

Amending The Bread and Flour Regulations 1998: Partial Business and Regulatory Impact Assessment (BRIA)

A Partial Business and Regulatory Impact Assessment (BRIA) to support the consultation on the implementation of the amending Regulations in Scotland.

May 2024

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# Title of Proposal

Amending the Bread and Flour Regulations 1998.

# Purpose and Intended Effect

## Background

The Bread and Flour Regulations 1998 (hereafter ‘the Regulations’ or ‘BFR’) lay down specific labelling and compositional rules for bread and flour sold in Scotland. Under these rules non-wholemeal wheat flour (NWWF) is required to contain specific quantities of certain vitamins and minerals. The Regulations also lay down chemical specifications for those compulsory added vitamins and minerals.

Food Standards Scotland (FSS) is consulting on the implementation of the amendments to the Regulations in Scotland which includes the introduction of the mandatory fortification of flour with folic acid. This follows the 12 week UK-wide consultation published in September 2022 and the publication of the Consultation and Government response published on 17 January 2024 which confirmed that the Regulations are to be amended as follows:

* Implement the public health policy across the UK to mandate the compulsory fortification of non-wholemeal wheat flour with 250 micrograms of folic acid per 100 grams of non-wholemeal wheat flour.
* Increase the minimum level of calcium carbonate, iron, and niacin in non-wholemeal wheat flour in line with the 15% Nutrient Reference Value (NRV) per 100g of flour.
* Replace the calcium specification in the BFR with the specification laid out in Regulation EC 231/2012 laying down the specifications for Food Additives.
* Specify in the Regulations that fortification only applies to non-wholemeal wheat flour derived from “common wheat”.
* Introduce an exemption from fortification for flour produced by small-scale mills (applying to those producing less than 500 metric tonnes per annum).
* Remove the requirement relating to minimum levels of iron, thiamine and niacin naturally present in wholemeal flour and replace with a legal definition that wholemeal flour must consist of the whole product from the milling and grinding of cleaned cereal.
* Provide for an adjustment period of 24 months.

**This partial BRIA is required to support the consultation on the implementation of the amending Regulations in Scotland to consider if there are any additional Scottish specific implications concerning the implementation of these changes that has not already been raised in discussion or in response to the** **12 week UK-wide consultation published in September 2022.**

## Objectives

### 2.2.1 Folic acid

The objective of this intervention is to reduce the incidence of neural tube defects in Scotland by increasing the dietary intake of folic acid, and therefore blood folate levels in women of childbearing age.

### 2.2.2 Other amendments

The objective of the other interventions is to update and improve the Regulations by aligning the fortification requirements with overlapping food regulations to ensure that the understanding of the Regulations is consistent throughout industry and enforcement. Key considerations for these measures include:

* Clarifying the scope of the regulations to enable consistent understanding and interpretation regarding the type of flour that is subject to the fortification requirements.
* Ensuring that the regulations are not disproportionately burdensome on businesses by introducing an exemption which does not compromise the public health outcomes which the regulations are designed to uphold.

2.2.3 On a measure-by-measure basis, the policy objectives are as follows:

#### Minimum Level of Nutrients Added to Flour

The main objective is to resolve the interpretation issues regarding how the Regulations interact with overlapping regulations (Assimilated Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods & Regulation 1169/2011 on the provision of food information to consumers) 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.

#### Calcium Carbonate Specification

The main objective is to resolve the interpretation issues regarding how the Regulations interact with overlapping regulations (Assimilated Regulation 231/2012laying down specifications for food additives listed in Annexes II and III to Assimilated Regulation 1333/2008 on food additives) 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.

#### 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 and provide a legal definition that wholemeal flour must consist of the whole product from the milling and grinding of cleaned cereal) is consistent throughout industry and enforcement. Thus, ensuring that the interpretation of the rules is clear for industry and enforcement authorities.

#### Exemption - Treatment of small-scale mills within existing Bread and Flour Regulations

The main objective is to mitigate the burden of the Regulations on small scale millers. In addition, 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. Furthermore, it is to achieve this without compromising the policy goals of wider health objectives.

## Rationale for Government intervention

### 2.3.1 Folic acid

Folate levels in women of all age groups have been in decline, despite public health advice in both Scotland and the UK, as a whole. This trend is likely to increase the risk of Neural Tube Defects (NTD) affected pregnancies in pregnant women or women who could become pregnant if it continues unabated.

Voluntary fortification is already permitted. This is in support of the government advice that women who could become (or are planning to become) pregnant should take a daily supplement of 400 micrograms of folic acid before conception, and until the 12th week of pregnancy. Supplements are therefore available, but current data suggests these approaches are unlikely to increase folate intakes in the Scottish population sufficiently.

There is, therefore, a rationale for Government intervention from a public health perspective to further increase folate intake levels and decrease the risk of NTD-affected pregnancies and Scottish Ministers have long advocated for the mandatory fortification of flour with folic acid to help reduce this risk in Scotland.

In September 2021 following a UK wide public consultation, the Scottish Government along with the UK Government and the devolved administrations in Wales and Northern Ireland announced their intention to proceed with arrangements to require additional mandatory fortification of non-wholemeal wheat flour with folic acid on a UK basis to help prevent foetal neural tube defects.

In December 2021, the then Scottish Minister for Public Health and Women’s Health agreed the recommendation to proceed with mandating the fortification of non-wholemeal flour, at a level of 250 micrograms (µg) folic acid per 100g of flour, a position supported by the 4 UK Chief Medical Officers and the Scientific Advisory Committee on Nutrition (SACN).

Implementation has been taken forward as part of the wider review of the Regulations to ensure that the legislation leads to improved public health outcomes, supports UK industry, assists enforcement authorities and protects consumer interests. 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.

### 2.3.2 Other amendments

There are inconsistencies currently between the Regulations and other overlapping food regulations. Government intervention is needed to address this ambiguity over how legislation is applied. This may also remove or reduce certain barriers to entry and level the playing field among millers.

Similarly, addressing the scope of the regulations (i.e. defining ‘wheat flour’) will clarify any potential differing interpretations over the scope of the fortification requirements for wheat flour. This allows for a common understanding across the flour supply chain and local enforcement authorities as to what types of flour are subject to these fortification requirements.

# Consultation

## Within Government

FSS has policy responsibility for the Regulations and has discussed this consultation package with Scottish Government officials from the Food and Drink Policy team and Population Health Directorate.

## Public Consultation

In September 2022, FSS along with the Department for Environment Food & Rural Affairs (Defra), and the Food Standards Agency (FSA) in Wales and Northern Ireland held a joint UK wide consultation on options to amend the Regulations. The policy options in that consultation were as follows:

* Option 1 - Raise the set minimum level of nutrients present in flour.
* Option 2 - Remove calcium carbonate criteria from the regulations.
* Option 3 - Introduce the legal requirement to add 250 micrograms of folic acid per 100g of non-wholemeal wheat flour.
* Option 4 - Add clarification on the scope of the regulations limiting fortification of flour derived from common wheat.
* Option 5 - Exempt small-scale mills producing less than 500 metric tonnes of flour per annum from fortification requirements.
* Option 6 – Exempt flour to be used in a product when it is present as an ingredient at 10%.
* Option 7 – Introduce improvement notices in England, Wales and Northern Ireland.

(Option 7 did not apply in Scotland as a separate consultation was held in Scotland on the introduction of Compliance Notices across food legislation in December 2021. The Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 then came into force on 30 June 2023 and covers the provisions of the Regulations in respect of the composition of flour.)

The consultation received responses from 369 participants from a wide range of stakeholders in Scotland and across the UK and the responses were mixed but were generally supportive of the proposals. Having reviewed and assessed responses to the consultation, policy officials in all four nations agreed in principle to progress all of the proposals with the exception of Option 6. Although this option received majority support from consultation respondents overall, on balance it was considered this option would compromise the ability to meet key policy objectives due to the complexity of complying, monitoring and enforcing this exemption.

FSS recommended to the Scottish Minister for Public Health and Women’s Health that all options with the exception of Options 6 and 7 would best fulfil the objectives of the review in Scotland and the Minister supported this. In addition, the Minister agreed to the provision of a 24 month adjustment period to allow industry to co-ordinate changes across a range of products to mitigate excessive re-labelling costs, reduce product and packaging waste as far as possible and implement the changes to composition in a responsible and effective manner to the benefit of the public. The full summary of responses received from the UK wide consultation is available in the published [Summary of Responses and Government Response](https://www.gov.uk/government/consultations/amending-the-bread-and-flour-regulations-1998-and-the-bread-and-flour-northern-ireland-regulations-1998/outcome/summary-of-responses-and-government-response#executive-summary).

## Business

In 2021, a Bread and Flour Technical Working Group was convened by Defra to initiate a UK wide review to explore the issues around the Bread and Flour Regulations. This included scope for discussion on the compositional requirements for bread and flour and providing definitions in respect of the terms referenced in any potential legislative changes that would be beneficial to protect consumers.

Defra hosted three stakeholder engagement meetings in 2021, with FSS and Scottish Government, along with the FSA and officials in other devolved government departments with an interest invited to attend. Following this initial stakeholder engagement, the areas considered appropriate for review were developed into options for the 12 week, UK wide public consultation.

In addition, FSS intend to carry out further informal face to face engagement with Scottish stakeholders during the 6 week consultation on the implementation of the amendments to the Regulations in Scotland to establish if the implementation of these changes has any additional impact on Scottish businesses specifically that has not already been raised.

# Options

## Overview of options

The options described below were fully covered in the UK-wide consultation and supporting Impact Assessment and Option 5 was agreed across the UK post-consultation.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Option | Introduce folic acid fortification | Amend fortificant levels | Remove calcium specification | Clarify wheat definition | Exemptions for small-scale millers |
| Option 1 | ✕ | ✕ | ✕ | ✕ | ✕ |
| Option 2 | ✓ | ✕ | ✕ | ✕ | ✕ |
| Option 3 | ✓ | ✓ | ✓ | ✕ | ✕ |
| Option 4 | ✓ | ✓ | ✓ | ✓ | ✕ |
| Option 5 | ✓ | ✓ | ✓ | ✓ | ✓ |

## Option 1: Do nothing

Do not amend the Regulations. This option would have involved not making any changes to the existing Regulations at all. 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 Regulations.

## Option 2: Introduce folic acid fortification of flour as the only amendment to the Regulations

This option would have entailed amending the Regulations to allow the fortification of flour with folic acid (at 250μg per 100g flour). No further amendments to the BFR would be made. This measure has already been subject to a pre-consultation IA undertaken by Department of Health and Social Care (DHSC), which was used as the basis for this Scotland-specific Business Regulatory Impact Assessment by FSS.

## Option 3: As per Option 2 plus address the Regulations interactions with wider food regulations

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

1. Amend the Regulations 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% Nutrient Reference Values (NRV) threshold specified in Regulation 1925/2006. Aligning the Regulations with the horizontal rules & wider nutritional legislation (Regulation 1925/2006 & Regulation 1169/2011) on the fortification of food, provides industry with clarity on the UK fortification requirements.
2. Amend the Regulations to remove existing calcium carbonate criteria, requiring millers to comply with the specification in Regulation 231/2012 instead – this option removes misalignment with the overlapping legislation on additives.

## Option 4: As per Option 3 plus clarify the scope of the regulation with respect to fortification requirements for wheat flour

This option builds 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:

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 “common wheat” Triticum aestivum only - this option provides legal clarity on the type of wheat that falls within the scope of the Regulations, removing ambiguity for industry and enforcement authorities in terms of the type of flour that requires fortification.

## Option 5: As per Option 4 plus introduce a specific exemption from the regulations to reflect industry feedback (agreed option)

This option builds on Option 4 above but also involves an additional measure to introduce specific flour fortification exemption, as per the below:

Introduce an exemption from all fortification requirements for small-scale millers – this option means any type of mill producing no more than 500 metric tonnes of flour per year is exempt from the requirement to fortify.

## Non-regulatory options

Non-regulatory options were considered as part of the range of options considered but were deemed to not effectively meet the policy objectives of this intervention.

## Sectors and groups affected

The following groups will be affected by the proposed changes.

* **Consumers** – it is anticipated that the general public will see health benefits owing to a reduction in NTD affected pregnancies as a result of an increase in folate intake across the population of women who could become pregnant.
* **Businesses** – in the short-term, manufacturers and businesses will experience a period of adjustment moving to the new requirements and making the necessary changing to packaging and product labelling.
* **Enforcement authorities** – will initially need to familiarise themselves with the new requirements but will benefit from clearer legislative provisions in respect of the scope and definitions within the Regulations.

## Benefits

The majority of the (monetised) benefits stem from the inclusion of folic acid fortification in Option 2. These benefits are assumed to be primarily in the form of health benefits, NHS treatment cost savings, and increased labour participation. Other benefits include regulatory clarity (Options 3-5) and reduced fortification costs for small millers (Option 5).

**To avoid duplication, each benefit listed here is in addition to the benefits from the previous option(s).**

Table 1. Benefits associated with each policy option.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Public** | **Private sector** | **Public sector** |
| **Option 1 (do nothing)** | .. | .. | .. |
| **Option 2** | + Reduced prevalence of NTDs  + Reduced severity of NTDs that do occur\*  + Reductions in B9 anaemia\*  + Labour participation  + Social care cost savings\*  + Reduction in psychological harm and stress caused by NTD-affected miscarriages, stillbirths, terminations\* | + Increased sales for folic acid producers\* | + Reduced NHS costs  + Reduced social care costs |
| **Option 3** |  | + Increased legal clarity\* |  |
| **Option 4** |  | + Increased legal clarity\* |  |
| **Option 5 (agreed option)** | + Increased choice for consumers compared to options 2-4 (fortified vs. non-fortified)\* | + Reduced fortification costs for small-scale millers  + Support viability for small millers\* |  |
| **\* Unmonetised benefit**; this could be due to a lack of (Scottish, UK, or international) data or evidence, or due to the difficulty in monetising it. | | | |

## Costs

The majority of the (monetised) costs stem from the inclusion of folic acid fortification in Option 2. These costs are assumed to be primarily in the form of industry costs: relabelling, package waste, fortification and familiarisation costs. Other costs include regulatory clarity (Options 3-5) and reduced fortification costs for small millers (Option 5).

**To avoid duplication, each cost listed here is in addition to the costs from the previous option(s).**

Table 2. Costs associated with each policy option.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Public** | **Private sector** | **Public sector** |
| **Option 1 (do nothing)** | .. | .. | .. |
| **Option 2** | - Adverse health impacts for those who now exceed the recommended folic acid intake\*  - Reduced availability or choice of non-fortified NWWF for consumers\* | - Increased fortification costs to millers  - Initial implementation costs associated with revised labelling and package waste costs  - Loss in profits due to some consumers preferring non-fortified NWWF\*  - Increased quality assurance check costs for millers\* | - Familiarisation costs for enforcement authorities |
| **Option 3** |  |  |  |
| **Option 4** |  |  |  |
| **Option 5 (agreed option)** |  | - Increased fortification costs (larger millers only)  - Initial implementation costs associated with revised labelling and package waste costs (larger millers only)  - Initial implementation costs associated with revised labelling and package waste costs (small-scale millers who choose to no longer fortify) |  |
| **\* Unmonetised cost**; this could be due to a lack of (Scottish, UK, or international) data or evidence, or due to the difficulty in monetising it. | | | |

# Regulatory and EU Alignment Impacts

## Intra-UK Trade

Policy leads from across the four nations have worked together under the provisional Food Compositional Standards and Labelling common framework to review the legislation, develop the UK wide consultation and agree the policy across the UK. As the addition of vitamins and minerals to food falls within the Nutrition Labelling and Composition Standards framework, relevant officials have also been engaged. These measures are being adopted across the UK and will come into force on a common commencement date. Therefore, there will be no divergence or impact on intra-UK trade.

## International Trade

These domestic measures are unlikely to impact significantly on international trade and investment.

### 5.2.1 Exports

Only 6% of flour produced domestically in the UK is exported – c.a. 270,000 tonnes annually – according to HMRC’s Overseas Trade Statistics[[1]](#footnote-2). Flour that is exported, whether as commodity or as an ingredient in a processed food, can be exempted from the Regulations if the exporter decides to do so. For these reasons, the proposed amendments would not have an impact on exported flour.

### 5.2.2 Imports

Producers who currently export their flour to the UK will also need to fortify and will therefore face increased fortification costs, which may impact the price or availability of such flour. However, the UK imports less than 2% of all flour consumed, meaning that the impact on UK consumers will likely be negligible.

## EU Alignment

Across the EU there is variation in the requirements around the fortification of food and more generally across a range of domestic legislation. The Regulations provide for longstanding domestic measures in Scotland, on the fortification of flour and as such will not impact on the Scottish government’s policy to maintain alignment with the EU. However, increasing the levels of calcium carbonate, iron, and niacin to align with the requirements set out in both EU and affiliated EU law will support the Scottish government’s policy to maintain alignment with the EU.

# Scottish Firms Impact Test

Engagement and consultation on the policy proposals with stakeholders including businesses, the public sector and consumers has shaped the development of the amendments being made to the Regulations. The additional consultation on the implementation of the Regulations in Scotland is seeking additional views to consider if there are any additional Scottish-specific implications concerning the implementation of these changes that have not already been raised. Any specific issues that emerge from respondents will be followed up in more detail.

# Competition Assessment

## Introduction

Following consultation responses, a more comprehensive, qualitative analysis of the competition impacts of the amendments can now be undertaken. This analysis will consider the four main competition assessment questions in turn, discussing each of the proposed amendments and their likely impacts on the relevant competition factors. Where no assessment is made in each sub-section on a particular amendment’s impact, this is because it is deemed to have no significant impact.

Generally speaking, flour is a homogenous product in the UK. Some subtle product differentiation is possible and explored in this assessment. As a result, most competition within UK industry occurs on price, as opposed to the ability to offer a unique product, or quality. In some cases, product differentiation is possible, such as when flour is produced locally in heritage mills, using traditional production processes. With this understanding of the industry, the competition assessment framework can be applied to the amendments.

Table 3. Summary table showing answers to the CMA’s competition assessment questions

|  |  |  |
| --- | --- | --- |
| **Question** | **Proposed measures** | |
| **Q1. Will the measure directly or indirectly limit the number or range of suppliers?** | Folic acid | Yes – it raises costs for millers, but fortificant costs are small. |
| Fortification at 15% | Yes – it raises costs for millers, but fortificant costs are small. |
| Calcium specification | Yes:   1. Calcium production is related to the local geography, so changing the specification may make it difficult for some calcium suppliers. 2. New specification calcium is more expensive as it needs to be imported. However, the UK source of previous specification calcium has closed down, so all premixes contain new specification anyway. 3. Fortificant costs are small so may not lead to business exiting the market. |
| Wheat definition | No. |
| Small-scale miller exemption | Yes – it reduces (fortification) costs for small scale millers. However, it is not necessarily going to increase the number of suppliers as it is a sector with high entry barriers (traditions, history, etc). |
| **Q2. Will the measure limit the ability of suppliers to compete?** | Folic acid | No – while it changes the characteristics of the product supplied, this does not limit the ability of suppliers to compete. It is not decisive in determining the competitive positioning of suppliers. |
| Fortification at 15% | No – while it changes the characteristics of the product supplied, this does not limit the ability of suppliers to compete. It is not decisive in determining the competitive positioning of suppliers. |
| Calcium specification | No – while it changes the characteristics of the product supplied, this does not limit the ability of suppliers to compete. It is not decisive in determining the competitive positioning of suppliers. |
| Wheat definition | No. |
| Small-scale miller exemption | No. |
| **Q3. Will the measure limit suppliers’ incentives to compete vigorously?** | Folic acid | No. |
| Fortification at 15% | No. |
| Calcium specification | No. |
| Wheat definition | No. |
| Small-scale miller exemption | No. |
| **Q4: Will the measure limit the choices and information available to consumers?** | Folic acid | No. |
| Fortification at 15% | No. |
| Calcium specification | No. |
| Wheat definition | No. |
| Small-scale miller exemption | No. |

## Will the measure directly or indirectly limit the number or range of suppliers?

### 7.2.1 ‘Amend the Regulations to allow the fortification of flour with folic acid’

As Table 1 shows, current fortification costs are a small fraction of total production costs, with the additional cost of adding folic acid expected to be around £0.15 per tonne of flour (under the dosage conditions outlined in Table 1). This is comparable in magnitude to the cost of raising levels of other fortificants to 15% (£0.10-£0.16)[[2]](#footnote-3). Therefore, the additional cost of including folic acid is likely to be very small, and as such is unlikely to influence business behaviour or strategy.

Table 4: Indicative costs of added nutrients to flour

|  |  |
| --- | --- |
| **Cost** | **£ per tonne of flour** |
| Cost of premix compliant with the levels specified in the Bread and Flour Regulations | £1.20 |
| Cost of premix with calcium, iron and niacin levels raised to 15% NRV | £1.30 to £1.36 |
| On-cost to flour millers of raising the fortification level to 15% NRV[[3]](#footnote-4) | £0.10 to £0.16 |
| On-cost to flour millers of premix including folic acid, dosed at 250g per tonne of flour[[4]](#footnote-5) | £0.15 |

### 7.2.2 ‘Amend the Regulations to remove existing calcium carbonate criteria, requiring millers to comply with specification in Regulation 231/2012 instead’

The removal of the distinct calcium specification provides flour millers with improved clarity on regulatory requirements. Unifying the calcium specification does leave flour millers with no choice but to purchase calcium carbonate from a sole supplier in France. However, we anticipate no additional competition impact as a result of the regulatory change. There is no realistic alternative supplier and there has not been since the closure of the UK calcium plant at Steeple Morden. The regulatory change is to keep pace with what is already happening in bread and flour markets, as in practice, premixes are already meeting the revised requirements.

### 7.2.3 ‘Amend the Regulations to raise required fortificant levels to the 15% level required by overlapping legislation on the addition of vitamins and minerals to food generally’

Fortification has been taking place for some time as part of the existing requirements, ensuring minimum standards of fortification. As this amendment seeks to formalise a new level of fortification, it is only expected to result in a small marginal increase in production costs, as shown in Table 4. The expected impact on costs is further reduced by the fact that 91% of premix sales in the UK are already compliant with Regulation 1925/2006, meaning this amendment has limited material impact on costs from an industry-wide perspective. Given these mitigations, and the fact that the costs affect all fortifying milling businesses equally, no discernible competition impact is expected.

### 7.2.4 ‘Amend the Regulations to introduce exemptions from all fortification requirements for small-scale millers’

The exemption for small-scale millers is for practical rather than competitive purposes; it is designed to avoid a significant increase in costs that would force small scale millers to leave the market. Therefore, avoiding the loss of wider, societal benefits, where small mills are also heritage mills.

The exemption would reduce the operating costs of small millers relative to larger ones but is unlikely to lead to significant market distortions. Heritage millers tend to serve a specific, local market and produce a differentiated product. They are generally social enterprises, rather than out-and-out commercial ones. Furthermore, barriers to entry are high. Modern, small millers may benefit, but only as far as the production threshold will allow.

## Will the measure directly limit the ability of suppliers to compete?

### 7.3.1 ‘Amend the Regulations to raise required fortificant levels to the 15% level required by overlapping legislation on the addition of vitamins and minerals to food generally’ and ‘Amend the Regulations to allow the fortification of flour with folic acid’

The amendments involving additional fortification (the 15% level and the addition of folic acid) will increase production costs and potentially therefore, prices. However, other factors, such as the variation in the price of wheat, are likely to have a greater influence on price.

These amendments will change the composition of flour products, particularly in the case of folic acid. Competition impacts are predicted to be minimal due to the aforementioned minimal impact on costs and the fact that this applies to all medium and large millers.

### 7.3.2 ‘Amend the Regulations to introduce exemptions from all fortification requirements for small-scale millers’

As small millers will be exempt from fortification under the proposed changes, the composition of flour from small mills will not necessarily change. This will mean that some unfortified flour will be placed on the domestic market. However, this is not expected to result in a significant competition impact, as consumers’ decisions to purchase from small millers are unlikely to be driven by fortification requirements.

Given that most of the identified competition risks are associated with the exemptions, Option 5 can be said to induce the highest risk to competition in the industry, while Options 2-4 also introduce some concerns in this area through the fortification requirements. Although, it must also be noted that Option 1’s ‘do nothing’ and the continuation of the Regulations as they stand, thus leaving the legal and enforcement ambiguity unresolved, presents its own competition risks by failing to ensure a level playing field across industry.

## Will the measure limit suppliers’ incentive to compete vigorously?

The proposed amendments to the Regulations are unlikely to incentivise coordination or collusion between firms.

## Will the measure limit the choices and information available to consumers?

### 7.5.1 ‘Amend the Regulations to introduce an exemption from all fortification requirements for small-scale millers’

There are no anticipated competition impacts on information and choice from implementing an exemption on small-scale millers. The exemption may protect consumers who cannot consume fortified flour-based products by ensuring these products are still commercially available, thus preserving consumer choice regarding fortification where this is necessary for health reasons. This is, however, an extremely small proportion of the market, meaning impact on choice overall is very limited. The exemption alone also does not improve anyone’s ability to make optimal decisions, as the protection of product variety is not accompanied by any improved information availability in areas such as public health.

Given the limited impacts on choice and information, as well as the limited impact on entry and exit discussed previously, none of the proposed options are considered to have adverse competition impacts in the areas covered by Question 4.

### 7.5.2 ‘Amend the Regulations to 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’

The proposed simplifications to the definition of wheat will provide additional benefits in consumer choice, as well as information access, by clarifying that grains falling outside this definition of common wheat are exempt from fortification. This will provide greater clarity to industry on fortification requirements for different grains, and therefore also improve consumer choice through the consequent availability of fortified and unfortified products. These improvements in choice and information complement similar impacts from the other proposed amendments to improve consumer choice.

# Consumer Assessment

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 fortification, these options may be more expensive.

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

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). 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. Modelling from FSS showed the risk given different levels of fortification of non-wholemeal wheat flour.

# Test Run of Business Forms

No new forms will be introduced.

# Digital Impact Test

The Regulations as they stand nor as amended with the changes being made have no impact on digital technologies and markets.

# Legal Aid Impact Test

The changes being made to the Regulations do not create a new procedure or right of appeal to a court or tribunal and are unlikely to have any implications for fulfilling individuals' right to access to justice through availability of legal aid and possible expenditure from the legal aid fund.

# Enforcement, Sanctions, and Monitoring

Enforcement of the regulations will be the responsibility of Local Authority Environmental Health Departments. Enforcement should be risk based and proportionate, in line with the approach taken with the current legislation. Enforcement officers would not be expected to initiate separate inspections in relation to the enforcement of these new provisions, but instead to include these as part of their existing regimes.

The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Authorities, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

An implementation monitoring group has been set up to establish key monitoring parameters for the policy. As the primary aim of the policy is to reduce the incidence of Neural Tube Defect-affected pregnancies (NTD-affected pregnancies), monitoring will be needed to establish whether this aim has been achieved.

Any proposed monitoring strategy will include measures of both positive and potential negative impacts of the policy on the health of the population in the UK and in Scotland. This will require pre- and post-implementation data collection and is likely to include monitoring of:

* Incidence of NTD-affected pregnancies
* folate intakes and blood status across the population, to assess improvements following fortification and any increase in the number of people with intakes above upper recommended levels.
* postulated adverse effects (such as certain types of cancer)

# Implementation and Delivery Plan

Subject to Minsterial agreement and Parliamentary scrutiny, the new requirements in respect of the small-scale miller exemption and the change in scope and definitions will come into force on a date to be confirmed. The new fortification requirements including the introduction of folic acid will come into force on a date to be confirmed.

## Post-implementation review

A post-implementation review of the legislation will be taken forward within 10 years.

# Summary and Recommendation

In considering the policy objectives, alongside the benefits and costs illustrated below, overall Option 2 would achieve the primary objective to reduce the incidence of neural tube defects in Scotland by increasing the dietary intake of folic acid, and therefore blood folate levels in women of childbearing age. Options 3 and 4 both add to that primary objective to allow for increased legal clarity for the same benefit outcome with a slight increase in cost. However, Option 5 fulfils all of the objectives, including supporting viability for small millers, by providing an exemption from the fortification requirements with an increase in (unmonetised or monetised) benefits and for a very small additional cost. As such, Option 5 has been identified as the preferred option to achieve the overall aims in the longer term in Scotland and across the UK due to the integrated operational nature of the milling industry.

## Central Estimate

Costs, benefits and net present values (NPVs) for each option have been estimated for Scotland. The majority of benefits and costs are already present in Option 2, owing to the large impact of folic acid fortification. Responses to the Scottish-specific consultation may still affect any assumptions being made, particularly those relating to how UK-wide results or data is apportioned to the Scottish population or industry.

Table 5. Overview of estimated total benefits, costs and net present values (NPVs) for each option (2024 prices, discounted over 10 year appraisal period, central estimate)

|  |  |  |  |
| --- | --- | --- | --- |
| **Option** | **Total benefit** | **Total cost** | **Net present value** |
| £000’s 2024 | £000’s 2024 | £000’s 2024 |
| 1 | 0 | 0 | 0 |
| 2 | 72,076 | 9,040 | 63,036 |
| 3 | 72,076 | 9,065 | 63,010 |
| 4 | 72,076 | 9,065 | 63,010 |
| 5 | 72,077 | 9,071 | 63,006 |

The NPV in Option 5 (exempting small-scale millers from fortification requirements) is marginally lower than Options 2-4 only because we have assumed a ‘worst case scenario’ in Option 5: the fortification cost savings are outweighed by increased relabelling costs for these small-scale millers, and any relabelling is done entirely outside of their regular relabelling cycle (despite the exemption being voluntary). In reality, it is likely that some or all relabelling costs for small-scale millers are absorbed in the regular relabelling cycle, and the fortification cost savings would lead to a slightly higher NPV than in Options 3 and 4.

Regardless of this, the monetised benefits of each Option outweigh the monetised costs, as evidenced by the NPV. Option 5, the preferred option, has a NPV of £63 million in 2024 prices. This is an estimate of the social benefit to Scotland, currently, of implementing these changes. A ten year appraisal period was used, meaning that any lifetime health or healthcare benefits for the cohorts born in these ten years are taken into account.

The monetised benefits are comprised of:

* Health benefits for those who would’ve otherwise been born with an NTD.
* Increased lifetime earnings for those who would’ve otherwise been born with an NTD.
* Increased earnings for parents of those who would’ve otherwise been born with an NTD.
* Decreased healthcare costs associated with NTD live births, stillbirths, miscarriages, or terminations.

While monetised costs are comprised of:

* Industry and enforcement familiarisation costs
* Fortification costs
* Relabelling and package waste costs

The full methodology for calculating the above costs and benefits is shown in Annex I and Annex II. The methodology follows [HMT’s Green Book](https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government/the-green-book-2020) methodology and has been developed in conjunction with analysts in the Department for Health and Social Care (DHSC), Defra and the FSA.

## Breakdown of Costs and Benefits for Option 5

A breakdown of costs and benefits is provided below for Option 5 (these are largely similar between Options 2-5, as evidenced in Table 5). Rather than just showing the central estimate, we also show the low and high estimates for each cost or benefit.

Table 6. Breakdown of the range of estimated benefits and costs for Option 5 (2024 prices, discounted over 10 year appraisal period)

|  |  |  |  |
| --- | --- | --- | --- |
| **Category** | **Value, £000’s 2024** | | |
| Low estimate | Central estimate | High estimate |
| *Public benefits* | | | |
| Health benefits | 38,721 | 59,401 | 84,482 |
| Increased earnings | 6,245 | 10,585 | 16,481 |
| *Government benefits* | | | |
| Healthcare cost savings | 1,362 | 2,090 | 2,973 |
| *Industry benefits* | | | |
| Fortification cost savings\* | 0 | 1 | 1 |
| **Total benefits\*\*** | **46,329** | **72,077** | **103,937** |
| *Government costs* | | | |
| Familiarisation | 1 | 1 | 2 |
| *Industry costs* | | | |
| Familiarisation | 1 | 1 | 3 |
| Fortification | 103 | 308 | 513 |
| Package waste | 1,738 | 6,336 | 23,804 |
| Relabelling | 2,180 | 2,424 | 4,596 |
| **Total costs\*\*** | **4,022** | **9,071** | **28,918** |
| \* Small-scale millers only; \*\* Totals may not sum due to rounding. | | | |

## Low and High Estimates

We constructed a low and high estimate for each Option (as shown above for Option 5). By combining our high cost estimate with our low benefit estimate, and vice versa, we can calculate the full possible range of NPVs for each Option:

Table 7. Overview of the range of NPV estimates for each option (2024 prices, discounted over 10 year appraisal period)

|  |  |  |  |
| --- | --- | --- | --- |
| **Option** | **Net present value, £000’s 2024** | | |
| Low benefits  High costs | Central benefits  Central costs | High benefits  Low costs |
| 1 | 0 | 0 | 0 |
| 2 | 17,460 | 63,036 | 99,925 |
| 3 | 17,418 | 63,010 | 99,917 |
| 4 | 17,418 | 63,010 | 99,917 |
| 5 | 17,411 | 63,006 | 99,915 |

Given these ranges are manually constructed using a combination of literature estimates, assumptions, and Scottish, UK or international data, we have no estimate for the likelihood of the low or high estimates (or a value in-between) occurring.[[5]](#footnote-6) However, all of the NPVs above remain positive, even if industry costs are on the higher end, and benefits on the lower end of our estimate range.

The similarities in costs and benefits between all Options and the large positive NPVs lend credibility to any of the four analysed Options. Given the additional benefits of Option 5, including unmonetised benefits like small business viability, we recommend Option 5 be taken forward.

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# Annex I. Calculation of Benefits

## Option 2 (folic acid fortification only)

The benefits of folic acid fortification for England were modelled by the Department of Health and Social Care. The same methodology was applied for Scotland, adapting data where possible to align more closely to Scotland’s population.[[6]](#footnote-7)

The analysis makes a number of broad assumptions about birth rates, NTD prevalence, reductions in NTD risk due to increased folate intake, health- and social care costs, labour market participation, and representative incomes. A low, central, and high estimate have been provided in an attempt to capture some of the uncertainty surrounding these assumptions.

Table 8. Assumptions

|  |  |  |
| --- | --- | --- |
| A1 | Flour is fortified at 250μg per 100g flour. | Policy option. |
| A2 | The baseline risk of NTDs remains constant throughout the assessment period. | Simplicity and lack of evidence to the contrary.  Although we have seen a worsening trends in blood folate levels, in recent years, NTD rates have been fairly stable.  Moreover, 89% of women aged 16-49 already have blood folate levels below a threshold indicating elevated risk of NTD affected pregnancies so we’re unlikely to see a significant change over the 10 year policy period. |
| A3 | The birth rate remains stable over the 10 year policy period. | The ONS forecasts the birth rate to remain relatively stable over the next 10 years; for simplicity’s sake we assume it remains exactly stable. |
| A4 | 30% of women of child-bearing age already take the recommended daily 400μg folic acid supplement. |  |
| A5 | The average results of two different models for estimating the impact on NTD risk from NWWF fortification (and ±20% low and high estimates) are an accurate representation of the possible spread of risk reduction percentages and are the same across all types of NTD. | This is the same assumption DHSC makes in their analysis and incorporates the most relevant estimates into the analysis. |
| A6 | The lifetime health profile of a typical individual from the English population is representative for an individual from the Scottish population (incl. its standard deviation) |  |
| A7 | The average life expectancy for a newborn in the UK in 2020 (81 years) is representative for a newborn in Scotland throughout the appraisal period of this policy. |  |
| A8 | The life expectancy, quality of life, and healthcare costs for a newborn with Spina Bifida is the same as those for a newborn with Encephalocele. | There was a lack of data on these measures for individuals with Encephalocele. |
| A9 | Newborn babies with Anencephaly, although they may live for a number of days, are assumed to gain the full lifetime QALY if the NTD is prevented (and correspondingly, their current QALY utility is set to zero). | Due to the devastating impacts on the quality of life we set the life expectancy of newborn babies with Anencephaly to zero. This also eases calculations. |
| A10 | Women who give birth in the first year of the policy benefit from the full impact of folic acid fortification and have the same folate levels as those that give birth in the later years of the appraisal period. | Ease of calculation, but may lead to overestimate in first cohort |
| A11 | A reduced number of NTD-related terminations, miscarriages, and stillbirths and lead to reductions in NHS costs. |  |
| A12 | The prevalence of early NTD-related miscarriages (at <20 weeks gestation) in Scotland is approximated by the prevalence of early NTD-related miscarriages for Wales. | The Welsh CARIS dataset registers miscarriages prior to 20 weeks where there are known registerable conditions. While this is still likely to underestimate the true number of early NTD-related miscarriages[[7]](#footnote-8), it is the best data available at the time of writing. |
| A13 | The average cost of an early miscarriage in Petrou et al (2006) is representative of costs in Scotland. | Although the costs are estimated using English data, the estimates are comprehensive and include costs associated with hospital care, medication, medical products, community health, social services, and work absences. |
| A14 | Costs (to the NHS) of both a late miscarriage (20-23 weeks) and a stillbirth (> 23 weeks) are the same as the estimated cost of an early miscarriage. | This is the same assumption used in the DHSC impact assessment. We recognise that late miscarriages are clinically more similar to stillbirths, and so may have more in common in terms of costs with stillbirths than early miscarriages. |
| A15 | The counterfactual NHS healthcare cost for a healthy newborn is £0. | In estimating the reduced healthcare costs stemming from a reduced number of NTD-related miscarriages and stillbirths, we assume a healthy newborn has an associated healthcare cost of £0. In reality, this is of course not accurate, since there are (usually) healthcare costs associated to live births as well. This also disregards the potential other healthcare costs associated throughout the newborn’s childhood and beyond due to the large degree of uncertainty. |
| A16 | The NHS healthcare costs associated with surgical and medical terminations in England are representative for the NHS healthcare costs in Scotland. | Due to the lack of Scottish cost estimates, English cost estimates were used (and in line with the DHSC impact assessment). |
| A17 | The split between medical and surgical terminations for total terminations in Scotland in 2021 is the same split as those for NTD-related terminations. | Data from Public Health Scotland. Note that this differs from the DHSC impact assessment for England, who use statistics for England & Wales – where the proportion of medical terminations was 87% in 2021. |
| A18 | The central employment rate for people with NTDs is 40%, slightly below the employment rate for disabled people aged 16 to 64 in Scotland (49.6% in 2021). | This brings it more in line with the literature on labour force participation among people with NTDs. Given the range of estimates in the literature, we also introduce a 30% and 50% employment rate for our high and low estimate, respectively. |
| A19 | All employed people (with NTDs or not) work full-time jobs (taken to mean a 52 week year, 36.375 hour working week[[8]](#footnote-9), and a working age between 15-64). | The 36.375 working week is taken from 2023 ONS labour data (for all full time employees). The week and working age assumptions are taken as given. Note that in reality, actual hours worked may differ based on a variety of factors, incl. disability and age. If people with NTDs are e.g. more commonly employed part time or working reduced hours, then the actual earnings gained will have been underestimated. |
| A20 | The lower labour participation rates by parents of Spina Bifida patients shown in [Yi et al (2011)](https://link.springer.com/article/10.1007/s00431-011-1492-8) (more specifically, the midpoint of a 24% reduction) are assumed to hold for parents of patients with Encephalocele as well. We also assume that the Yi et al study translates to Scotland, and that all individuals with a would-be NTD come from a two parent (or two carer) household. | There is a limited amount of data on reduced labour force participation of the parents of NTD parents, and the literature review by Yi et al is a comprehensive overview of a number of studies. We recognise that this labour force participation reduction may be highly dependent on e.g. health and social care |
| A21 | The average labour participation rate and wage of adults aged 18-49 in the UK is not affected to a significant degree by parents of NTD patients, and if a proportion of NTDs are prevented, parents of these individuals will revert to this national average labour participation rate and wage. | This was primarily assumed due to the lack of data on wages for parents of NTD patients. NTDs present a relatively small proportion of total live births in the UK so this is likely not far off the true figure. |
| A22 | The reduction in labour force participation rate among parents of children with NTDs is only present until the child is 18 years old. After that, they revert to the national average labour force participation rate. | In reality, this may vary depending on the person and the amount of health, social, or carer support needed as the child grows up. A proportion of parents will likely still have a reduced labour force participation rate even after the child turns 18. |

The primary health benefit that will accrue due to the policy is the reduction in risk and cases of NTD-affected pregnancies as a result of the higher blood folate level in women who could become pregnant.

Modelling conducted by FSS in 2017 (see [*Stochastic modelling to estimate the potential impact of fortification of flour with folic acid in the UK*, Food Standards Scotland](https://www.foodstandards.gov.scot/publications-and-research/publications/stochastic-modelling-to-estimate-the-potential-impact-of-fortification-of-f)) estimated the decrease in risk of the three main types of NTD (Spina Bifida, Anencephaly, and Encephalocele) for given levels of fortification.

DHSC deemed ‘Model C’ from this paper to be most applicable to this scenario. This model accounts for variations in folate status across the population, and assumes that 30% of women already take the recommended daily 400μg folic acid supplement (A4). This model had two variations, based on different prediction equations from literature. For the purpose of assessing the impact of flour fortification, DHSC is using an average of the two variations (19% risk reduction) as their central estimate, and a ±20% low and high estimate based on the Daly and Crider model variation, respectively (A5).

Table 9. Assumed effect of fortification of all NWWF and reduction in NTD risk

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Fortification** | **Estimated reduction in risk of developing NTD** | | **Our assumed risk reduction** | |
| μg / 100g | Daly (%) | Crider (%) | % | |
| 250 | 15.4 | 22.4 | Low |  |
| 250 | 15.4 | 22.4 | Medium |  |
| 250 | 15.4 | 22.4 | High |  |

Assumes 30% of women planning to become pregnant also take 400μg folic acid supplement.  
Source: FSS, 2017; DHSC calculations.

If a foetus develops an NTD, there are three possible outcomes:

* The pregnancy goes to term and the baby is born with an NTD.
* The pregnancy is terminated.
* The mother has a miscarriage or stillbirth.

For the purpose of this analysis, we only consider the *health benefits* associated with a reduced number of NTD live births. Benefits associated with a reduced number of miscarriages, stillbirths, and terminations are only modelled through the reduced healthcare costs. This is done primarily for the sake of simplicity and keeping the analysis tractable; establishing a ‘boundary’ for the analysis. It is likely that a number of would-be terminations, miscarriages, or stillbirths are prevented as a result of folic acid fortification and these pregnancies could then lead to an additional live birth. Similarly, prevented NTD live births would also lead to reduced health and social care costs (as opposed to only increases in the quality of life and increased earnings) which are not estimated in this analysis.

### Health benefits of reducing the number of NTD live birth cases

Data from Public Health Scotland shows that there was an average of 16.6 NTD live births year in Scotland between 2016-20. Using the central risk reduction estimate of 18.9%, we anticipate 3.14 prevented NTD cases per year.

Table 10. NTD live births in Scotland, 2016-20 average, and estimated prevented cases.

|  |  |  |
| --- | --- | --- |
| **NTD** | **Annual cases, Scotland** 2016-20 average | **Estimated cases prevented** Assuming 250μg / 100g |
| Spina Bifida | 12.2 | 2.31 |
| Anencephaly | 1.0 | 0.189 |
| Encephalocele | 3.4 | 0.643 |
| **Total** | **16.6** | **3.14** |

The approach taken to monetise the health benefits of a reduction in the number of NTD cases was to calculate the loss in Quality Adjusted Life Years (QALYs) that would occur in an individual with an NTD when compared to a typical individual born without an NTD (and with otherwise average health). If an NTD was prevented, this loss would be considered prevented.[[9]](#footnote-10)

#### QALY for an individual without an NTD

The lifetime health profile of a typical individual without an NTD is taken from [McNamara et al (2023)](https://www.sciencedirect.com/science/article/pii/S1098301522021015#tbl1) as expressed by EQ5D scores in varying age bands. It is assumed the English population results in this paper are representative to Scotland as well (A6). These EQ5D scores are converted into discounted QALYs using the standard [Green Book](https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020) discount rate of 1.5% for health factors. The standard deviation of the EQ5D score was 0.24. This is used when constructing the range of health benefit estimates in Table 10 below.

We assume that individuals without NTDs live for 81 years (A7). This was the average life expectancy of a new-born in the UK in 2020 (see the [National Life Tables, ONS, 2021](https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesunitedkingdomreferencetables)). The resulting expected QALYs of a typical new-born when discounted was 41.9.

#### QALY for an individual with an NTD

The above process was repeated for new-borns with Spina Bifida and Anencephaly. The average life expectancies for new-borns with these NTDs were 43 years ([Rabovskaja et al, 2013](https://academic.oup.com/jn/article/143/1/59/4569794)) and less than 1 day ([UK Government, 2020](https://www.gov.uk/government/publications/anencephaly-description-in-brief/anencephaly-information-for-parents#outcome)), respectively. No data was identified for the life expectancy, or average quality, of children born with Encephalocele; this analysis assumes this is the same as Spina Bifida (A8). This is likely to understate the benefits of fortification, as Encephalocele is a more serious condition.

Life years for Spina Bifida were converted to discounted QALYs using different weighted QALY utility values from literature ([Tilford et al, 2005](https://link.springer.com/article/10.1007/s11136-004-3305-2)). These more accurately reflect the decreased quality of life compared to someone of average health (as Green Book QALYs do). For Spina Bifida, this adjustment was 0.55, resulting in an assumed discounted QALY of 17.6. It is assumed this holds for Encephalocele as well (A8), in the absence of data. Anencephaly is assumed to have a QALY utility of 0 as per assumption A9. The discounted QALY figures were then subtracted from the QALY life expectancy for a new-born without an NTD in order to calculate the QALY loss (see Table 10).

#### Monetised QALY benefits

A single QALY is valued at £70,000, as per the standard Green Book practice (in 2020 prices). Multiplying each of the NTD discounted lifetime QALYs loss produces the monetised health benefit for a single prevented case. This benefit is £1.9m for someone who would’ve had Spina Bifida or Encephalocele, and £3.4m for someone who would’ve had Anencephaly.

Table 11. Monetised central health benefit for each prevented NTD live birth

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NTD** | **Life expectancy** | **QALY adjustment** | **Discounted lifetime QALYs** | **Discounted lifetime QALY loss** | **Discounted value of loss per individual\*** |
| Years |  |  |  | 2024 prices |
| Spina Bifida | 43 | 0.55 | 17.6 | 24.2 | £1.9m |
| Anencephaly | 0 | 0 | 0 | 41.9 | £3.4m |
| Encephalocele | 43 | 0.55 | 17.6 | 24.2 | £1.9m |

\* Using an inflated QALY value in 2024 prices of £80,286.24.

Preventing cases of Anencephaly produces the largest monetised benefits due to the fact that a majority of cases lead to death within hours or days of being born, meaning each prevented case is a full lifetime gained in terms of QALYs (A9).

#### Monetised QALY benefits over appraisal period

In line with cross-government impact assessment guidance, the ‘policy lifetime’ we use to assess the costs and benefits was taken to be 10 years. This is purely for the purposes of the analysis and has no bearing on how long we think the policy will last. As a result, there are 10 annual cohorts of new-borns that would benefit from a reduction in NTD cases. In line with DHSC guidance, we assess the lifetime health benefits for each cohort.

Note that there is a possibility that some women giving birth in the first year of the policy will not have had enough time to increase their blood folate levels through the intake of products containing fortified flour (i.e. some of the preconception period and first 12 weeks of pregnancy occurred before the policy was put in place). For the sake of simplicity, we ignore these marginal cases – noting that it may increase in an over-estimation of the impacts on the first cohort (A10).

The total live birth health benefits from the first 10 annual cohorts given a 250μg / 100g fortification level are estimated to have a present value of £59.4 million under the central estimate (in 2024 prices).

Table 12. Monetised lifetime health benefits by NTD (250μg / 100g flour)

|  |  |  |  |
| --- | --- | --- | --- |
| **NTD** | **Monetised QALY loss prevented (£m 2024, discounted)** | | |
| Low | Central | High |
| Anencephaly | 3.9 | 5.9 | 8.4 |
| Encephalocele | 7.6 | 11.7 | 16.6 |
| Spina Bifida | 27.3 | 41.8 | 59.5 |
| **Total** | **38.7** | **59.4** | **84.5** |

### NHS costs savings of reducing the number of people living with NTDs

DHSC has undertaken a literature review on the cost estimates to healthcare systems of NTD treatment costs. Many of these were based on the US healthcare system, which is very different from that of the UK and therefore these sources were not deemed appropriate. One study from Europe was identified, and none from the UK. This European study offered a comprehensive account of the treatment costs of NTDs, both in and out of hospital.

[Bowles et al (2014)](https://www.sciencedirect.com/science/article/abs/pii/S0033350613003983?via%3Dihub) investigate the economic burden of NTDs in Germany and found that the average annual healthcare expenditure per person with Spina Bifida was €3,032 (in 2014 prices). This includes the cost of in- and outpatient care, GP care, rehab, medication and medical aids. This is the incremental cost, over and above standardised healthcare costs calculated by Bowles et al.

No (European) studies looked specifically at the costs of Encephalocele, so for the purpose of this analysis we assume that these costs are identical to those of Spina Bifida (A8). For the treatment costs of Anencephaly, DHSC proposes using the findings from a US study (see [Yi et al, 2011](https://pubmed.ncbi.nlm.nih.gov/21594574/)). This study finds that the average annual cost was €3,131 (in 2011 prices) and was only study of its kind investigating costs of Anencephaly. Due to the differences in healthcare systems (and systematically higher prices in the US healthcare system), this cost was downscaled.[[10]](#footnote-11) The incremental healthcare costs of Anencephaly are lower because patients with this condition typically pass away within minutes, hours or days of being born.

Applying this annual cost to the number of reduced NTD cases in each of the 10 cohorts, and applying a GDP inflator and exchange rates to express in prices in £2024 terms, we obtain a total healthcare cost saving present value of £2.0m (2024 prices).

Table 13. Central NHS cost savings due to the reduced number of people living with NTDs

|  |  |  |  |
| --- | --- | --- | --- |
| **NTD** | **Estimated reduction in NTD live births per year** | **Estimated annual treatment costs per patient** | **Total discounted lifetime cost savings** |
| 2024 prices | 2024 prices |
| Anencephaly | 0.189 | £962 | £0.0m |
| Encephalocele | 0.643 | £3,481 | £0.4m |
| Spina Bifida | 2.31 | £3,4812,882 | £1.6m |
| **Total** | **3.14** | **..** | **£2.0m** |

Source: DHSC and FSS calculations using data from Bowles et al (2011) and Yi et al (2014).

Given the uncertainty surrounding the NTD risk reduction, we use the low and high estimates mentioned earlier to construct low and high estimates of this cost saving.

Table 14. Low, central, and high NHS cost savings due to the reduced number of people living with NTDs

|  |  |  |
| --- | --- | --- |
| **Total NTDs** | **Estimated reduction in NTD live births per year** | **Total discounted lifetime cost savings** |
| 2024 prices |
| Low | 2.05 | £1.3m |
| Central | 3.14 | £2.0m |
| High | 4.46 | £2.9m |

### NHS costs savings of reducing the number of NTD-related terminations, miscarriages, and stillbirths

Similar to the NHS cost savings seen for the reduced number of people living with NTDs, we also assume (a) that there will be a reduced number of NTD-related terminations, miscarriages, and stillbirths and (b) that these lead to reductions in NHS costs (A11).

#### Miscarriages and stillbirths

Data on early miscarriages (at <20 weeks gestation) was not available from the Scottish congenital and rare condition register.[[11]](#footnote-12) In line with EUROCAT guidance, the register does not include babies from pregnancies ending in early miscarriage. We approximate NTD-related miscarriages for Scotland using Welsh CARIS data (A12). This dataset does register miscarriages prior to 20 weeks where there are known registerable conditions.[[12]](#footnote-13) In practice (for NTDs), this will generally include cases where an NTD is detected on the early booking scan, after which either:

1. the mother decides to continue with the pregnancy, but subsequently miscarries before 20 weeks gestation, or
2. the mother plans a termination of pregnancy but miscarries before that is carried out (again, before 20 weeks gestation).

There may additionally be a small number of cases where an NTD was not detected on the early booking scan, but where the mother miscarries prior to 20 weeks gestation after which an NTD is confirmed.

This data will still likely underestimate the total number of early pregnancy losses with an NTD, as many early losses will have an unknown NTD status. We make no attempt to estimate this due to the lack of data.

The prevalence of NTD-related miscarriages in Wales (0.47 per 10,000 births, an average over 1998-2021) are scaled up to [total Scottish birth figures](https://publichealthscotland.scot/publications/births-in-scotland/births-in-scotland-year-ending-31-march-2022/). Welsh CARIS data is also used to account for stillbirths. The combined prevalence for NTD-related miscarriages and stillbirths is 0.55.

The reduction in NTD-related miscarriages and stillbirths is then estimated using the same low, central, and high risk reduction estimates as before.

Literature on Scottish-specific NHS healthcare costs of a miscarriage or stillbirth is sparse. [Hughes et al (1996)](https://pubmed.ncbi.nlm.nih.gov/8968239/) estimate the healthcare costs of treating a miscarriage through medical or surgical means. The average cost for these methods was £613 (surgical) and £536 (medical) in 2019 prices, respectively (adjusting the original 1996 costs using standard GDP deflators).

DHSC, in their impact estimate for England, are using a study on (early) miscarriage costs from [Petrou et al (2006)](https://doi.org/10.1111/j.1471-0528.2006.00998.x). They find that the average cost is £1,363 in 2002 prices, which includes hospital care, medication, medical products, community health, social services, and work absences. Since this is a more comprehensive cost estimate, and from a more recent study, we assume these English costs are representative to Scotland (A13) as well.

In line with the DHSC impact assessment for England, we assume that the cost (to the NHS) of both a late miscarriage (20-23 weeks) and a stillbirth (> 23 weeks) is the same as the estimated cost of an early miscarriage (A14) (note that late miscarriages are arguably more clinically similar to stillbirths, and so may have more in common in terms of costs with stillbirths than early miscarriages).

Table 15. Estimated reduction in number of NTD-related miscarriages and stillbirths and associated NHS cost savings

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Estimated number of NTD-related miscarriages and stillbirths** | **Estimated reduction in NTD-related miscarriages and stillbirths** | **Assumed cost of miscarriage** | **Total discounted cost saving over 10 year appraisal period** |
| Annual | Annual | Annual, 2024 prices | 2024 prices |
| Low | 2.90 | 12.3% | £2,389 | £7,341 |
| Central | 2.90 | 18.9% | £2,389 | £11,262 |
| High | 2.90 | 26.9% | £2,389 | £16,017 |

Source: FSS and DHSC calculations; Welsh CARIS data; Petrou et al (2006); HMT GDP deflators.

Note that this is likely to be a relatively crude approximation of the actual NHS costs involved in stillbirths. However, the prevalence is so small that the end result would not be drastically different even if the costs were vastly over- or underestimated.

Implicit in all of this is the assumption that the NHS costs associated with a (healthy) newborn are equal to our Business-As-Usual scenario, Option 1 (i.e. our counterfactual). Crucially, family planning decisions made after the miscarriage, stillbirth, or termination will highly affect this (e.g. a mother or family might decide to try to conceive again following a miscarriage, but not following a live birth, and the healthcare cost associated with that subsequent live birth may be different). We acknowledge that this may not be accurate, as each live birth and each family is different. Due to the high degree of uncertainty in this, and in order to keep the analysis proportionate, we do not attempt to estimate this. (A15)

#### Terminations

It is anticipated there will be a reduction in the number of NTD-related pregnancy terminations as a result of the increased folate intake. We assume this reduction is the same NTD risk reduction as assumed before (i.e. in line with the 2017 FSS study) (A5).

Data on the number of NTD-related terminations in Scotland is obtained through Public Health Scotland, similarly to live births. Terminations are the most common outcome for NTD-affected pregnancies in Scotland, with 35 occurrences annually between 2016-20 on average (compared to e.g. 16.6 live births).

The cost of a termination are assumed to be the same as those in the English NHS Tariff data ([2022/23 National Tariff Payment System](https://www.england.nhs.uk/publication/national-tariff-payment-system-documents-annexes-and-supporting-documents/)), primarily because data on Scotland-specific healthcare costs is scarce (A16). Costs are different whether a medical or surgical method is used, and the point during the pregnancy at which the foetus is aborted. This usually depends on when the NTD is detected. In 2024 prices, the cost of a medical termination is assumed to be £531 (for a point of detection at 11-13 weeks, as is common with Anencephaly) and the cost of a surgical termination £1,163 (again, at 11-13 weeks). Costs for Encephalocele and Spina Bifida are higher due to the assumed point of detection at 18-20 weeks (see Table 15).

Not that unlike miscarriage costs, this includes only the healthcare costs associated with a termination – and excludes e.g. community health, social services, and work absence costs. This means that the costs below are likely an underestimate of the ‘true’ cost of a medical or surgical termination.

Table 16. Assumed healthcare costs of pregnancy termination, Scotland

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Typical point of detection** | **Assumed cost of medical termination** | **Assumed cost of surgical termination** |
| Weeks | 2024 prices | 2024 prices |
| Anencephaly | 11-13 | £531 | £963 |
| Encephalocele | 18-20 | £874 | £1,388 |
| Spina Bifida | 18-20 | £874 | £1,388 |

Data on the split between medical and surgical terminations comes from Public Health Scotland (see Table 8 in [Termination of Pregnancy Statistics, Year Ending Dec 2022, Public Health Scotland, 2023](https://publichealthscotland.scot/publications/termination-of-pregnancy-statistics/termination-of-pregnancy-statistics-year-ending-december-2022/#:~:text=Termination%20rates%2C%20Scotland%2C%202013%20to%202022&text=The%20rate%20of%20terminations%20in,in%20the%20rate%20to%2016.1.&text=Termination%20rates%20increased%20steeply%20between,regardless%20of%20level%20of%20deprivation.)). In 2021, 99.2% of all pregnancy terminations were medical, with the remainder surgical (data for 2022 was provisional at the time of writing).[[13]](#footnote-14) We assume this same distribution of methods applies to NTD-related terminations (A17).

This is different from the DHSC impact assessment for England, who use statistics for England & Wales – where the proportion of medical terminations was 87% in 2021.

The total present value of the cost savings over the 10 year evaluation period is £40,778 (central estimate).

Table 17. Central NHS cost savings due to the reduced number of NTD-related terminations

|  |  |  |  |
| --- | --- | --- | --- |
| **NTD** | **Annual number of NTD-related terminations** | **Estimated reduction in number of terminations** | **Annual NHS cost saving per termination** |
|  | 2016-20 average |  | 2024 prices |
| Anencephaly | 23 | 4.35 | 536 |
| Encephalocele | 3.4 | 0.64 | 1,061 |
| Spina Bifida | 8.6 | 1.63 | 1,061 |
| **Total** | **35** | **6.62** | **..** |

Given the uncertainty surrounding the NTD risk reduction, we use the low and high estimates mentioned earlier to construct low and high estimates of this cost saving (A5).

Table 18. Total discounted NHS cost savings due to the reduced number of NTD-related terminations

|  |  |  |
| --- | --- | --- |
|  | **Annual NHS cost saving** | **Total discounted cost saving over 10 year appraisal period** |
| 2024 prices | 2024 prices |
| Low | £3,088 | £26,581 |
| Central | £4,737 | £40,778 |
| High | £6,738 | £57,995 |

Source: FSS and DHSC calculations; NHS England and Public Health Scotland data.

### Lifetime earnings gains of would-be NTD sufferers

People who suffer from Spina Bifida and Encephalocele are more likely to be out of work and have shorter life expectancies than those without. It is also likely they will earn less while in work due to their poorer health. Reducing the incidence of NTDs will therefore have a positive impact on the lifetime earnings of would-be NTD sufferers. This is in addition to the positive impacts on their quality of life, which should already be captured through QALY gains.

A range of studies exist that estimate the employment rate of NTD sufferers. Values range from 19% to 63% (as reported in [New Zealand Food Safety's Folic Acid Fortification Impact Assessment, 2019](https://www.mpi.govt.nz/dmsdocument/37230-Folic-acid-fortification-both-society-and-individuals-benefit)), with many recent studies reporting employment rates between 36% and 42%.

The employment rate for disabled people aged 16 to 64 in Scotland was 49.6% in 2021 ([Scottish Government, 2022](https://www.gov.scot/publications/scotlands-labour-market-people-places-regions-protected-characteristics-statistics-annual-population-survey-2021/pages/8/)). Given this includes other disabilities and conditions beyond NTDs, we assume a 40% employment rate for NTD sufferers instead in our central estimate (A18). This brings it more in line with the literature, and could be taken to introduce an assumption that the ‘average’ NTD sufferer may be slightly less likely to be employed than an ‘average’ disabled person in Scotland. Given the range of estimates in the literature, we also introduce a 30% and 50% employment rate for our high and low estimate, respectively (A18).[[14]](#footnote-15)

We do not have data on the wages of people with NTDs, but note that disabled people have lower median wages than non-disabled people. Analysis of the most recent UK census ([Disability Pay Gaps in the UK: 2021, ONS, 2022](https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/disability/articles/disabilitypaygapsintheuk/2021#pay-gaps-by-uk-country)) shows that Scotland had the widest disability pay gap of any UK country in 2021. A disabled employees’ median pay was £11.54 per hour, 18.5% less than non-disabled employees (£14.16 per hour) in Scotland. In 2024 prices, this is an assumed wage of £13.28 (disabled) and £16.29 (non-disabled). Assuming that wages for disabled people in general are representative of those with NTDs, and assuming a 52 week year, 36.375 hour working week[[15]](#footnote-16), and a working age between 15-64 (A19), we can calculate the annual difference in earnings.

Accounting for (a) higher wages, (b) higher employment rates, and (c) longer life expectancy of non-NTD sufferers suggests that the total discounted renumerations experienced by the cohorts born during the 10-year appraisal period would be £6.3m over their lifetime, in the central estimate.

Table 19. Increase in lifetime earnings for would-be NTD sufferers (central estimate)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NTD** | **Assumed life expectancy** | **Assumed employment rate** | **Assumed annual income gain** | **Estimated total discounted lifetime earnings gain** |
| Years | Percentage (%) | 2024 prices | 2024 prices |
| Anencephaly | 0 | .. | £23,385 | £1.0m |
| Encephalocele | 43 | 40 | £13,338 | £1.2m |
| Spina Bifida | 43 | 40 | £13,338 | £4.2m |
| **Total** | **..** | **..** | **..** | **£6.3m** |

‘Lifetime earnings’ here are assumed to be the median wage multiplied by the years in spent working age (taken to mean from 15 to 64 years old). This may not fully take into account an individual’s career and wage progression through their working years, or the potential of would-be NTD sufferers to choose a different career path or working pattern with potentially different earnings.

Table 20. Increase in lifetime earnings for would-be NTD sufferers (overview)

|  |  |
| --- | --- |
|  | **Estimated total discounted lifetime earnings gain** |
| 2024 prices |
| Low | £3.5m |
| Central | £6.3m |
| High | £10.5m |

### Increased labour productivity of would-be parents and/or carers of NTD sufferers

In addition to increases in lifetime earnings of would-be NTD sufferers, there is also a potential positive impact on the lifetime earnings of would-be NTD parents and carers.

NTD cases generally lead to a reduced labour participation in the parents and/or carers of the NTD sufferer. A literature review by [Yi et al (2011)](https://link.springer.com/article/10.1007/s00431-011-1492-8) states that on average, parents of Spina Bifida patients have between a 21% and 27% lower labour participation rate. For the purpose of this analysis, we assume a 24% lower labour participation rate (the midpoint). In the absence of data for Encephalocele, we assume this reduction in labour participation holds for that condition as well. We also assume that the Yi et al study translates to Scotland, and that all individuals with a would-be NTD come from a two parent (or two carer) household (A20).[[16]](#footnote-17)

According to ONS analysis of the 2021 UK census ([Dataset A05 SA: Employment, unemployment and economic inactivity by age group (seasonally adjusted), ONS, 11 July 2023](https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/employmentandemployeetypes/datasets/employmentunemploymentandeconomicinactivitybyagegroupseasonallyadjusteda05sa/current)), the average labour participation rate of people aged 18-49 in the UK is 77%, with the average annual income in the same age bracket being £29,188 (when adjusted to 2024 prices, this is £33,584). We assume these figures are representative of Scottish NTD parents and carers as well (where a 24% reduction in the 77% labour participation rate is 58%) (A21).

We estimate that there are on average 2.95 fewer live Spina Bifida and Encephalocele births per year at the 250μg/100g NWWF fortification level (using the central reduction estimate). Given the labour participation and incomes assumed above, for each prevented NTD birth we estimate an undiscounted annual central income gain of £12,232.12 per household, or £36,065 per year in total.

Assuming this income gain is present until the child is 18 years old (A22), we estimate the total discounted income gain over 10 cohorts of prevented NTD cases – similar to the estimation of lifetime health benefits. The total labour market participation gain over the 10 year appraisal period is estimated to be £4.2 million (2024 prices). Given our range of risk reduction estimates, we can construct a low, central, and high estimates of this gain:

Table 21. Estimated increased parent/carer earnings as a result of a reduced number of would-be NTD sufferers

|  |  |  |
| --- | --- | --- |
|  | **Estimated reduction in number of parents/carers of would-be NTD sufferers each annual cohort** | **Total discounted cost saving over 10 year appraisal period** |
| 2024 prices |
| Low | 3.8 | £2,762,474 |
| Central | 5.9 | £4,237,887 |
| High | 8.4 | £6,027,217 |

Source: FSS and DHSC calculations; ONS, 2021; Yi et al 2011; HMT, 2023.

The impact on labour market participation (or increased potential earnings) of parents of would-be Anencephaly sufferers (who would have had a very short life expectancy) is not taken into account in this analysis. The primary reason for this is that the magnitude and direction of impact depends on many factors, some of which are behavioural and difficult to estimate.

### Non-monetised benefits

#### Health benefits of reducing the number of NTD-related terminations, miscarriages, and stillbirths

We recognise there may be a significant benefit of this policy in the form of an increase in the number of live births through pregnancies that would’ve otherwise not resulted in a live birth.

These benefits could potentially be quantified in a similar way as for NTD live births through the use of QALYs. However, there is additional uncertainty in these cases, where we cannot say for certain that each NTD-related termination, miscarriage, or stillbirth will result in a live birth simply as a result of increased folate intake. Factors leading to any of these outcomes are complex, and for that reason we have decided to not take these benefits into account. Given the large benefits already seen in e.g. the reduced number of NTD live births we do not anticipate the exclusion of these benefits to drastically change the overall picture (i.e. the cost-benefit ratio). This has the added benefit of keeping the analysis tractable.

#### Social care cost savings

Those affected by NTDs often require life-long health- and social care (see e.g. [Neural tube defects in Australia: prevalence before mandatory folic acid fortification, Australian Institute of Health and Welfare](https://www.aihw.gov.au/reports/mothers-babies/neural-tube-defects-prevalence-before-folic-acid/summary)). We anticipate the social care burden to fall as a result of the introduction of folic acid fortification, which in turn leads to a reduction in opportunity costs (separate a labour productivity increase) and a reduced social cost for those that have would have had to give up time to care (without pay) for those suffering with NTDs. This reduction in social care costs has not been quantified due to a lack of evidence and available data.

#### Reduction in psychological harm and distress caused by NTD related miscarriages, stillbirths, terminations, and live births

In addition to the many monetised benefits above, including increased labour participation and lifetime earnings of would-be parents, we want to highlight the potential positive impact on the mental (and physical) wellbeing of would-be parents of NTD sufferers.

Pregnancies resulting in a miscarriage, stillbirth, or termination, whether related to NTDs or not, can cause great psychological harm and distress on parents and their families. This is well-documented in the literature (see for example [Nynas et al, 2015](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4468887/) and [Farren et al, 2020](https://www.sciencedirect.com/science/article/abs/pii/S0002937819313699?via%3Dihub)). It stands to reason, therefore, that a reduction of incidences of NTD-related miscarriages, stillbirths, and terminations could contribute to a reduction in negative mental health impacts in society. This same reasoning could also apply to parents whose pregnancy resulted in an NTD live birth – which can be a shocking and traumatic event on its own, and is of course particularly relevant in the case of Anencephaly. The precise impacts of these factors have not been monetised, again due to a lack of data.

People currently living with an NTD often live independent, fulfilling lives and are valued members of their families and communities. Nonetheless, disabilities can have a pronounced impact on mental health, as shown in [ONS data for 2019](https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/disability/bulletins/disabilitywellbeingandlonelinessuk/2019). This data shows that disabled people in the UK report (a) lower happiness and life satisfaction ratings, (b) higher anxiety ratings, and (c) four times the levels of loneliness[[17]](#footnote-18) than non-disabled people. Data on the mental wellbeing specifically for those living with NTDs is lacking. Some people living with NTDs may also face disability discrimination, which has documented negative impacts on mental wellbeing ([Hackett et al, 2020](https://bmjopen.bmj.com/content/10/3/e035714)). These negative mental health/wellbeing impacts have also not been monetised in this impact assessment, as the data is scarce and impacts difficult to monetise.

#### Wider benefits

There are potentially wider benefits to increasing the population folate intake beyond reducing the prevalence of NTDs. However, in many cases the evidence remains mixed, and for this reason we make no attempt to estimate or monetise impacts beyond a reduction in the prevalence of NTDs.

## Option 3

### Monetised benefits

No additional benefits have been calculated and monetised in addition to those in Option 2.

### Non-monetised benefits

#### Legal clarity

The option provides legal clarity to businesses, making it easier to be compliant with the calcium criteria rules as it removes the possibility of ambiguity or confusion between the two overlapping regulations in the BFRs and Regulation 231/2012. The same legal clarity can have unmonetised benefits for enforcement authorities as well, saving costs associated with enforcement and potentially prosecution.

## Option 4

### Monetised benefits

No additional benefits have been calculated and monetised in addition to those in Options 2 and 3.

### Non-monetised benefits

#### Legal clarity

The option provides additional legal clarity to businesses, resolving the ambiguity as to what grains they are expected to fortify. This legal clarity can have unmonetised benefits for enforcement authorities as well, saving costs associated with enforcement and potentially prosecution.

#### Consumer choice

This option has an added indirect benefit to consumers in the form of increasing consumer choice by providing alternative unfortified 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 could be advised. This is unmonetised due to the difficulty of placing a monetary value on consumer choice.

## Option 5 (introduce exemptions)

### Monetised benefits

#### Reduction in fortification costs for small-scale millers

This option would qualify small-scale millers to no longer fortify their flour, lowering their fortification costs to zero. While this benefits small-scale millers, it is presented as a reduction in estimated costs and closer to the Business-As-Usual scenario (for these millers).

#### Impact on fortified NWWF supply by exempting small-scale millers

Exempting small-scale millers would potentially reduce the amount of fortified non-wholemeal wheat flour on the market, and could therefore reduce the population intake of fortified flour – which would *reduce* the total benefits. However, small-scale millers tend to produce a variety of flours, including wholemeal wheat flour or non-wheat flour and/or not be a major component in the average person’s flour intake. Therefore, we assume that any potential reduction in the population intake of fortified NWWF is marginal, and that the worst effects of this still fall within our estimated range of benefits (i.e. on the lower end of the range).

### Non-monetised benefits

#### Viability of small-scale millers

This option would support the viability of small or micro-scaled millers, given the removal of fortification requirements for these types of millers and the practical, legal and technological limitations for these businesses.

# Annex II. Calculation of Costs

The analysis makes a number of broad assumptions on labelling, package waste, and familiarisation costs, as well as on the number of businesses affected in Scotland. Enforcement costs may also vary. A low, central, and high estimate have been provided in an attempt to capture some of the uncertainty surrounding these assumptions.

Table 22. Assumptions

|  |  |  |
| --- | --- | --- |
| A23 | Costs of familiarisation with legislation can be approximated by the amount of time to read and/or explain the legislation text. | There is a lack of data on actual industry or enforcement familiarisation costs. |
| A24 | The new regulations and guidance are of a similar length to existing Bread and Flour Regulations (1988), and someone reading/explaining this would read/explain the entire piece of text. |  |
| A25 | The person reading and explaining this new legislation is an ‘R&D Manager’ as per the ONS ASHE classification (or has a similar wage). | Ease of calculation and data availability. |
| A26 | The R&D Manager explains the legislation to two managers or directors (‘Corporate Manager and Director’), with the time taken to explain being identical to the reading time. | Ease of calculation and data availability. |
| A27 | The number of R&D/Corporate Manager reading, explaining, or listening to the legislation does not vary depending on miller size. | There is a lack of data on the proportion of managers to total employees in millers. |
| A28 | Average wages for the UK for these professions are representative of the wages in Scotland. | A lack of data for Scotland in the 2021 ONS ASHE dataset (due to suppression). |
| A29 | There are no millers in Scotland with 250 or more employees. | The ONS IDBR 2022 dataset reports there being 5 micro-sized millers, and 0 additional millers (all rounded to the nearest 5, or 0. Given the apparent concentration of micro-sized millers in Scotland, we assume that there are potentially some suppressed small or medium-sized millers in Scotland – but no large millers. |
| A30 | Familiarisation costs are only borne in the first year of the policy, and are £0 thereafter. |  |
| A31 | Relabelling changes to packaging due to NWWF fortification are assumed to amount to ‘minor’ changes, meaning ‘a change to the text on a single face of a label with no packaging size modification.’ |  |
| A32 | The biggest four supermarkets sell all branded products containing NWWF currently on the market. | Ease of calculation and lack of data. |
| A33 | The proportion of own-label products containing NWWF in the four largest supermarkets is the same for the remaining grocery retailers. | Data for the four largest supermarkets was available, but not for the remaining grocery retailers. It is assumed these sell (or stock) the same proportion of own-label products containing NWWF. |
| A34 | The proportion of food products containing NWWF that are imported is the same as the national average (42%) shown in Defra’s Agriculture in the UK (2022) publication. | There is insufficient data on the origins of products containing NWWF. |
| A35 | The proportion of food products containing NWWF produced in Scotland is the same as the proportion of Scottish food businesses in the UK. | There is insufficient data on the number of SKUs produced in Scotland compared to the UK. |
| A36 | All categories of flour except brown flour and wholemeal breadmaking flour contain NWWF. | Other categories, such as biscuit flour, cake flour, or starch manufacture do not specify the type of flour contained. In the absence of data, we assume all of these other categories contain NWWF. |
| A37 | The midpoint of a business size’s employee range is a suitable approximation for the number of employees in that business (e.g. a micro sized businesses with 0-9 employees is assumed to have 5 employees). | There is insufficient data on the actual (or e.g. average) number of employees for each business size band. The ceiling of the number is used when it is not a whole number (e.g. 4.5 employees is rounded up to 5). In the case of very large businesses (1,000+ employees), we assume they have 1,000 employees exactly (note assumption A29). |
| A38 | A single trading standards officer from each Local Authority will need to familiarise themselves with the new legislation, and does so in the same manner as R&D managers in millers (see A23, A24). |  |
| A39 | (Option 3) We assume that 9% of premix sales are currently not compliant with the minimum levels required by Regulation 1925/2006, and that this is an accurate proxy for the proportion of NWWF that is not being fortified to these levels. | There is sparse data on the exact fortification specifications used among UK millers. Data received from a premix supplier suggests 91% of premix sold is compliant with Reg 1925/2006. |
| A40 | (Option 3) All millers are using E170 grade calcium carbonate to fortify their flour. | Since July 2021, UK-produced food grade calcium carbonate is no longer available in significant amounts. |
| A41 | (Option 5) Small-scale millers still need to familiarise themselves with the new regulations even if they are exempt. | Ease of calculations. |
| A42 | (Option 5) ‘Small-scale millers’ are taken to mean micro-sized milling businesses with between zero and nine employees. | There is insufficient data on individual millers’ production volumes to isolate millers below a certain cut-off. |
| A43 | (Option 5) The proportion of UK micro-sized millers in Scotland is a good approximation of the volume of UK NWWF produced in Scotland. | There is insufficient data on individual millers’ production volumes. We do have access to TCMG’s data on NWWF produced by (member) small-scale millers in the UK. |
| A44 | (Option 5) Each small-scale miller produces one SKU, and 30% of all SKUs produced by small-scale millers are NWWF. | We do not know the true number of SKUs produced by each small-scale miller. TCMG estimates that 30% of all flour miller by small-scale millers is NWWF, and so we assume this translates to SKUs as well. |

## Option 2 (folic acid fortification only)

### Business familiarisation costs

Millers and other manufacturers of flour will need to familiarise themselves with the new regulations and folic acid fortification levels. We assume (A23) that this cost can be estimated by multiplying the length of the legislation (in words) by an assumed reading speed (words per minute) and the wage costs (£ per hour).

A report by EFTEC (2013)[[18]](#footnote-19) found that typical reading speeds for ‘normal’ prose are 250-300 words per minute, and 50-100 words per minute for ‘technical’ prose. The revised regulations and guidance will predominantly consist of technical text. Assuming they are a similar length to the existing Bread and Flour Regulations (1988) and guidance (a total of 5,547 words) (A24) we assume it would take between 55-110 minutes for an employee (‘R&D Manager’ in ASHE) to become familiar with and understand the updated legislation (A25).

We then assume that this employee also explains the legislation to two managers or directors (‘Corporate Manager and Director’ in ASHE) involved in the manufacturing process. The length of time is assumed to be the same as the reading time (A26).

The number of employees involved is an arbitrary assumption and in reality may vary depending on the size of the miller. Due to the lack of data on the proportion of R&D Managers and Corporate Managers to total employees, we assume this remains constant even if the size of the miller varies (A27). The range of salaries we assume may be able to account for some of this uncertainty (e.g. explaining it to 3 managers rather than 2, or taking longer to explain the legislation).

Table 23. Assumed reading, explanation, and listening time needed for familiarisation

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Reading speed** | **Legislation + guidance length** | **R&D Manager** | | **Listening time** | |
| Reading time | Explaining time (per Corporate Manager) | Corporate Manager 1 | Corporate Manager 2 |
| Words/min | Words | Hours | Hours | Hours | Hours |
| Low | 100 | 5,547 | 0.9 | 0.9 | 0.9 | 0.9 |
| Central | 75 | 5,547 | 1.2 | 1.2 | 1.2 | 1.2 |
| High | 50 | 5,547 | 1.8 | 1.8 | 1.8 | 1.8 |

Source: EFTEC, 2013; DHSC analysis of current BFR legislation; HMT GDP deflators.

For wages, ONS’ [Annual Survey of Hours and Earnings 2021](https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/indexoflabourcostsperhourilch/julytoseptember2020) was used. While Scottish data is available in Table 15, a lot of wages were supressed due to the low sample. For this reason, we use the UK ASHE dataset[[19]](#footnote-20) and assume these wages are representative for Scotland (A28). To account for non-wage labour costs, 19% was added to the wage costs based on the [latest ONS data](https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/indexoflabourcostsperhourilch/julytoseptember2020) for July-September 2020. The 25th and 75th wage percentiles were used to construct our low and high estimates, in line with the DHSC impact assessment.

Table 24. Estimated familiarisation cost per miller

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **R&D Manager** | | **Corporate Manager** | | **Wage uplift** | **Familiarisation cost per miller** |
| Hours | Wage (£ 2024) | Hours | Wage (£ 2024) | % | £ 2024 |
| Low | 1.8 | 22.37 | 1.8 | 18.06 | 19 | 113.57 |
| Central | 2.4 | 27.85 | 2.4 | 27.00 | 19 | 201.73 |
| High | 3.6 | 35.90 | 3.6 | 41.39 | 19 | 419.10 |

ONS data from 2022 reports there being five grain millers in Scotland – although this figure is rounded to the nearest five (and rounded down to zero in cases where there are two or less). The five businesses that are shown in the data are all micro-sized businesses with zero to nine employees, which means that there could be between three and seven micro-sized grain millers, and up to two millers of each other size (provided the total is also between three or seven).

Table 25. Number of millers in the UK by employment size band, 2022

|  |  |  |
| --- | --- | --- |
| **Employment size band** | **Number of millers in Scotland** | **Number of millers in the United Kingdom** |
| 0 to 9 | 5 | 50 |
| 10 to 49 | 0 | 15 |
| 50 to 249 | 0 | 15 |
| 250 to 499 | 0 | 5 |
| 500 to 999 | 0 | 0 |
| 1,000+ | 0 | 0 |
| **Total** | **5** | **85** |

Source: ONS IDBR 2022 data, figures rounded to nearest five thousand (or zero).

We use this range to construct our low to high estimates, and assume there are no millers with 250 employees or more in Scotland (A29). Multiplying the cost per miller gives us total industry costs:

Table 26. Estimated total familiarisation cost in Scotland

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Number of grain millers** | | | **Familiarisation cost per miller** | **Total familiarisation cost** |
|  | Micro (0-9 empl.) | Small (10-49) | Medium (50-249) | £ 2024 | £ 2024 |
| Low | 3 | 2 | 0 | 113.57 | 567.86 |
| Central | 3 | 2 | 1 | 201.73 | 1,210.36 |
| High | 3 | 2 | 2 | 419.10 | 2,933.69 |

We assume this familiarisation cost is only borne by the grain millers the first year of the new BFR regulations, with familiarisation costs being £0 for the remainder of the 10-year appraisal period (A30).

#### A note on small-scale millers and Option 5’s exemption

It’s important to note that in the ‘Low’ estimate, we have not assumed that there are only micro-sized millers in Scotland (i.e. three micro-sized millers), as this would mean all flour production in Scotland would be exempt from fortification under Option 5. This essentially sets all industry (fortification) costs to zero. If we also assume those three micro-sized millers supply the entirety of Scotland’s flour demand, there would be no fortification benefits either – which would be highly unrealistic. Instead, we have assumed a range of five to seven total millers, including three micro- and two small-sized millers in each estimate. In each estimate, it is assumed that the three micro-sized millers do not account for enough of the population’s flour consumption to significantly change the benefits associated with increased folate intake (see Option 5’s monetised benefits in Annex I).

### Relabelling costs

Another transition cost for grain millers and manufacturers of food containing grains is created by the need to amend the labels of products containing UK-milled non-wholemeal wheat flour to include ‘folic acid’ amongst the list of ingredients that the flour was fortified with. This would be stated in brackets after ‘flour’ on the ingredients list, alongside the other fortificants.

#### Cost of labelling change

Like DHSC in their impact assessment, we use a 2010 Campden BRI study ([Developing a framework for assessing the costs of labelling changes in the UK](https://webarchive.nationalarchives.gov.uk/ukgwa/20110318121117/http:/www.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf)) to monetise the costs of labelling changes. This study looks at the total cost of all stages of the label cycle, from familiarisation, re-design, and auditing through to printing. It also provides estimate based on the magnitude of change.

It presents costs in terms of the average cost of relabelling per Stock Keeping Unit (SKU), which is a unique code used to identify products and track inventory.

The estimated average cost per SKU is used to represent a relabelling cost per product, and multiplied by the estimated number of products requiring relabelling. Campden BRI’s study concluded that the following costs would be incurred by businesses depending on whether the label change was ‘minor’ or ‘major’:

|  |  |
| --- | --- |
| **Extent of change** | **Average cost per SKU** |
|  | £ 2010 |
| Minor | 1,810 |
| Major | 3,800 |

Source: Campden BRI, 2010

Adjusting these to 2024 prices using HMT’s GDP deflators at market prices, we obtain:

|  |  |
| --- | --- |
| **Extent of change** | **Estimated average cost per SKU** |
|  | £ 2024 |
| Minor | 2,553.54 |
| Major | 5,361.02 |

We assume that adding ‘folic acid’ to the list of fortificants constitutes a ‘minor’ change (A31), which is defined by Campden BRI as “a change to the text on a single face of a label with no packaging size modification”.

#### Number of SKUs affected

To estimate the number of products that would require a labelling change, we used Kantar data provided to DHSC, FSA, and FSS by the UK Flour Millers’ Association. This was a bespoke request which showed the number of SKUs containing non-wholemeal wheat flour (NWWF) in the largest four UK supermarkets by market share.

This data showed that there were 10,184 individual SKUs containing NWWF in the biggest four UK supermarkets (Tesco, Sainsbury’s, Asda, and Morrisons). This figure includes own-label products as well as branded products, some of which would be sold across different supermarkets. We assume these four retailers sell all branded NWWF-containing products that exist in the market, with additional ‘own-label’ brands sold in other grocery retailers (A32).

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%. Using the ratio of market shares between these two groups of retailers, and 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.

From the Kantar data, we know that 31.4% of own-label SKUs contained NWWF on average in the four largest supermarkets. We assume this is the case for other grocery retailers as well (A33).

Table 27. Estimated market share of ‘Big Four’ grocery retailers, May 2021

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Big Four** | **Other** | **Total** |
| Market share | *67.1%* | *32.9%* | *100%* |

Source: Kantar

Using data on the market share and proportion of SKUs containing NWWF, DHSC has estimated the total number of NWWF-containing products sold in the UK that may need relabelling.

Table 28. Estimated number of unique products containing NWWF in the UK grocery retail market, May 2021

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Big Four** | **Other** | **Total** |
| *Kantar data* | *Estimated* | *Estimated* |
| **Branded SKUs containing NWWF** | | | | |
|  | Low estimate (-10%) | 9,166 | .. | 9,166 |
|  | Central estimate | 10,184 | .. | 10,184 |
|  | High estimate (+10%) | 11,202 | .. | 11,202 |
| **Own-label SKUs containing NWWF** | | | | |
| *Total own-label SKUs* | | *17,786* | *8,721* | *26,507* |
| *of which contain NWWF:* | | | | |
|  | Low estimate (-10%) | 5,027 | 2,464 | 7,491 |
|  | Central estimate | 5,585 | 2,738 | 8,323 |
|  | High estimate (+10%) | 6,144 | 3,012 | 9,155 |
| **Total SKUs containing NWWF:** | |  |  |  |
|  | **Low estimate** | **14,193** | **2,464** | **16,657** |
|  | **Central estimate** | **15,769** | **2,738** | **18,507** |
|  | **High estimate** | **17,346** | **3,012** | **20,357** |

Source: DHSC analysis of May 2021 Kantar data

Many of the estimated 18,507 SKUs (central estimate) sold in the UK grocery retail market are likely to be imported and so are out of scope of the cost estimates in this impact assessment.[[20]](#footnote-21) Data published by Defra in their [Agriculture in the United Kingdom 2022](https://www.gov.uk/government/statistics/agriculture-in-the-united-kingdom-2022) publication shows that 42% of the food the UK consumes is imported from overseas. Naturally, this includes food products that do not contain NWWF – but we do not have a specific import proportion estimate for NWWF-containing products.

Using this 42% as a proxy (A34), we estimate that 10,734 UK-produced SKUs will be affected by the legislation in our central estimate.

Multiplying this by the estimated unit cost of relabelling a single SKU, we arrive at a total cost of £27.4 million for all UK-produced products for our central estimate.

Table 29. Estimated total relabelling costs for UK-produced products

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated UK-produced SKUs containing NWWF** | **Estimated total UK relabelling cost, £m 2024** |
| Low | 9,661 | 24.7 |
| Central | 10,734 | 27.4 |
| High | 20,357 | 52.0 |

We do not have data on the Scottish proportion of UK-produced products containing NWWF. To approximate a Scottish split (A35), we use [the proportion of UK food manufacturers located in Scotland](https://www.ons.gov.uk/businessindustryandtrade/business/activitysizeandlocation/adhocs/14402foodmanufacturingbyregion) as a proxy[[21]](#footnote-22) and assume that 8.8% of all UK-produced NWWF-containing products are produced by Scottish manufacturers. The costs borne in Scotland are as follows:

Table 30. Estimated total relabelling costs for Scottish-produced products

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated Scottish-produced SKUs containing NWWF** | **Estimated total Scottish relabelling cost, £m 2024** |
| Low | 853 | 2.2 |
| Central | 947 | 2.4 |
| High | 1,797 | 4.6 |

It’s worth noting that these figures are likely to be an overestimate as some millers or manufacturers will have planned to make labelling changes anyway. The incremental cost of making the labelling change for folic acid will be much lower for those manufacturers that manage to align their relabelling cycle with changes to comply with these regulations.

### Package waste costs

Some packaging meant for products containing non-fortified NWWF will have to be discarded. This results in additional one-off costs for a business in the form of package waste costs.

During DHSC’s engagement with the Food and Drink Federation, a number of businesses stated that they order 12 weeks’ worth of packaging at a time. Therefore, in a worst case scenario, they’d need to discard 12 weeks’ worth of packaging due to the labelling change. We’ve assumed that on average, each business has 6 weeks’ worth in stock at the point that they have to change to the new packaging.

DHSC’s engagement with the sector also suggested a package wastage cost of between £2,000 and £13,000 per SKU, with an average of £7,000 (in 2024 prices).

Taking the average of the industry estimates[[22]](#footnote-23) suggests that the package wastage cost per SKU would be around £6,700 (2024 prices). The lowest estimate received was just over £2,000 per SKU, and the highest estimate received was just over £13,000. Multiplying this range by our range of estimated SKUs that contain NWWF that are produced in Scotland (853 to 1,797) gives the total wastage costs below:

Table 31. Estimated total package waste costs for Scottish-produced products

|  |  |  |  |
| --- | --- | --- | --- |
| **Estimate** | **Estimated Scottish-produced SKUs containing NWWF** | **Assumed package waste cost, £ 2024** | **Estimated total Scottish package waste cost, £m 2024** |
| Low | 853 | 2,038 | 1.7 |
| Central | 947 | 6,688 | 6.3 |
| High | 1,797 | 13,248 | 23.8 |

### Fortification costs

The purchase of folic acid for fortification purposes will incur an additional cost for flour millers. It is understood that the folic acid will be added to the pre-mix that millers already buy for the existing mandatory fortification requirements for NWWF – calcium, iron, thiamine, and niacin. Evidence received during the FSA consultation from a major pre-mix supplier suggests that the incremental cost of adding the folic acid to the existing pre-mix will be £595 per tonne of pre-mix. Based on the 250μg folic acid concentration per 100g NWWF flour, this equates to an incremental cost of 16p per tonne of finished flour, or roughly 0.08p for an 800g loaf of bread (in 2024 prices).

The UK as a whole produced an estimated 4,528 thousand tonnes of flour in 2020-21 [according to the UK Flour Millers’ Association](https://www.ukflourmillers.org/_files/ugd/329f2f_ca7df1a4f5f8424693169a4ec2edd6c9.pdf) (UKFMA). The UKFMA also provides data on the flour type produced, shown below.

Table 32. Types of flour produced by UK flour millers, 2020-21

|  |  |
| --- | --- |
| **Flour type** | **2020-21 production (%)** |
| White breadmaking | 52.2 |
| Brown breadmaking | 1.1 |
| Wholemeal breadmaking | 4.1 |
| Biscuit | 10.2 |
| Cake | 1.7 |
| Pre-packed (household flour) | 4.5 |
| Food ingredient | 8.9 |
| Starch manufacture and other | 17.2 |
| **Total** | **100** |

Source: UK Flour Millers Association, [*Flour Milling in the UK: Facts and Figures*](https://www.ukflourmillers.org/_files/ugd/329f2f_ca7df1a4f5f8424693169a4ec2edd6c9.pdf), May 2021.

For the purpose of this analysis, we assume that all categories of flour except brown and wholemeal breadmaking will contain NWWF (A36) – meaning roughly 94.7% (4,288 thousand tonnes) of all flour produced by UK millers will be NWWF (or contain NWWF).

As shown in the business familiarisation cost calculation, there are a total of five reported flour mills in Scotland according to 2022 [ONS NOMIS](https://www.nomisweb.co.uk/) data (accessed November 2022). All of these were classed as micro-sized businesses. Since this figure is rounded to the nearest five (incl. the total), we assume the same make-up of businesses as in Table 25.

In addition, we also assume that the split of total flour production can be better approximated by using the number of employees than the number of millers – especially given the millers that are located in Scotland are relatively small. To estimate the number of employees, we assume the midpoint of each employment range is a suitable approximation for the total number of employees (A37).

Table 33. Estimating the number of employees working in Scottish flour millers

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Employment size band** | **Assumed midpoint** | **Low estimate** | **Central estimate** | **High estimate** |
|  |  | 3 micro-sized millers, 2 small millers | + 1 large miller | + 1 large miller |
| 0 to 9 | 5 | 15 | 15 | 15 |
| 10 to 49 | 30 | 60 | 60 | 60 |
| 50 to 249 | 150 | 0 | 150 | 300 |
| 250 to 499 | 375 | 0 | 0 | 0 |
| 500 to 999 | 750 | 0 | 0 | 0 |
| 1,000+ | 1,000 | 0 | 0 | 0 |
| **Total** | **..** | **75** | **225** | **375** |

Using the same employment midpoints, and taking the number of millers in the UK at face value (i.e. not assuming a low and high estimate as for Scotland), we estimate the total number of miller employees at 4,665 in the UK as a whole.[[23]](#footnote-24) This allows us to estimate a proportion of Scottish-produced NWWF flour:

Table 34. Estimated annual Scottish flour production and fortification cost

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Estimate** | **Estimated proportion of UK miller employees in Scottish millers** | **Estimated annual UK NWWF flour production** | **Estimated annual Scottish NWWF flour production** | **Estimated annual Scottish fortification cost** |
|  | % | Thousand tonnes | Thousand tonnes | £ 2024 |
| Low | 1.6 | 4,288 | 66.7 | 10,942 |
| Central | 4.7 | 4,288 | 200.0 | 32,825 |
| High | 7.8 | 4,288 | 333.3 | 54,708 |

Assuming this is a recurring annual cost, we apply the same discounting over a 10-year appraisal period as with calculating benefits:

Table 35. Estimated total Scottish discounted fortification cost

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated annual Scottish fortification cost** | **Estimated total discounted Scottish fortification cost** |
|  | 2024 prices | 2024 prices |
| Low | 10,942 | 94,182 |
| Central | 32,825 | 282,545 |
| High | 54,708 | 470,909 |

### Enforcement familiarisation costs

We do not anticipate there being additional enforcement/inspection costs associated with the change in BFR legislation, as there will already be inspections ensuring non-wholemeal wheat flour is fortified with the four current fortificants. However, there will be a similar familiarisation cost as trading standards officers incorporate the new regulation into their inspections.

Assuming that a single trading standards officer in each local authority will familiarise themselves with the regulations, and that they spend the same amount of time reading as R&D managers at grain millers (A38), we can calculate the familiarisation costs the same way as we did for millers.

Using the 2021 UK median wage for ‘inspectors of standards and regulations’ from ONS’ ASHE dataset (which covers trading standards officers), we obtain:

Table 36. Estimated familiarisation costs for enforcement officers in Scotland

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Reading time** | **Wage** | **Wage uplift** | **Cost per officer** | **Total cost for 32 LAs** |
| Hours | £ 2024 | % | £ 2024 | £ 2024 |
| Low | 0.9 | 15.91 | 19 | £17.51 | 560.22 |
| Central | 1.2 | 17.39 | 19 | £25.50 | 816.09 |
| High | 1.8 | 22.58 | 19 | £49.67 | 1,589.50 |

Source: EFTEC, 2013; DHSC analysis of current BFR legislation; HMT GDP deflators.

### Non-monetised costs

#### Industry

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 which would be associated with introducing a new process.

Smaller and traditional millers may find their manufacturing process impacted more, however under the preferred option (Option 5) millers that produce less than 500 tonnes of flour annually will be exempt from the folic acid fortification requirement, which will cover the majority of these cases.

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.

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.

Food manufacturers who produce products that contain NWWF will see the list of fortificants in the flour they buy change following the implementation of this legislation. They’ll need to take some time to understand these changes and the implications for their packaging. But since these changes are minor from their point of view - they’re used to using fortified flour - this should be very quick and easily absorbed into existing operations. Since these costs are likely to be negligible, we’ve not estimated them.

#### 17.1.6.2 Consumers

There will be a small non-monetised 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 fortification, these options may be more expensive. We have not monetised this cost due to the difficulty of placing a monetary value on this consumer welfare loss.

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 (previous 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).

The SCF and EVM considered the potential masking of diagnosis of pernicious anaemia (an autoimmune condition that affects the stomach and prevents absorption of vitamin B12) to be the main concern. In people with vitamin B12 deficiency, high dose folic acid supplementation can improve the symptoms of anaemia. This can make it more difficult to detect the vitamin B12 deficiency which can lead to the damage of nerves and the spinal cord. This can result in severe disability if the deficiency continues undetected. 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.

Modelling from FSS showed the proportion of people that could exceed the Guidance Level of folic acid given different levels of fortification of non-wholemeal wheat flour.

Table 37. 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% |

Table 36 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.

Mandatory fortification at the proposed level of 250 micrograms per 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.

The [Scientific Advisory Committee on Nutrition (SACN) has considered in depth the potential risks associated with sustained high doses of folic acid](https://www.gov.uk/government/publications/folic-acid-updated-sacn-recommendations). 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.

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 small proportion of those exceeding the Guidance Level will be at risk from B12 deficiency.

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.

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.

#### 17.1.6.3 Cost pass-through

There is a chance that producers may pass-on the costs from the policy to consumers. However, these costs are mainly transitory in nature, and are spread across a very large number of products (Kantar data obtained by DHSC suggests that around 11bn individual items containing NWWF are produced in England and sold in Great Britain each year).

Dividing the one-off costs to business (relabelling, packaging waste and familiarisation) across the units sold only in one year would mean a temporary average per unit cost increase of under 1 pence for that year only.

#### 17.1.6.4 Government

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

## Option 3 (as per Option 2 plus address BFR’s interactions with wider food regulations)

### Familiarisation, relabelling, and package waste costs

We expect the familiarisation, relabelling, and package waste costs as described in Option 2 to be similar to those in Option 3 and do not anticipate any additional costs (for either businesses or enforcement authorities).

### Fortification costs

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.[[24]](#footnote-25)

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 BFRs below.

Table 38. Indicative costs of added nutrients to flour

|  |  |
| --- | --- |
| **Premix** | **£ per tonne of flour** |
| Premix compliant with the levels specified in the BFRs | 1.20 |
| Premix with calcium, iron, and niacin levels raised to 15% NRV | 1.30-1.36 |

Source: Information provided to DHSC by UKFM

We assume that the 9% of premix sales that are currently not compliant with the minimum levels required by Regulation 1925/2006 is also an accurate proxy for the proportion of NWWF that is not being fortified to these levels (A39). Using the data provided in Table 33, we have:

Table 39. Estimated non-compliant annual Scottish flour production and added fortification cost (Option 3)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Estimate** | **Estimated annual Scottish NWWF flour production** | **Estimated non-compliant Scottish NWWF flour production** | **Assumed added fortificant cost for nutrients** | **Estimated added annual Scottish fortification cost** |
|  | Thousand tonnes | Thousand tonnes | £ 2024 | £ 2024 |
| Low | 66.7 | 6.0 | 0.10 | 985 |
| Central | 200.0 | 18.0 | 0.13 | 2,954 |
| High | 333.3 | 30.0 | 0.16 | 4,924 |

Discounted using the same 10 year appraisal period as before:

Table 40. Estimated additional total Scottish discounted fortification cost (Option 3)

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated added annual Scottish fortification cost** | **Estimated added total discounted Scottish fortification cost** |
|  | 2024 prices | 2024 prices |
| Low | 985 | 8,476 |
| Central | 2,954 | 25,429 |
| High | 4,924 | 42,382 |

These fortification costs are in addition to the fortification costs presented in 17.1.4.

Since July 2021, UK-produced food grade calcium carbonate is no longer available in significant amounts[[25]](#footnote-26), therefore we assume that all millers are using E170 grade calcium carbonate to fortify their flour (A40). Consequently, the proposed removal of the existing calcium carbonate criteria is not expected to result in any changes to miller’s fortification costs.

Note that if there were more significant amounts of calcium carbonate produced in the UK, the change in requirements would lead to an additional indirect cost. UK supplied calcium would no longer meet the new standards unless the composition of the product was changed, which is difficult to do as it would involve changing the chemical makeup of the calcium carbonate.

## Option 4

No additional costs have been calculated and monetised in addition to those in Options 2 and 3.

## Option 5

### Familiarisation costs

We expect the familiarisation costs as described in Option 2 to be similar to those in Option 5 and do not anticipate any additional costs (for either businesses or enforcement authorities). We assume here that small millers – even if they are now exempt for fortifying NWFF – would still need to familiarise themselves with the regulations (A41).

### Fortification costs

Due to the small-scale miller exemption, a proportion of millers are now exempt from fortifying their flour. This means that these millers could now face reduced fortification costs. As noted earlier, we assume that this does not impact the estimated benefits calculated in Annex I. For the purposes of this analysis, we assume that all the exempted millers are classed as ‘micro-sized businesses’ (i.e. they have between zero and nine employees) (A42). ‘Small-scale millers’ in this Option is therefore referring to micro-sized millers by employee size.

During DHSC and Defra’s engagement with The Traditional Cornmillers Guild (TCMG), they estimated that roughly 30% of the flour produced by small-scale millers is NWWF. Given this propensity for these small-scale millers to produce other non-NWWF products (e.g. wholemeal and brown flours, including from grains like rye or ancient grains), using the proportion of employees employed in small-scale millers and multiplying this by total NWWF production (as in 17.1.4) is likely to vastly overestimate the production of NWWF from small-scale millers.[[26]](#footnote-27)

TCMG estimate that roughly 700 tonnes of NWWF is produced annually by small-scale millers in the UK. Given IBDR data for 2022 reports Scotland as having five micro-sized millers, and the UK as having 50 (see Table 24), we assume 10% of these 700 tonnes are produced in Scotland (A42). In order to construct a low and high estimate, we assume there are between three or seven micro-sized millers in Scotland (similarly to Table 32), so between 6% and 14% of total micro-sized millers in the UK. Using these three proportions, we can construct a low, central, and high estimate for the volume of NWWF produced by small-scale millers in Scotland:

Table 41. Estimated annual fortification cost savings (Option 5)

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated NWWF production from small-scale millers** | **Estimated saved annual Scottish fortification cost** |
| Tonnes | £ 2024 |
| Low | 42 | 50.40 |
| Central | 70 | 84.00 |
| High | 98 | 117.60 |

Discounted using the same 10 year appraisal period as before:

Table 42. Estimated total discounted fortification cost savings (Option 5)

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated saved annual Scottish fortification cost** | **Estimated saved total discounted Scottish fortification cost** |
|  | 2024 prices | 2024 prices |
| Low | 50.40 | 433.83 |
| Central | 84.00 | 723.05 |
| High | 117.60 | 1,012.26 |

These fortification cost savings are in addition to the fortification costs presented in 17.1.4 and 17.2.2.

### Relabelling and package waste costs

Small millers who are currently fortifying their NWWF, and who choose to no longer do so given their exemption in Option 5, will need to produce new labelling. This would involve removing the fortificants from the labelling on the flour they produce currently (e.g. calcium). As a result of this labelling change, they could also incur package waste costs (depending on when in their relabelling cycle this occurs). However, this change is entirely voluntary and they can align these changes with their existing relabelling cycle. This would minimise, or even nullify, any additional costs incurred as a result of this policy change.

Additionally, the relabelling and package waste costs calculated for all Scottish millers (due to folic acid fortification) already include costs incurred by small-scale millers.

Despite these millers now being exempt from fortifying their flour with folic acid under Option 5, they may still incur similar relabelling and package waste costs as explained above. Therefore, the total relabelling and package waste costs calculated for Scotland under Option 2 would be reasonably accurate under Option 5 as well.

As a worst case scenario, we calculate and include the relabelling costs to small-scale millers, assuming these are entirely additional to existing costs (under the status quo and Option 2). We use the same ‘minor change’ relabelling cost as used in 17.1.2.

To estimate the number of products that would require a labelling change (i.e. SKUs containing NWWF produced by small-scale millers), we assume each small-scale miller has one SKU, and that 30% of all SKUs are NWWF (as per TCMG’s estimate that 30% of the total flour miller by small-scale millers’ is NWWF) (A44). That leads to 0.9 to 2.1 SKUs being NWWF. Rounding up to the nearest whole number, we can estimate the relabelling costs:

Table 43. Estimated annual relabelling costs for small-scale millers (Option 5)

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated Scottish small miller-produced SKUs containing NWWF** | **Estimated total Scottish relabelling cost, £ 2024** |
| Low | 1 | 2,554 |
| Central | 2 | 5,107 |
| High | 3 | 7,661 |

Given the small-scale millers could work these labelling changes into existing package change cycles, we assume there are no additional package waste costs. If we were to use the same estimates and assumptions as above, we could estimate package waste costs similarly to 17.1.3 as follows:

Table 44. Estimated annual package waste costs for small-scale millers (not included) (Option 5)

|  |  |  |
| --- | --- | --- |
| **Estimate** | **Estimated Scottish small miller-produced SKUs containing NWWF** | **Estimated total Scottish package waste cost, £ 2024** NOT INCLUDED |
| Low | 1 | 2,038 |
| Central | 2 | 13,375 |
| High | 3 | 39,744 |

1. [HMRC](https://www.uktradeinfo.com/trade-data/); Assuming no imported flour is re-exported. [↑](#footnote-ref-2)
2. Pre assessment information request from UKFM [↑](#footnote-ref-3)
3. Interpreted as the difference between current and proposed BFR fortification levels for these fortificants. [↑](#footnote-ref-4)
4. On-cost estimate provided by premix supplier during a DEFRA stakeholder engagement exercise [↑](#footnote-ref-5)
5. i.e. these ranges are not confidence intervals. [↑](#footnote-ref-6)
6. All monetised benefits are assessed over a policy period of 10 years in line with RPC and DHSC guidance on the default time period that should be used in any appraisal. However, the health benefits of those 10 annual cohorts born during that period are assessed over their whole lifetime, again in line with DHSC guidance. This is because the benefits of avoided NTDs will be seen throughout an individual’s whole life due to the severe and lasting impacts of the condition(s). The main costs are transitional in nature, so the duration of the appraisal period has little impact on the cost estimates. Where costs persist across the policy (e.g. the purchase of fortificants), these are assessed over the full 10 year period. [↑](#footnote-ref-7)
7. The Welsh CARIS dataset includes only miscarriages (a) known to be affected by an NTD and (b) reported to the register. In many cases of an early NTD-related miscarriage, the NTD will not be identified. This means the data will likely underestimate the true number of total NTD-related miscarriages (in Wales). [↑](#footnote-ref-8)
8. This is based on data from [ONS (2023)](https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/timeseries/ybuy/lms) on full-time employees. [↑](#footnote-ref-9)
9. This assumes that the individual would instead be born and live with average health throughout their life. [↑](#footnote-ref-10)
10. This cost was downscaled by using the ratio of Anencephaly costs to Spina Bifida costs found in Yi et al (2011) and applying this ratio to the Spina Bifida costs for Germany from Bowles et al (2014). [↑](#footnote-ref-11)
11. Late spontaneous foetal abortions between 20-23 weeks gestation are recorded in the Scottish data. [↑](#footnote-ref-12)
12. The Welsh CARIS dataset includes only miscarriages (a) known to be affected by an NTD and (b) reported to the register. In many cases of an early NTD-related miscarriage, the NTD will not be identified. This means the data will likely underestimate the true number of total NTD-related miscarriages (in Wales). [↑](#footnote-ref-13)
13. Note that the proportion of medical terminations has risen in the last decade, e.g. from 87.7% in 2019 to 98.8% in 2022 (provisional). This may be in part due to changes in legislation. From 27 October 2017, Scottish Ministers approved a patient’s place of ordinary residence in Scotland as a class of place where treatment for termination of pregnancy may be carried out, allowing misoprostol (the second drug) to be administered there. On 31 March 2020, Scottish Ministers agreed to approve a patient’s place of ordinary residence in Scotland as a class of place where mifepristone (the first drug) may also be taken where clinically appropriate, and where it was not advisable for the patient to attend a clinic or hospital for their treatment due to risks associated with spread of COVID-19. On 12 May 2022, the Scottish Government removed the requirement for the coronavirus to be a serious and imminent threat to public health and to continue to allow mifepristone (the first drug) to be taken at home. [↑](#footnote-ref-14)
14. The higher labour participation rate (50%) is used in our low estimate (and vice versa for our high estimate) since increasing this rate will *reduce* the increase in lifetime earnings. [↑](#footnote-ref-15)
15. This is based on data from [ONS (2023)](https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/timeseries/ybuy/lms) on full-time employees. [↑](#footnote-ref-16)
16. We did not identify data on the split between two- and single-parent households for NTD sufferers. There is an implicit assumption that both parents work and household labour participation is distributed equally between them. [↑](#footnote-ref-17)
17. Reporting feeling lonely ‘often or always’. [↑](#footnote-ref-18)
18. As quoted in BEIS’ Business Impact Target assessment guidance (2017), available at: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609201/business-impact-target-guidance-appraisal.pdf> [↑](#footnote-ref-19)
19. ASHE Table 14 and 15, gross hourly pay for all employee jobs. [↑](#footnote-ref-20)
20. See [HMT’s Green Book (2022)](https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020), p. 40. [↑](#footnote-ref-21)
21. Business in SIC 2007 Division 10 – Manufacture of food and food products. [↑](#footnote-ref-22)
22. We (and DHSC) use the central estimates provide by industry (some provided a range). [↑](#footnote-ref-23)
23. See Table 17 for the total number of UK millers in 2022. [↑](#footnote-ref-24)
24. Pre-impact assessment information from premix manufacturer. [↑](#footnote-ref-25)
25. The quarry producing the calcium carbonate in the England stopped producing calcium carbonate for human consumption after this date. [↑](#footnote-ref-26)
26. If we do calculate it this way, we’d estimate a NWWF production from small-scale millers in Scotland of 13,300 tonnes annually, an order of magnitude more than the TCMG data for the UK as a whole. [↑](#footnote-ref-27)