
- i. Interaction with wider food regulations*

To resolve the interpretation issues regarding how the BFR's interact with overlapping food regulations.
 - ii. Scope of the regulations*

To ensure that the understanding of the regulations is consistent throughout industry and enforcement. Thus, ensuring that the interpretation of the rules is clear for industry and enforcement authorities.
 - iii. Exemptions*

To ensure that the regulations do not disproportionately affect certain businesses or types of businesses without compromising the targeted outcomes.
165. The requirement to add calcium, iron, thiamin and niacin to non-wholemeal flour is to protect population health. The proposals include raising the minimum levels for calcium, iron, and niacin. The National Diet and Nutrition Survey (NDNS) Rolling Programme would be used to monitor the impact of this policy. The NDNS Rolling Programme is a continuous cross-sectional survey of diet and nutritional status of the UK population which has been running since 2008, covering adults and children from 18 months upwards living in private households. It provides detailed, quantitative information on food consumption, nutrient intakes, nutritional status, and related characteristics in the general population by age and sex. Dietary intake of iron, calcium, niacin, and food supplement intake is recorded and reported through the dietary data collection method.

⁴⁸ [DHSC Folic acid consultation](#)

8.1 How will assessment determine whether the original objectives have been met, or whether the intervention should be amended?

166. The exact process will be confirmed in consultation with industry stakeholders. At this stage, we plan to undertake surveys and, potentially workshops with industry to gain information on inputs, outputs, and outcomes. This will be approximately 5 years after the amendments have passed, alongside the post-implementation review.

167. Surveys will include questions to collect evidence on how businesses have experienced the updated legislation, and whether, in their view, the amendments have made a tangible difference to the clarity and consistency of the existing regulations. If any major issues came up in their responses, then further consultation via workshops may be appropriate.

168. This would likely be sent out to trade associations and other industry bodies, such as “UK Flour Millers”.

8.2 What are the monitoring and evaluation provisions in place for the current system, and how can they maintain the appropriate flexibility?

169. Enforcement of the regulations is carried out by trading standards officers and environmental health officers from local authorities and district councils. The regulations are generally enforced at the milling stage where the nutrients are added. They generally visit the mills and require them to demonstrate that they are complying with the regulations. We expect that the changing regulations will be absorbed into the current monitoring provisions and thus they should not change as a result.

170. In terms of current engagement with stakeholders, there is a BFR technical working group which acts as a forum for members such as millers, food manufacturers and trade bodies to raise any concerns they have. It is expected that this group will continue to meet annually beyond the implementation period.

9 Annex

Annex A

Option 3 Shortlists- BFR Interaction Resolution

Option 3a, 3b, 3c Shortlist: Legislation Interaction Resolution

Policy Option	Consideration	Shortlisted	Comparison
Option 3a- Amend BFRs to make clear that it has legal precedence over Regulation 1925/2006	This option would involve consolidating an updated version of the BFR's establishing the legal precedence of the minimum levels stipulated in the regulations for the mandatory addition of nutrients to flour, retaining the current levels set out in the existing regulations	Yes	
Option 3b- Amend BFRs to raise required fortificant levels to the 15% level required by Regulation 1925/2006	This option would involve raising the minimum levels of nutrients so that they are all level with or higher than the 15% NRV threshold specified in Regulation 1925/2006.	Yes	Compared to option 3a, this policy has the following additional costs: <ul style="list-style-type: none"> For Business: Minor increased in fortification

	By aligning BFRs with the horizontal rules & wider nutritional legislation (Regulation 1925/2006 & Regulation 1169/2011) on the fortification of food, industry will get clarification on UK fortification requirements		<p>costs for millers who were not already fortifying flour to the levels required in Regulation 1925/2006. D</p> <ul style="list-style-type: none"> For Consumers: Minimal increases in retail prices as a result of increased fortification costs. I <p>Compared to option 3a, this policy has the following additional benefits:</p> <ul style="list-style-type: none"> For Consumer: Health Benefits from the consumption of additional nutrients found in the extra fortificants. D For Government: Reduced burden of maintaining awareness of differing requirements in food regulations. Option 3a has different fortification levels for bread and flour compared to other foods. I
Option 3c- Business as Usual	This option would involve no action being taken to rectify the differing interpretations of BFR's and Regulation 1925/2006	Yes	
Discounted option D	Take a policy view that the levels stipulated in 1925/2006 regulation do not apply to BFR.	No	This option would give some clarity to businesses on the level of fortification required. However, it would still provide issues for enforcement authorities as there would still be missing the opportunity to improve the regulatory framework and provide greater clarity in legislation. There is also no guarantee that the code will include fortification at the higher level required.

Option 3i, 3ii, 3iii Shortlist: Calcium Carbonate Fortification Requirements

Policy Option	Consideration	Shortlisted	Comparison
Option 3i- Amend BFR's by removing calcium carbonate criteria. Millers would instead apply the calcium specification in Regulation 231/2012	This would remove misalignment with the overlapping regulations on additives.	Yes	<p>Compared to option 3ii, this policy has the following additional costs:</p> <ul style="list-style-type: none"> For consumers: Small opportunity cost associated with the lack of health benefits to most consumers who consume additional calcium carbonate and would have gained health benefits from option 3ii. I <p>Compared to option 3a, this policy has the following additional benefits:</p> <ul style="list-style-type: none"> No additional production costs as all millers are already using E170 standard calcium. D

Option 3ii- Adapt calcium specification within BFR's to match the EU's calcium purity criteria contained in Regulation 231/2012	Instead of removing the calcium specification, this option would change the BFR specification so that it matches the specification in wider food rules.	Yes	
Option 3iii- Business as Usual. This option would involve retaining the BFR calcium specification and taking no further action	This option would involve retaining the BFR calcium specification and taking no further action.	Yes	
Discounted option 3iv	Explain through guidance that millers can use calcium that meets calcium purity criteria in Regulation 231/2012 to meet both domestic and export requirements.	No	This option would provide some further guidance to industry to facilitate compliance regarding the calcium carbonate criteria. However, the opportunity to improve the regulatory framework and provide greater within legislation would be missed.

Option 4 Shortlist: Clarification of the scope of regulation through defining "wheat"

Policy Option	Consideration	Shortlisted	Comparison
Option 4a- Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to "common wheat" Triticum aestivum only	This option would provide greater clarity on the type of wheat that falls within the scope of the BFR's removing ambiguity for industry and enforcement authorities in terms of what flour requires fortification.	Yes	<p>Compared to option 4c, this policy has the following additional costs:</p> <ul style="list-style-type: none"> For Businesses: Minor reduction in sales for pre-mixers. D For Business: Labelling costs. D For Consumers: Minor reduction in health benefits relating to a small amount of flour now being unfortified. D <p>Compared to option 4c, this policy has the following additional benefits:</p> <ul style="list-style-type: none"> Minor reduction in fortification costs. D
Option 4b- Business as Usual	Under this option, no further clarification for the definition for "wheat" would be provided.	Yes	
Option 4c- Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to both "common wheat" and ancient grains such as spelt	This option would provide greater clarity on the type of wheat that falls within the scope of the BFR's removing ambiguity for industry and enforcement authorities in terms of what flour requires fortification – but would involve a wider definition than option 1. Whilst option 1 would involve a change in the regulations themselves, this option would only require updates to associated guidance given the wording in the existing legislation.	Yes	
Discounted option 4d	Develop a common understanding between government, enforcement authorities and industry regarding which species (of wheat) should be fortified.	No	Whilst this option would probably lead to less confusion amongst millers as to grains in and out of scope, it would not see the surrounding legislation updated and hence would not provide legal certainty for industry and enforcement authorities.

Discounted option 4e	Produce guidance that clarifies what is meant by "wheat flour"	No	Whilst this option would improve clarity amongst millers as to grains in and out of scope, it would not see the surrounding legislation updated and hence would not provide legal certainty for industry and enforcement authorities.
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Option 5 Shortlist: Exemptions

Option 5a, 5b, 5c Shortlist: Treatment of small-scale mills within existing BFR

Policy Option	Consideration	Shortlisted	Comparison
Option 5a- Introduce exemptions from all fortification requirements for small-scale millers - any type of mill producing at least 500t per year would not be exempt from the requirement to fortify	Any type of mill producing less than 500t per year would not be exempt from the requirement to fortify.	Yes	<p>Compared to option 5c, this policy has the following additional costs:</p> <ul style="list-style-type: none"> For Businesses: Millers just over 500t threshold may choose to reduce output given saving on fortification costs. I <p>Compared to option 5c, this policy has the following additional benefits:</p> <ul style="list-style-type: none"> For government: Prevented opportunity cost associated with likely consultation and legal costs involved with creating a new definition. I
Option 5b- Business as Usual	This option would require no action and the regulations would still require all millers to fortify flour regardless of their scale. Should the requirement to fortify also with folic acid be introduced, small-scale millers would need to comply with this.	Yes	
Option 5c- Define a 'small-scale milling process' and exempt those that use this method - This could mean specified water and wind powered small-scale mills would not need to fortify the flour they produce	This could mean specified water and wind powered small-scale mills would not need to fortify the flour they produce.	Yes	
Discounted option 5d	Provide grants to small-scale millers to assist with the costs of upgrading existing or purchasing new mixing and testing machines	No	This option would require significant government investment in expensive machinery which would be difficult to justify given only small health benefits. Investment in the machinery would also create the risk of substantial changes having to be made to listed buildings – or the businesses being relocated from them.
Discounted option 5e	Introduce a larger tolerance around specified fortificant levels to apply to small-scale mills only	No	This option blurs the lines in relation to what BFR compliance looks like. It will also significantly complicate labelling and enforcement processes and potential incur potentially considerable costs relating to those as a result.
Discounted option 5f	Government commissions a project to produce technical guidance for small-scale millers to try to help those type of businesses meet the fortification	No	Considering this option will come at a cost to government, it does not guarantee that policy objectives will be met – there is no guarantee that a contractor will be able to produce guidance that

	requirements without threatening their viability.		helps these type of businesses meet requirements without threatening their viability. In addition, it would not remove some of the practical limitations of production facing the businesses - such as the use of listed buildings.
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Option 5i, 5ii, 5iii Shortlist: Treatment of final products containing less than 10% of flour

Policy Option	Consideration	Shortlisted	Comparison
Option 5i- Exempt products that contain less than 10% flour from fortification	This option would involve an exemption for millers, removing the requirement to fortify flour when it is destined for sale to manufacturers intending to incorporate it in products where the flour forms less than 10% of the total product. This is the preferred option.	Yes	Compared to option 5ii, this policy has the following additional benefits: <ul style="list-style-type: none"> For businesses: Prevented opportunity cost associated with listing items. I For government: Prevented opportunity cost associated with setup costs. I For government: Prevented opportunity cost associated with ongoing enforcement of CN code monitoring. I
Option 5ii- Construct a list of products containing less than 10% flour and specify that listed products do not need to be fortified	This would work by identifying foods to be exempt by their CN code. CN code 1905 captures products with high percentages of flour like bread, cakes and pastries.	Yes	
Option 5iii- Business as usual / do nothing: no regulatory changes	Under this option no action would be taken, and all millers would be required to fortify flour regardless of what it is used for (unless exempt for other reasons).	Yes	
Discounted option 5iv	Produce marketing materials around the health benefits of fortification to try to influence European consumer preferences	No	This option is seen to be costly to government given the scale of the influence the campaign would need to have. There is also no guarantee of success given these are established consumer preferences. In addition, this option does not reduce regulatory burden as it is a non-regulatory option

Annex B - Folic acid – Full Context and Analysis

Folic acid – Updated Content for BFR Impact Assessment.

This analysis regarding the mandatory fortification of all UK-milled non-wholemeal wheat flour with folic acid builds on the previous consultation exercise. We are now consulting on the level of fortification, which we propose to be 250 micrograms of folic acid per 100g of non-wholemeal flour.

Contained in this annex are the complete details of updates to the previous consultation, which predominantly consist of the quantification of the health benefits expected from the policy as well as the costs to business and Government.

Problem under consideration and rationale for intervention

0. 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.

1. There are around 1,000 NTD affected pregnancies per year in the UK this equates to a rate per 1,000 births of around 1.3 or 1.2 NTD affected pregnancies.⁴⁹ 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 in women who could become pregnant from food sources have been falling over time, a trend which would increase NTD risk if it continued unabated.

2. NTDs can be serious in nature and significantly reduce the life expectancy of those affected, as well as reducing the quality of life throughout those years. Although relatively uncommon, the treatment costs associated with NTDs are high, with a study from Germany suggesting life-long annual direct medical costs of £3,580 for Spina Bifida patients⁵⁰.

3. 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 devolved administrations 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 NTD in their family (or that of the baby's father) are advised to take 5 milligrams⁵¹ of folic acid every day until the 12th week of pregnancy. In addition, women in a high-risk category for an NTD-affected pregnancy, such as those 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.⁵² Folic acid is the synthetic equivalent of folate, although there are differences in how they are metabolised. Essentially, folic acid increases folate levels in the blood, which then reduces the risk of NTDs.

4. However, supplements may not be taken early enough, particularly if the pregnancy is unplanned.⁵³ This risk would be mitigated if folic acid intakes were increased across society. Despite voluntary fortification, data from the last 9 years shows folate intakes of women who could become pregnant have continued to decline and are particularly low in areas of

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STOCHASTIC MODELLING TO ESTIMATE THE POTENTIAL IMPACT OF FORTIFICATION OF FLOUR WITH FOLIC ACID IN THE UK - FINAL REPORT - July 31 2017.pdf (foodstandards.gov.scot)

⁵⁰ Economic burden of neural tube defects in Germany - ScienceDirect

⁵¹ Conversion: 1 milligram (mg) equals 1,000 micrograms (µg)

⁵² 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.

⁵³ 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'.

deprivation. There is therefore an opportunity to increase women’s background dietary intake of folate to a level which offers greater protection against NTD-affected pregnancies. 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 ensure prevention of as many NTD affected pregnancies as possible. Supplements will therefore continue to have an important role in NTD prevention.

5. The risk of NTD affected births from unplanned pregnancies can be reduced by increasing incidental intake of folic acid through the consumption of products that contain UK-milled non-wholemeal wheat flour. Such products include staple foods such as bread which is purchased by 99.8% of British households⁵⁴, meaning many women at risk of NTD affected pregnancies are expected to see an increase in their folate intake.
6. 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 intakes which lead to lower blood folate status. The need for supplementation 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

7. The table above shows that in 2015-2016, only 10% of women aged between 16-49 had a daily folate intake above the recommended folic acid supplement level of 400 micrograms a day. Aside from women who 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).⁵⁵
8. While only a proportion of these women will become pregnant, they 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 who could become pregnant have a red blood cell folate concentration indicative of elevated risk of NTD affected pregnancies, a level which has risen over time.⁵⁶
9. 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

⁵⁴ [Flour & Bread Consumption \(ukflourmillers.org\)](http://ukflourmillers.org)

⁵⁵ 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

⁵⁶ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/699241/NDNS_results_years_7_and_8.pdf

fortification is required to help achieve a significant reduction in the incidence of NTD affected pregnancies.

What are the policy objectives and intended effects?

10. 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. We plan on mandating the fortification all UK milled non-wholemeal wheat flour with folic acid at a level of 250 micrograms per 100g. A set level of fortification was preferred over a range due to the ease at which it could be monitored and enforced.
11. Other countries (including the US, Australia and Canada) have implemented mandatory folic acid fortification policies for many years and have seen reductions in NTD rates of between 16% and 58%⁵⁷. However, they may have had different diets, populations, or fortification rules to those that might be expected in the UK. In the US, cereal grain products labelled as 'enriched' are fortified with 140 micrograms of folic acid per 100g of flour⁵⁸, whilst in Australia Since October 2009, **all wheat flour used for bread making (except organic) must** contain between 200-300 micrograms folic acid per 100g flour, meaning that every 100g of bread is fortified with 135 micrograms of folic acid⁵⁹. Modelling by Food Standards Scotland (FSS) in 2017 considered a range of scenarios and suggested a reduction of between 8% and 25% in NTD rates could be achieved in the UK without increasing the numbers of people who currently consume more than the Guidance Level of folic acid, either with or without limits placed on the amount of folic acid in breakfast cereals, reduced-fat spreads and supplements.
12. It is important that any new UK regulations are safe, proportionate, effective and enforced. This creates additional objectives in support of the main policy:
 - Minimise the number of people who exceed recommended upper levels of folic acid intake and ensure that any risks are mitigated.
 - Ensure that any particular groups who cannot consume folic acid due to allergy⁶⁰, 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).
13. The preferred option was judged using the above criteria, with it being deemed as having a strong balance between the primary policy objective of reducing cases of NTDs affected pregnancies as well as potential burdens. Many other countries have introduced fortification policies successfully, but circumstances in the UK may not be the same, and so will require bespoke consideration.

⁵⁷ <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.

⁵⁸ [Folic acid Fortification and Supplementation | CDC](#)

⁵⁹ [FSANZ Conf Posters Folic.pdf \(foodstandards.gov.au\)](#)

⁶⁰ [Side effects of folic acid - NHS \(www.nhs.uk\)](#)

Previous Consultation

14. In 2019 the UK Government and devolved administrations consulted on the mandatory fortification of flour with folic acid. The options within the consultation were as follows:

- 14.0. just non-wholemeal wheat flour in the UK (the most commonly used type)
- 14.1. just non-wholemeal wheat flour used to make bread in the UK
- 14.2. all flour in the UK, including wholemeal and other grains
- 14.3. all flour in the UK and other non-wheat products such as 'gluten free'
- 14.4. there are no products that should have mandatory fortification with folic acid

15. The option to mandate only non-wholemeal wheat flour used only for breadmaking was not taken forward into this consultation, with the food vehicle chosen being all non-wholemeal wheat flour.

16. Only fortifying with non-wholemeal wheat flour used for breadmaking would have presented a significant technical challenge to millers, as they do not use separate hops for flour milled for various products. The manufacturing process would need to be largely adjusted to accommodate this option. This means that going forward with this option would create additional large burdens for business without representing a greater health benefit than fortifying all non-wholemeal wheat flour.

17. The option to fortify only non-wholemeal flour used for breadmaking would also lead to a lesser reduction in NTD risk across the population than if all non-wholemeal flour were fortified. The costs to business would largely be the same however, (if not greater due to the challenges posed to the manufacturing process) meaning the option would represent a lower benefit to cost ratio.

18. In comparison the baseline option to mandate the fortification of all UK-milled non-wholemeal wheat flour would lead to the least impact on manufacturing processes, as this type of flour is already fortified with thiamine, niacin, iron and calcium in line with the Bread and Flour Regulations (BFR) – millers would simply need to add folic acid in addition to these fortificants.

19. A breakdown of key consultation responses is presented below:

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

Response	Total	Percentage
I agree with the proposal	746	52.6%
I disagree with the proposal	562	39.6%
I don't know if I agree or disagree with the proposal	75	5.3%
Not answered	36	2.5%

20. The majority of respondents agreed with the proposal to mandate the fortification of non-wholemeal wheat flour in the UK with folic acid, 52.6% agreeing with the proposal compared to 39.6% disagreeing.

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

Response	Total	Percentage
Just non-wholemeal wheat flour in the UK (the most commonly used type, and our base line)	128	9.0%

Just non-wholemeal wheat flour used to make bread in the UK	42	3.0%
All flour in the UK, including wholemeal and other grains	124	8.7%
All flour in the UK and other non-wheat products such as 'gluten free'	483	34.0%
There are no products that should have mandatory fortification with folic acid	546	38.5%
Not answered	96	6.8%

21. The responses in support for mandatory fortification in the majority favoured the most comprehensive level of fortification, covering all flour in the UK and non-wheat products such as 'gluten free'. The percentage of respondents who favoured no fortification is very close to the number who disagreed with the policy in general.

22. Although we did not ask respondents to rank the options, and therefore we cannot conclude with certainty, it would be plausible to assume that those who supported wider fortification would rather some level of fortification over none. A fuller breakdown is presented below.

Which of the following do you think mandatory fortification with folic acid should apply to?	Grand Total	2.1 Non-wholemeal wheat flour UK	2.2 Non-wholemeal bread flour	2.3 All UK flour	2.4 All flour and more	2.5 No fortification
All Respondents	1,419	10%	3%	9%	37%	41%
View on proposed policy generally						
Agree with proposals	746	14%	4%	17%	65%	1%
Disagree with proposals	562	2%	2%	0%	0%	96%
Don't know	75	24%	10%	3%	17%	46%
No answer	36	80%	0%	0%	20%	0%
Type of respondent						
As an individual	1,268	8%	3%	10%	36%	42%

On behalf of a business	27	32%	0%	9%	18%	41%
On behalf of a non-governmental org.	38	23%	3%	3%	51%	20%
On behalf of a public sector body	18	14%	0%	14%	64%	7%
Other	68	17%	3%	8%	32%	39%

Option 1: Do Nothing

23. If the preferred option was not taken forward, then there would be a 'business as usual' state in which there would be no mandatory fortification of all UK-milled non-wholemeal wheat flour with folic acid. This would lead to the rate of NTD affected pregnancies remaining constant or potentially increasing slightly given trends of falling blood folate levels in women of childbearing age.

24. Given the significant health and economic benefits associated with implementing mandatory fortification with folic acid, a business-as-usual state would represent a large opportunity cost to Government and wider society.

25. Although option 1 would impact business the least, the costs to business as a result of the policy are for the most part transitory and should not represent a long-term increase in costs or impact on profits. Additionally, the primary issue of NTD affected pregnancies and the large costs they impose on society and Government would continue indefinitely unless there is government intervention.

Preferred Option: Option 2 – Mandate the fortification of all UK-milled non-wholemeal wheat flour with folic acid

26. The preferred option that the Government plans to take ahead is to mandate the fortification of all UK-milled non-wholemeal wheat flour with folic acid. This option is best suited to serving the policy objective of reducing the number of NTD affected pregnancies in the UK whilst also minimising the risk of people exceeding Guidance Level, as well as providing those who do cannot or do not wish to consume added folic acid with an option to avoid increased intake. 57% of consultation respondents in England were in support of this option, as were 67%, 68% and 68% of respondents in Scotland, Wales and Northern Ireland respectively.

27. We are seeking views in consultation on the level of fortification – currently we propose the level to be 250micrograms of folic acid per 100g of flour. This level is expected to provide reductions in the number of NTD affected births in the region of 15.4-22.4% as well as ensuring that the risk of exceeding the Guidance Level is minimal. We assume in the analysis that millers will be responsible for the fortification, by purchasing folic acid in bulk or as part of pre-mix bags of other fortificants, which is then added to flour. The proposal will only cover flour milled in the UK, with the majority of flour consumed in the UK being milled domestically.⁶¹

⁶¹ Imports & Exports: Wheat & Flour (ukflourmillers.org)

28. Adding folic acid at a set level will support more straightforward data collection for monitoring the impacts of the policy. We believe allowing industry to fortify within a range – as seen in Australia – would lead to difficulties in monitoring and evaluating the policy.

29. By not restricting voluntary fortification or supplements, we will avoid the need for further consultation with industry and possible opposition from businesses who would be affected, such as those currently voluntarily fortifying foods who would need to stop, allowing for a faster implementation of the policy.

30. Voluntary fortification will not be restricted as part of the proposal, meaning manufacturers such of products that are currently fortified with folic acid such as some breakfast cereals will not need to change their processes.

Alternative Levels of Fortification

31. Levels both higher and lower than the preferred option of 250micrograms/100g were considered. The preferred level best meets the policy objectives of reducing the incidence of NTDs whilst minimising the number of people who will exceed the Guidance Level as a result of fortification. At 250 micrograms/100g flour, FSS modelling estimates an increase in those exceeding the Guidance Level from 0.4% to 0.6% of the population

32. Levels below 250micrograms/100g were considered to have too little clinical effect given the policy objective of reducing the incidence of NTDs – at a level of 100micrograms/100g FSS modelling estimates a risk reduction of between 7.6%-11.3%, as opposed to 15% to 22% with the proposed level. The difference in health benefits between the levels (more details are provided in the benefits section below), however fortifying at a lower level than 250micrograms/100g would represent an insignificant reduction in costs to industry.

33. Fortifying at levels above 250micrograms/100g would allow for greater reductions in NTD risk but would lead to a higher number of people exceeding the Guidance Level of folic acid intake. Fortifying at a level of 350micrograms/100g, for example, would lead to more than 1% of the population exceeding the Guidance Level.. The reasoning for 250 micrograms/100g flour is:

33.0. This is the lowest amount of folic acid/100g that would support a policy aim to reduce NTD affected pregnancies by around 20% a year (15-22%).

33.1. The number of people exceeding the Guidance Level would increase by around 0.2% (0.4% to 0.6%), while still increasing daily consumption of folic acid by around 97micrograms.

33.2. This would take the least amount of time to implement and would have the option to later consider the restriction of voluntary fortification or increasing levels of folic acid following monitoring of the policy.

34. Whilst we would ideally do a cost-benefit analysis of a range of fortificant levels, considering the relative benefits of reducing the impact of NTDs against the risks of more people exceeding the Guidance Level of folic acid, we have therefore taken this initial pragmatic approach.

Costs and Benefits of Option 2 (preferred option)

35. The methodology of the quantification of the costs and benefits of the policy is covered in this section.

36. The table below outlines the costs and benefits captured in the analysis of the policy.

Table 1: Costs and Benefits of Option 2

Monetised costs	Transition costs associated with businesses familiarising themselves with the new regulations
	Transition costs associated with distributing familiarisation information to businesses
	Transition costs of redesigning packaging to adhere to the new regulations
	Transition costs associated with enforcement authorities becoming familiar with the new regulations
	Fortification costs of flour millers purchasing folic acid
Non-monetised costs	Supply chain costs to manufacturers
	Possible loss in profits due to consumer preference
	Loss of choice for consumers that do not wish to consume additional folic acid
	Possibility of small number of people exceeding recommended daily folic acid intake levels, and associated health risks
	Quality assurance costs to millers associated with ensuring relevant products comply with the new regulation, in connection with enforcement and local authorities.
Monetised benefits	Health benefits of reduced NTD cases
	NHS treatment cost savings due to fewer NTD cases
	Increased labour productivity in would-be parents of NTD patients
Non-monetised benefits	Social care cost savings
	Wider increase in folic acid intake

37. The net present value of the policy is assessed over a period of 10 years. The benefits of avoided NTDs will be seen throughout an individual's life, beyond 10 years and so this will underestimate the total benefits expected from this policy. However, this time-period allows for an adequate representation of health benefits throughout 10 cohorts as well as capturing the main effects on business which are primarily transitional in nature, such as relabelling costs.

Key Assumptions

38. It is important to note that the costs estimated here are derived using the best available data and evidence. However, where data is not available, DHSC is required to make reasonable assumptions which will be tested through the consultation and sensitivity analysis. The consultation will also include questions seeking to gather further evidence and data where possible.

39. In modelling the health benefits derived from the policy a number of assumptions were used in order to produce the final estimate, these are listed in the below table.

Table 2: Key assumptions used in analysis

Assumption	Rationale
Where an individual is born without an NTD, they are born in perfect health	Simplicity – for comparison purposes in terms of QALY losses prevented this assumption makes the analysis simpler without majorly affecting the estimate, as most babies are born healthy
The baseline risk of NTDs remains constant throughout the assessment period	Simplicity – We have seen a worsening trend of blood folate levels however assumption should not significantly affect the results as 89% of women aged 16-49 already have blood folate levels below a threshold indicating elevated risk of NTD affected pregnancies
All NTD cases are assumed to be reported medically	Simplicity – often NTD cases lead to terminations or miscarriages, not all of which are reported as being NTDs. It is not easy to ascertain the number of these instances and as such in the analysis we assume the remaining cases of NTDs are all reported medically at birth

Costs of Preferred Option: Option 2

Costs to business

Transition Costs

40. The transition costs to business are expected to fall into two main categories:

40.0. Familiarisation costs

40.1. Relabelling costs

41. As indicated above, where no data or evidence is available, assumptions may have been used in order to provide a best estimate for the costs businesses will face, for example the amount of time it would take for an employee to become familiarised with the policy.

Familiarisation

42. Millers and other manufacturers of flour will face familiarisation costs as certain employees will need to understand and then distribute this information to relevant parties within the organisation.

43. We assume that it would take one hour for an employee to become familiar with and understand the policy, and then an additional hour to explain the changes to two directors or managers invested in the manufacturing process. These timeframes are arbitrary assumptions; however, salary estimates have been tested as part of sensitivity analysis in which higher and lower costs can be interpreted as also being due to differences in time taken. This would then be a total of 8 working hours spent familiarising with the policy at each miller and other flour manufacturers.

44. Data from The Office for National Statistics' (ONS) Annual Survey of Hourly Earnings (ASHE) has been used to estimate the hourly wage of employees involved in the familiarisation process. A non-wage cost uplift of 22% has been applied to the figures to account non-wage employment on-costs such as national insurance contributions. The median wage for a research and development manager in 2020 was £24.11, and £22.73 for corporate managers and directors. Applying the non-wage uplift increases these figures to £29.41 and £27.73 respectively.

45. We assume that the familiarisation process requires 3 hours of a research and development manager's time, and 1 hour each from 2 corporate managers and directors. Across the 32 millers in the UK the central estimate for the total familiarisation cost is £4.6k. We acknowledge the uncertainty around the wages of the employees involved, therefore sensitivity

analysis has been conducted with 25th and 75th percentile earnings from the ASHE data. A summary of the industry-wide familiarisation costs can be seen in the below table:

Table 3: Industry-Wide Familiarisation Cost

	Industry-Wide R&D Manager Cost, 2 hours, £	Industry-Wide Corporate Manager + Director Cost, 2 hours, £	Industry-Wide Total Familiarisation Cost, £
Lower	£2,200	£1,200	£3,400
Central	£2,800	£1,800	£4,600
Upper	£3,700	£2,800	£6,500

46. Although we do not believe there will be an additional cost for enforcement officers on-job inspecting this regulation (as there will already be inspections ensuring non-wholemeal wheat flour is fortified with the four current fortificants), there will be an initial familiarisation cost as trading-standards incorporate the new regulation into their inspections.

47. According to the National Careers Service for England, a TSO works around 38 to 40 hours per week and earns between £19k and £50k a year⁶². Using the midpoint of this range we estimate an hourly salary assuming a 38.5-hour working week, 5 weeks holiday and 8 days of bank holidays. Uplifting this hourly wage by 22% for non-wage uplift implies the hourly cost of employing a trading standards officer is £23.26. Assuming familiarisation and dissemination of information to other TSOs for the regulation will take a total of two hours per Local Authority, and that only one officer familiarises with the legislation in the first instance, we estimate that familiarisation costs for all 408⁶³ Local Authorities in the UK would be around £19k.

Relabelling

48. Another transition cost for manufacturers is one created by the need to amend the labels of all products containing UK-milled non-wholemeal wheat flour to include ‘folic acid’ amongst the list of ingredients that the flour was fortified with. This is stated in brackets after flour on the ingredients list.

49. Information from the 2010 Campden BRI study “Developing a framework for assessing the costs of labelling changes in the UK” looks at the total cost of all stages of the label cycle, from familiarisation of new legal requirements, re-design and auditing through to printing. It also provides estimates based on the magnitude of change, which we have used in this analysis. It provides an average cost of relabelling per Stock Keeping Unit (SKU), which are unique codes used to identify products and track inventory⁶⁴.

50. This is used to represent a cost per product basis for relabelling, and later multiplied by the number of products requiring relabelling. The study concluded that the following costs would be incurred by businesses making label changes based on whether the change was ‘minor’ or ‘major’:

Table 4: Relabelling Costs, 2010 prices	
Extent of change	Average cost (£/Stock Keeping Unit)
Minor	1,810
Major	3,800

⁶² National Careers Service (ND) Trading standards officer, <https://nationalcareersservice.direct.gov.uk/job-profiles/trading-standards-officer> (accessed 16/12/20)

⁶³ [Local government | The Institute for Government](https://www.investopedia.com/terms/s/stock-keeping-unit-sku.asp)

⁶⁴ <https://www.investopedia.com/terms/s/stock-keeping-unit-sku.asp>

Source: Developing a framework for assessing the costs of labelling changes in the UK⁶⁵

51. As the paper was published in 2010, we have updated the estimates to account for inflation by multiplying the values in the paper by 1.17, the change between 2010 prices and 2019 prices calculated using the GDP deflators⁶⁶ at market prices:

Extent of change	Average cost per SKU (2019 prices)
Minor	2,116
Major	4,442

52. As the relabelling change that will occur is simply adding 'folic acid' to the list of fortificants within flour, we use the average cost for a minor change. A minor change is defined as a change to the text on a single face of a label with no packaging size modification. This means a relabelling cost of £2,116 per affected product.

53. To estimate the number of products that would require a labelling change we used Kantar data provided by the UK Flour Millers' Association which showed the number of SKUs containing non-wholemeal wheat flour in the largest four UK supermarkets by market share.

54. The data showed that there were 10,184 individual SKUs containing non-wholemeal wheat flour in the included UK supermarkets. This figure includes own-label products as well as branded products, some of which would be common across different supermarkets.

55. When estimating the number of SKUs contained in all other retailers, we assumed that all branded goods would be represented in the largest four supermarkets. To estimate the number of own-label SKUs in all other retailers, we assumed that the number of own-label SKUs were proportionate to their market share.

56. Evidence showed that as of May 2021 the largest four supermarkets had a market share of 67.1%, leaving all other grocery retailers with a market share of 32.9%. Dividing the others' market share by the largest four's market share and then multiplying by the number of all individual own-label SKUs in the largest four supermarkets (including products without wheat) gave an estimate of 8,721 own-label SKUs in all other grocery retailers.

57. From the Kantar research, 31.4% of own-label SKUs contained non-wholemeal wheat flour on average in the largest four supermarkets, and when applied to the estimate of 8,721 total own-label SKUs in other grocery retailers this produced a central estimate of 2,738 own-label SKUs containing non-wholemeal wheat flour.

58. When combined with the 10,184 individual SKUs from the largest four supermarkets this gives a total of 12,922 products that will require relabelling. This is then multiplied by the uplifted unit cost of relabelling to give the central estimate for total relabelling costs. Given the uncertainty owing to the assumptions used in producing this estimate, sensitivity analysis was conducted changing the assumed expected percentage of total SKUs in the other retailers that contain non-wholemeal wheat flour. For the upper estimate, we assume an additional 5% of own-label products contain non-wholemeal wheat flour, whilst for the lower estimate we assume only 5% of products contain non-wholemeal wheat flour to reflect the different range of products smaller retailers may stock, especially if they are more geared to convenience products. The results of the sensitivity analysis along with the central estimate are shown in the table below.

⁶⁵ Source: Table 5: Average costs of label changes by extent of the change, May 2010, Developing a framework for assessing the costs of labelling changes in the UK, <https://webarchive.nationalarchives.gov.uk/20110318121117/http://www.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf>

⁶⁶ GDP deflators at market prices, and money GDP December 2021 (Quarterly National Accounts) - GOV.UK (www.gov.uk)

Table 6: Total Relabelling Cost by Number of Affected SKUs

Number of Affected SKUs	Total Relabelling Cost, £m
10,620 – Lower Estimate	£22.5m
12,922 – Central Estimate	£27.3m
13,358 – Upper Estimate	£28.3m

Fortification

59. There will be a cost accruing to flour millers due to the requirement to purchase folic acid for use in the mandatory fortification. Following engagement with industry, UKFM provided a range of between £0.5m-£1m as an annual cost for flour millers due to the purchase of existing pre-mix fortificants with the addition of folic acid.

60. As a central estimate, an average of the upper and lower bound was used for analysis, at £0.75m. The upper and lower bounds were used as part of sensitivity analysis which can be found later in the document. The annual costs were discounted and totalled over the 10-year policy appraisal period, with the figures summarised in the below table.

Table 7: Flour Millers Fortification Costs

	Annual Cost, £m	Discounted Total 10-year Cost, NPV £m
Lower Estimate	£0.5m	£4.3m
Central Estimate	£0.75m	£6.5m
Upper Estimate	£1.0m	£8.6m

Non-Monetised Costs to Industry

61. There may be costs associated with the technical process of flour milling as a result of the mandated addition of folic acid. We assume that millers will add the folic acid as part of the existing fortification process with the other four fortificants, mitigating costs.

62. Smaller and traditional millers may find their manufacturing process impacted more, however there is a planned exemption for millers that produce less than 500t of flour annually, which would cover the majority of these cases.

63. Industry may also face reduced profits as a result of consumer preference, with some consumers unwilling or unable to purchase products containing folic acid. We have not quantified this impact due to a lack of evidence surrounding consumer opinion on folic acid, and due to the fact that many consumers who will shift their purchases from products fortified with folic acid will be able to substitute for non-fortified wholemeal alternatives meaning minimal lost-profits to industry as a whole.

64. Millers would face costs owing to additional quality assurance measures that would be required in order to ensure that the non-wholemeal wheat flour they produce complies with the new regulation. We have not monetised this additional cost as it should be minimal due to existing quality assurance measures in place to comply with current regulations regarding other fortificants.

Non-Monetised Costs to Consumers

65. There will be a small cost to consumers from a decrease in choice of products that do not contain folic acid. Some consumers may choose not to consume products containing folic acid and as such will need to alter their consumption habits. Whilst there will be alternatives such as wholemeal wheat flour or non-wheat based flour which will not require mandatory, these options may be more expensive.

66. We have not monetised this cost due to the difficulty of placing a monetary value on this consumer welfare loss.

67. There will be a small increase in the risk of people exceeding the Guidance Level of folic acid consumption as a result of the policy (FSS modelling estimates 0.4-0.6% of the population). A number of risk assessment bodies have assessed the potential effects of excess folic acid intake, including the US institute of Medicine Food and Nutrition Board (IOM, 1998), the EU Scientific Committee on Food (SCF, 2000) and the UK Expert group on Vitamins and Minerals (EVM, 2003).

68. The SCF and EVM considered the potential masking of diagnosis of pernicious anaemia to be the main concern. This is because whilst folic acid would help improve haematological status, it would not prevent the neurological effects associated with the condition, which can lead to irreversible damage without treatment.⁶⁷

69. Modelling from Food Standards Scotland (FSS) showed the risk given different levels of fortification of non-wholemeal wheat flour.

Table 8: Potential percentage of people exceeding the Guidance Level of folic acid intake, (FSS analysis)

Level of fortification (ug/100g)	Without restrictions on voluntary fortification	With restrictions on voluntary fortification of breakfast cereals, spreads and supplements.
0	0.42%	0.02%
100	0.48%	0.03%
200	0.55%	0.06%
250	0.64%	0.07%
300	0.83%	0.10%
350	1.11%	0.20%
450	1.80%	0.54%

70. Table 5 shows the potential percentage of people that would exceed the Guidance Level of folic acid consumption. Around 0.4% of people already exceed the Guidance 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.

71. Mandatory fortification at the proposed level of 250micrograms/100g for all non-wholemeal wheat flour, without restrictions is estimated to lead to 0.635% of people exceeding the Guidance Level of folic acid intake, constituting roughly 0.2% more of the population.

72. SACN has considered in depth¹⁴ 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. The Committee found that there was limited evidence to suggest that overconsumption would lead to serious health risks. More details on each risk area are given below.

⁶⁷ cotfolicacidstatement.pdf (food.gov.uk)

73. 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 Guidance Level will be at risk from B12 deficiency.

74. 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.

75. 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.

76. There is a chance that producers may pass-on the costs from the policy to consumers – however given these costs are mainly transitory in nature, and that spread across the number of products produced and sold that contain non-wholemeal wheat flour are relatively low (data from UKFM suggests that approximately 12 million loaves of bread are produced in the UK each day), we believe that there will not be, if any, a significant increase in the price of staple goods such as bread.

Non-Monetised Costs to Government

77. There will be existing routines in place to enforce the current laws regarding mandatory fortification of non-wholemeal wheat flour with niacin, iron, thiamine and calcium. We assume that adding folic acid to the fortificants will not create an additional burden on the trading standards officers that enforce the current laws beyond the initial familiarisation costs set out above as no additional products or premises would require inspection.

Benefits of Chosen Option

Health Benefits

78. The main health-benefit that will accrue due to the policy is the reduction in risk and cases of NTD affected pregnancies as a result of a higher blood-folate level in women who could become pregnant. Modelling conducted as part of the FSS analysis estimated the percentage decrease in risk of the three main types of NTD for a given level of fortification.

79. One of the modelling scenarios used in this analysis from FSS accounted for variation in individuals' folate intake including women who take a daily 400micrograms folic acid supplement. The table below shows the results of the modelling.

80. The modelling conducted by FSS was done twice using different equations predicting the relationship between blood folate level and the associated reduction in risk of an NTD affected pregnancy.

81. Model C was deemed to be the most realistic model in the FSS modelling, with Model C accounting for variation in folate status across the population, as well as assuming that 30% of women take the recommended 400ug/d folic acid supplementation.

82.

Table 9: Effect of fortification of all non-wholemeal wheat flour and reduction in NTD risk, assuming 30% of women **planning to become pregnant** also take 400 mcg folic acid supplement (FSS modelling)

Capping	Fortification µg/100g	Mean folate intake µg/day	Mean red cell folate nmol/L	Model C (Daly)	Model C (Crider)
No capping	0	251	570	0	0
	100	286	606	7.58	11.3
	200	321	638	13.1	19.2
	250	338	653	15.4	22.4
	300	356	668	17.5	25.3
	350	373	682	19.3	27.8
	450	408	708	22.6	32.2

83. As seen in Table 7, fortifying with 250micrograms/100g would lead to a 15.4% and 22.4% reduction in NTD risk according to modelling using the equations from Daly and Crider respectively. The Daly prediction is based on an Irish population which is likely to be more similar in diet and genetics to a UK population but is older with the study having been carried out in 1995.

84. The Crider prediction is based on a Chinese population but was carried out more recently, in 2014 which may mean the evidence base supporting the equation is more developed than for Daly. The sample size was also larger. The FSS report states a preference for the Daly prediction due to the Irish sample, which produced a lower risk reduction.

85. The Daly and Crider prediction equations lead to different results, and as stated in the FSS report it is unclear which is more relevant. As a result, an average of the two - 19% - was used in this analysis.

86. Research from SACN estimates that there are approximately 700-900 NTD affected pregnancies in the UK annually, however due to potential underreporting in Scotland and Northern Ireland, as well as an increased live birth count since the report was published, we assume 1,000 cases annually in the analysis.

87. As established in paragraph X, a fortification level of 250micrograms/100g may lead to an estimated 19% reduction in NTD risk, meaning we anticipate 190 fewer cases of NTDs annually in the UK. Data from Eurocat⁶⁸ (Average of data from 2013-2019) provides a split of the three major types of NTD – Spina Bifida is the most common, representing 50% of NTDs, whilst Anencephaly and Encephalocele each represent 40% and 10% of cases respectively. Using this split alongside the data on the annual number of NTD affected pregnancies in the UK, an estimated reduction in the number of cases for each NTD was produced, summarised in the table below.

Table 10: Split of NTD Cases and Estimated Prevented Cases

NTD	% of NTD Cases	Estimated Annual Cases, UK	Estimated Cases Prevented, 250ug/100g
Spina Bifida	50	500	95
Anencephaly	40	400	76
Encephalocele	10	100	19

88. The approach taken to monetise the health benefits of a reduction in NTD cases was to calculate the loss in Quality Adjusted Life Years (QALYs) that would occur in an individual with an

⁶⁸ [https://eu-rd-platform.jrc.ec.europa.eu/eurocat/eurocat-data/prevalence_en?%0-0\\$1-\\$-1-39,29,2,90,41,21,83,3,38,60,88,81,66,5,80,54,19,34,33,75,49,10,79,11,18,104,8,51,25,50,23,13,59,67,76,28,30,93,86,55,32,35,71,20,62,72,73,84,68,57,70,95,14,52,43\\$Cprevalence_table\\$X0_-1-a\\$X0_9-num](https://eu-rd-platform.jrc.ec.europa.eu/eurocat/eurocat-data/prevalence_en?%0-0$1-$-1-39,29,2,90,41,21,83,3,38,60,88,81,66,5,80,54,19,34,33,75,49,10,79,11,18,104,8,51,25,50,23,13,59,67,76,28,30,93,86,55,32,35,71,20,62,72,73,84,68,57,70,95,14,52,43$Cprevalence_table$X0_-1-a$X0_9-num)

NTD when compared to an individual born in perfect health. This loss would be considered prevented if an NTD case was avoided, with the assumption that the individual would instead be born in perfect health, meaning the monetised health benefits for that individual would be the QALYs that would have been lost if they had been born with an NTD. There would also likely be an increase in the number of live births, due to the fact that a number of NTD affected pregnancies end in miscarriage or termination. This has not been specifically quantified as many of these cases are not medically reported as being attributed to NTDs.

89. The first 10 years of life for individuals born in perfect health who are captured by the model were converted into discounted QALYs based on the assumption of perfect health carrying a QALY utility of 1, using the standard Green Book⁶⁹ discount rate of 1.5% for health factors. A QALY utility weighting of less than 1 infers that due to a medical condition an individual will always have less QALYs than if they did not have the condition. The resulting expected QALYs of a new-born in perfect health when discounted was 48.5.

90. The above process was repeated for new-borns with Spina Bifida, Anencephaly and Encephalocele. The average life expectancies for new-borns with these NTDs are 43⁷⁰, 0⁷¹, and 33.2⁷² years respectively. When converted to discounted QALYs using different weighted QALY utility values from literature⁷³ (Anencephaly is assumed to have a QALY utility of 0), these figures become 23.7, 0, and 14.9 QALYs. The discounted QALY figures were then subtracted from the QALY life expectancy for a new-born in perfect health to calculate the QALY loss for an individual with each of the NTDs. The process is summarised in the table below.

Table 11: Discounted Lifetime QALY Loss of NTDs

NTD	Life Expectancy (Years)	QALY Adjustment (Utility)	Discounted Lifetime QALYs	Disc. Lifetime QALY Loss	Value of Loss, Individual (£m)
Spina Bifida	43	0.55	17.6	30.9	£2.2
Anencephaly	0	0	0	48.5	£3.4
Encephalocele	33.2	0.45	11.8	36.7	£2.6

91. A single QALY is valued at £70,000 as per standard Green Book practice. Multiplying each of the NTDs discounted lifetime QALY loss produces the monetised health benefit for an individual prevented case, £1.9m, £2.9m, and £2.2m for Spina Bifida, Anencephaly and Encephalocele respectively.

92. The evaluation period for the costs and benefits of the policy is set at 10 years. As a result, there are 10 annual cohorts of new-borns that stand to benefit from reduced cases of NTDs, with the full 10 years of benefits included for the first cohort, 9 years for the second cohort (as they will not yet be born when the policy will be implemented) and so on until 1 year of benefits for the final included cohort. There is the possibility that some women giving birth in the first year will not have seen increased blood folate levels as the majority of their pregnancy occurred before the start date. For the sake of simplicity these cases are not factored into the analysis, but it should be noted that the first cohort may be an over-estimation as a result.

93. The total health benefits over the 10-year evaluation period for fortifying non-wholemeal wheat flour with folic acid at 250ug/100g are estimated to be £454.6m. The table below breaks the

⁶⁹ [The Green Book \(publishing.service.gov.uk\)](http://publishing.service.gov.uk)

⁷⁰ [Cost-Effectiveness of Mandatory Folic acid Fortification in Australia | The Journal of Nutrition | Oxford Academic \(oup.com\)](http://www.oup.com)

⁷¹ [Anencephaly: information for parents - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

⁷² [Survival of infants diagnosed with encephalocele in Atlanta, 1979–98 - Siffel - 2003 - Paediatric and Perinatal Epidemiology - Wiley Online Library](http://www.wiley.com)

⁷³ [Health state preference scores of children with spina bifida and their caregivers | SpringerLink](http://www.springerlink.com)

total health benefits down for each NTD and also shows the health benefits for a 100ug/100g fortification level for comparison.

Table 12: Monetised Health Benefits by NTD and Fortification Level

NTD	Monetised QALY Loss Prevented, 100ug/100g, £m	Monetised QALY Loss Prevented, 250ug/100g, £m
Spina Bifida	£71.3m	£150.4m
Anencephaly	£126.7m	£267.4m
Encephalocele	£17.4m	£36.8m
Total	£215.3m	£454.6m

94. Preventing cases of Anencephaly produces the largest monetised health benefits due to the fact that the majority of cases lead to death within minutes or hours of being born, meaning each prevented case is essentially a full life of QALYs gained. Whilst Encephalocele is usually more severe than Spina Bifida, as there are less cases of it the health benefits from the policy are lower.

Wider Economic Benefits

95. There would also be wider economic benefits arising from the policy. These focus on increases in labour productivity and savings made due to the requirement for fewer treatments and surgeries, as well as social care services.

NHS Treatment Cost Savings

96. The policy and resulting reduction in cases of NTDs would mean the NHS would need to spend less money on treatment and surgeries for affected patients.

97. Finished Consultancy Episode (FCE) data⁷⁴ displays how many unique hospital consultancies occurred for specific conditions in a year. We assume that the reduction in cases is in equal proportion to the resulting reduction in FCEs. This assumption was tested as part of the sensitivity analysis.

98. The combined figure for Spina Bifida, Anencephaly and Encephalocele was 898 for the financial year ending March 2021. Using the average expected reduction in NTD risk from the FSS modelling of 19% at a fortification level of 250ug/100g this figure falls to 727.

99. The total NHS spend on all Congenital Malformations, Deformations and Chromosomal Abnormalities as defined by the World Health Organisation⁷⁵ (WHO) was £256.5m in the financial year ending March 2020. In total there were 77,251 FCEs involving all Congenital conditions, meaning that with 898 FCEs NTDs accounting for 1.2% of total episodes in this category, and with an assumption that all conditions in the category carry an equal treatment cost, we estimate a cost to the NHS of £3m.

100. With FCEs relating to NTDs expected to fall to 727, NTDs would account for 0.9% of total episodes with the assumption that the FCEs for other Congenital conditions remains constant. This would mean that the NHS spend would be estimated to fall to around £2.4m, with an annual saving of £0.6m.

⁷⁴ [Hospital Admitted Patient Care Activity 2020-21 - NHS Digital](#)

⁷⁵ [ICD-10 Version:2010 \(who.int\)](#)

101. After accounting for the 10 cohorts born during the 10-year assessment period, the total discounted NHS savings due to the reduction in cases attributed to fortification is estimated at £25.3m.

Labour Productivity Gains

102. NTD cases lead to reduced labour participation in both the patient and the parents and/or carers of the patient. A literature review by Yi et al.⁷⁶ states that on average, parents of Spina Bifida patients have between a 21% and 27% lower labour participation rate. We assume this translates to the UK, as well as that all individuals with a would-be NTD come from two-parent households.

103. According to ONS data⁷⁷, the average labour participation rate of people aged 18-49 in the UK is 0.775, with the average annual income in the same age bracket being £29k. As the figures in the literature review are pertinent to only Spina Bifida, we only estimate the labour productivity gains from reduced cases of Spina Bifida, predicted to be 95 at the 250micrograms/100g fortification level. This figure is then doubled to 190 account for both parents, with the assumption that both parents work and household labour participation is distributed equally between them.

104. The aggregated average annual income for 190 people is £4.3m. Using a central value from the literature review of a reduction of 24% in labour participation the aggregated average annual income for 190 parents of Spina Bifida patients is £3.3m implying an annual income loss of £1m owing to Spina Bifida cases.

105. Following the cohort approach used in the health benefits and NHS treatment cost analyses, the total labour productivity gain owing to the policy over the 10-year assessment period is estimated to be £46m. This is potentially an underestimate given that the analysis only accounts for parents of those with Spina Bifida – parents of those with Encephalocele will also likely have a lower labour participation rate, however this would not majorly affect the results as the prevalence rate of Encephalocele is much lower.

Social Care Savings

106. Those affected by NTDs often require lifelong healthcare and social care⁷⁸. As a result of a reduction in cases of NTDs, the overall social care burden created by these conditions will fall, which means a reduction in the opportunity cost (separate to a labour productivity increase), as well as a reduced social cost of those that have to give up time to care without pay for those suffering with NTDs.

107. We have not quantified this benefit due to a lack of evidence and will seek views and evidence to fill this gap through consultation.

108. There will likely be an increase in the labour productivity in individuals with prevented cases of NTDs, however there is a lack of clear evidence to suggest the magnitude of this effect. One study suggests that on average Spina Bifida patients require 10.8 sick days from work annually; however, the study goes on to discuss issues regarding the heterogeneity of the Spina Bifida population with regards to disease severity, as well as the fact that sick days were allocated to all persons rather than just those theoretically able to work, which would bring the figure down.

⁷⁶ [Economic burden of neural tube defects and impact of prevention with folic acid: a literature review | SpringerLink](#)

⁷⁷ [A05 SA: Employment, unemployment and economic inactivity by age group \(seasonally adjusted\) - Office for National Statistics \(ons.gov.uk\)](#)

⁷⁸ [Neural tube defects in Australia: prevalence before mandatory folic acid fortification, Summary - Australian Institute of Health and Welfare \(aihw.gov.au\)](#)

Summary of Costs and Benefits

109. As seen in the analysis above, the benefits of the policy far outweigh the costs, totalling £526m and £34m respectively when considering the central estimate. The majority of the costs from the policy are transitory in relabelling, and while there is an annual cost involved in purchasing pre-mix containing folic acid the health and economic benefits seen each year outweigh these. The table below summarises the central estimate costs and benefits of the policy.

Table 13: Summary of Costs

Impact	Cost, £m
Industry Familiarisation	£0.04m
Enforcement Familiarisation	£0.01m
Relabelling	£27m
Fortification	£7m
Total	£34m

Table 14: Summary of Benefits

Impact	Benefit, £m
Health Benefits (QALY gain)	£455m
NHS Cost Savings	£25m
Economic Benefits (Labour Participation)	£46m
Total	£526m

Sensitivity Analysis

110. It is recognised that many of the calculations within this Impact Assessment currently only generate illustrative impacts based on plausible assumptions. The specific choices of these assumptions can have a substantial impact on the final estimates. We have selected the key variables for sensitivity analysis based on the degree to which they are uncertain, and the extent to which they determine the direction and magnitude of the policy's NPV. These variables are:

- 110.0. The various factors underlying transition cost calculations
- 110.1. The cost per FCE to calculate NHS cost savings
- 110.2. The reduction in NTD risk to calculate health benefits

Cost to Business

Relabelling Costs

111. We used a range of SKUs that would need to be relabelled to reflect the uncertainty of the assumption used in the central estimate that all other food retailers would stock the same proportion of own-label SKUs as the average of the four largest UK supermarkets, 31.4%.

112. In sensitivity analysis, we increased the average by 5% to account for a reasonable margin of error. For a lower bound, we tested a scenario in which only 5% of own-label SKUs contain non-wholemeal wheat flour, which would reflect smaller stores which may only sell drinks and a very limited range of products. Other than the adjustment of this input, the methodology is the same as explained earlier in the impact assessment. The results can be seen in the below table.

Table 15: Relabelling Cost Sensitivity Analysis

% of SKUs containing non-wholemeal wheat flour	Number of Products Affected	Total Relabelling Cost
31.4%	12,922	£27m
5.0%	10,620	£23m
36.4%	13,358	£28m

Familiarisation Costs

113. We adjusted the wages that are earned by research and development managers, as well as by corporate managers and directors, using the 75th and 25th percentile wages to produce upper and lower estimates. The 25th percentile wage for research and development managers is £23.22 and £18.42 for corporate managers and directors. The 75th percentile wages are £38.49 and £43.35 respectively, after non-wage uplift has been applied.

Table 16: Industry-Wide R&D Manager Familiarisation Cost, Wage Adjustment

Wage Percentile	Uplifted Hourly Wage, £	Industry-Wide Cost, £
25 th	23.22	2,200
50 th	29.41	2,800
75 th	38.49	3,700

Table 17: Industry-Wide Corporate Manager Familiarisation Cost, Wage Adjustment

Wage Percentile	Uplifted Hourly Wage, £	Industry-Wide Cost, £
25 th	18.42	1,200
50 th	27.73	1,800
75 th	43.35	2,800

Table 19: Total Industry-Wide Familiarisation Cost, Wage Adjustment

Wage Percentile	Total Industry-Wide Cost, £
25 th	3,400
50 th	4,600
75 th	6,500

Health Benefits

114. To account for the uncertainty regarding whether the use of the Daly or Crider equation in the FSS modelling produced a more accurate estimate of NTD risk reduction, we used the risk estimate from each individually rather than an average of the two to produce an upper and lower estimate of health benefits.

115. As seen in table 7, at a fortification level of 250ug/100g the Daly model predicts a reduction of 15.4% in NTD risk, whilst the Crider model predicts a 22.4% reduction. The number of cases prevented for Spina Bifida, Encephalocele and Anencephaly given each adjustment can be seen in the table below.

Table 20: Estimated NTD Cases Prevented Using Different Equations Seen in FSS Modelling

NTD	Estimated Cases Prevented, Daly	Estimated Cases Prevented, Crider
Spina Bifida	75	110
Encephalocele	15	22
Anencephaly	60	88
Total	150	220

116. The methodology to estimate the monetised health benefits from the number of NTD cases prevented with the adjusted equations was the same as in the main analysis. The results are summarised in the below table.

Table 21: Summary of Monetised Health Benefits by NTD, Risk Reduction Adjustment

NTD	Individual Lifetime QALY Loss	Daly Total QALY Loss Prevented	Daly Total Monetised Benefits, £m	Crider Total QALY Loss Prevented, £m	Crider Total Monetised Benefits, £m
Spina Bifida	22.62	1700	£102	2490	£149
Encephalocele	27.65	410	£25	610	£37
Anencephaly	50.27	3010	£181	4420	£265
Total			£308		£451

117. The use of the Daly equation risk reduction forms the lower estimate, whilst the Crider equation provides the upper estimate. The central estimate using an average of the risk reductions produced by the equations is £390m.

Economic Benefits

Caregiver Labour Participation

118. The study that provided the 24% reduction figure in labour participation for parents of Spina Bifida patients stated that there was a range of 21%-27%; and in the main analysis the middle value was used. To account for the range given, we adjusted the reduction in labour participation using the upper and lower bounds of the range, whilst using the same methodology as in the main analysis. The results are summarised in the below table.

Table 22: Summary of Labour Benefits by Initial Reduction in Labour Participation

	Lower Estimate (21%)	Central Estimate (24%)	Upper Estimate (27%)
Annual Loss in Aggregate Income, £m	£0.90m	£1.0m	£1m
10-Year Cohort Total Loss, Discounted, £m	£40m	£46m	£52m

NHS Treatment Cost Savings

119. To account for the uncertainty of the assumption that NTD consultation episodes cost the same as all other consultation episodes, we adjusted the cost-per FCE for NTDs using a value seen in literature and an arbitrary value of half the central estimate. We believe it is unlikely that the treatment costs for NTDs would be significantly cheaper than those of other Congenital conditions.

120. The upper estimate is taken from research by Bowles et al.¹⁷ regarding the medical costs of NTDs in Germany, where it is estimated that the annual per capita treatment cost of Spina Bifida is £3,580 (converted from Euros, and already discounted at 3.5%). The central estimate used in the main estimate is the total NHS spend on Congenital conditions divided by the total number of consultation episodes for Congenital conditions, at £3,320. The lower estimate is then half of this amount at £1,660.

121. The estimated reduction in FCEs relating to NTDs was the same as in the main analysis, being an equal percentage reduction as the total number of cases, and this figure was multiplied by each adjusted value of cost-per FCE and run through the same methodology as in the main analysis to find the total 10-year NHS treatment cost savings. The estimates for the adjustments are summarised in the table below.

Table 23: Summary of NHS Treatment Cost Savings by Cost-per FCE

Cost-per FCE, £	Annual Treatment Cost Reduction, £	Total 10-year Cost Reduction, £m
£1,660	£283,000	£12.6m
£3,320	£566,000	£25.3m
£3,885	£663,000	£29.6m

Net Present Value

122. The table below shows the central, lower and upper estimate for the overall net present value (NPV) of the policy where key assumptions have been tested in sensitivity analysis. Although some of the lower and upper estimates are unlikely to occur, it is useful to see what the costs and benefits of the policy could be in extreme conditions. Even in the unlikely extreme example where all the highest costs and lowest benefits are combined the quantified benefits of this proposal significantly outweigh the costs with an NPV of £375m.

123. The NPV for each scenario was calculated by inputting impacts from the analysis into the Estimated Annual Net Direct Cost to Business (EANDCB) calculator⁷⁹, which summarises the lower, central and upper estimate scenarios and produces NPV figures for the policy.

Table 24: Summary of Discounted Costs and Illustrative Benefits – Option 2 (£m, 10-year appraisal period for profit loss and benefits)				
Group affected	Impact	Low estimate	Central estimate	High estimate
Manufacturers	Transition – Familiarisation	-0.005	-0.004	-0.003
	Transition – Relabelling	-28.3	-27.3	-22.5
	Fortification	-8.6	-6.5	-4.3
Total manufacturer impact		-36.9	-33.8	-26.8
Government	NHS Cost savings	12.6	25.3	29.6
	Transition - Enforcement Familiarisation	-0.009	-0.009	-0.009
Total Government impact		12.6	25.2	29.5
Wider society	Health benefits	358.9	454.6	526.4
	Economic benefits (Parent labour participation)	40.2	46.0	51.7
Total wider societal impact		399.1	500.6	578.1
NPV		374.9	492.0	580.9

⁷⁹ Impact assessment calculator - GOV.UK (www.gov.uk)

124. We estimate the policy to generate large benefits, including when uncertain assumptions are tested and made more conservative. The majority of the benefits generated by the policy come from the substantial monetised health benefits – this is partly attributable to the fatal nature of Anencephaly; for which each prevented case essentially leads to an additional full life, estimated to be valued at around £3.4m.

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