

Explanatory Memorandum to The Bread and Flour (Wales) Regulations 2025.

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Bread and Flour (Wales) Regulations 2025. I am satisfied that the benefits justify the likely costs.

Sarah Murphy MS
Minister for Mental Health and Wellbeing
29 January 2025

PART 1

1. Description

These Regulations propose measures that will revoke and replace the Bread and Flour Regulations 1998, so far as they apply to Wales.

Changes are being made to provide for the fortification of non-wholemeal wheat flour with folic acid, and to introduce exemptions for small mills, aimed at avoiding disproportionate impacts for businesses.

Changes are being made to the regulations to clarify the requirements and definitions.

A new approach to enforcement is also being incorporated, providing for the use of improvement notices as the frontline enforcement option.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

None

3. Legislative background

In Wales, the FSA has undertaken a review to assist Welsh Ministers in reaching a decision in this matter under its function of developing policy and providing advice relating to matters connected with food compositional standards and labelling regulations. The Welsh Ministers have had regard to advice from the Food Standards Agency as required by section 48(4A) of the Food Safety Act 1990.

The Food Standards Agency in Wales (FSA) alongside the Department for Environment, Food and Rural Affairs (Defra), the Food Standards Agency in Northern Ireland and Food Standards Scotland (FSS) worked together on a review of policy relating to bread and flour, this review being conducted under the Food Compositional Standards and Labelling provisional common framework in efforts to align UK policy as far as possible. This work was also undertaken in conjunction with Welsh Government, the Department of Health and Social Care (DHSC), Scottish Government and Department of Health Northern Ireland who have responsibility for matters of public health. The addition of folic acid to flour was also considered by officials from across the UK under the Nutrition Labelling and Composition Standards (NLCS) framework as the addition of vitamins and minerals to food fall in scope of this framework.

The Welsh Ministers make these Regulations in exercise of the powers conferred by sections 6(4), 16(1)(a), (c), (e) and (f), 18(1)(c), 26(1)(a), (2)(e) and (3) and 48(1) of the Food Safety Act 1990.

A public consultation was carried out as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety during the preparation and evaluation of these Regulations.

This instrument is subject to the negative procedure.

4. Purpose and intended effect of the legislation

What does the legislation do?

This instrument revokes and replaces (with amendments) the Bread and Flour Regulations 1998 which set minimum compositional and labelling requirements for bread and flour. The amendments update current requirements on the addition of specified vitamins and minerals to non-wholemeal wheat flour and introduces the mandatory addition of folic acid to help reduce incidences of Neural Tube Defect (NTD) affected pregnancies. NTDs are birth defects of the brain, spine, or spinal cord of the foetus. The instrument introduces exemptions for small-scale producers and modernises the enforcement regime by moving to an improvement notice approach. The amendments also clarify requirements and certain definitions, as well as removing some technical barriers to compliance to ensure the regulations are fit for purpose.

Context

What is being done and why?

NTDs affect approximately 1,000 pregnancies annually in the UK. The risk of NTDs is associated with low blood folate levels among pregnant women and those who could become pregnant. In the UK, women who could become pregnant are advised to take a daily supplement of 400 micrograms of folic acid (the synthetic form of folate) prior to conception and up until the 12th week of pregnancy. However, since approximately half of pregnancies are unplanned, many women do not take folic acid supplements during this critical period.

The instrument mandates the addition of folic acid to non-wholemeal wheat flour, which is expected to reduce the incidence of NTD-affected pregnancies by 15-22% annually, preventing around 150-220 potentially life-threatening spinal conditions in the UK. This policy is supported by recommendations from the Science Advisory Committee on Nutrition and research modelling the potential impact of folic acid fortification. Similar changes have already been made in England, Scotland, and Northern Ireland.

This instrument also makes changes to:

- Ensure consistency with other food standards legislation by aligning with assimilated EU rules in regulation 1925/2006, thereby facilitating understanding and compliance regarding the addition of vitamins and minerals to food.

- Enhance clarity of requirements and definitions to promote common interpretation and prevent future disputes.
- Introduce a new definition for wholemeal flour, providing clarity to aid compliance while maintaining consumer protection.
- Minimise regulatory burdens by exempting small-scale producers.
- As a clearer way of delivering existing policy, Wales will introduce a direct prohibition on the use of exempted flour for non-exempted purposes.
- Update enforcement provisions by introducing improvement notices, that will allow for more proportionate and efficient enforcement action and will reduce the risk of excessive court costs associated with criminal proceedings.

What was the previous policy, how is this different?

The Bread and Flour Regulations 1998 set minimum levels of calcium carbonate, iron, thiamin, and niacin in non-wholemeal wheat flour, along with chemical specifications for these substances. The amendments now include the addition of folic acid at a level of 250 micrograms per 100g of flour.

Previously, the minimum levels for calcium carbonate, iron, and niacin in non-wholemeal wheat flour were not aligned with general rules for adding vitamins and minerals to food, which require that added nutrients result in a 'significant amount' in the food to benefit consumers. This amendment aligns the minimum levels of these substances to 15% of the Nutrient Reference Value (NRV), meeting the accepted definition of 'significant'. It also updates the specification criteria for the required vitamins and minerals, ensuring consistency with other food standards legislation and maintaining high standards based on the latest specifications and analytical techniques.

The instrument removes the requirements for minimum natural levels of specified nutrients in wholemeal flour but introduces a legal definition of wholemeal flour to ensure the natural nutritional value of wheat is retained.

It clarifies that the legislation applies only to flour made from common wheat, not other wheat species. This ensures consistent interpretation across the industry and enforcement, avoids disproportionate burdens on the industry, and maintains consumer choice.

The instrument exempts flour produced by mills that produce less than 500 metric tonnes of flour per year, mitigating the disproportionate burden on smaller producers without compromising public health outcomes.

The instrument will address ambiguity in policy interpretation of the outgoing regulations. Clearly stating the obligation for individuals operating within food businesses prohibiting the use of exempted flour for non-exempted purposes.

Previously, prosecution was the only enforcement tool for non-compliance with The Bread and Flour Regulations 1998. This instrument introduces improvement notices to address non-compliance, and failure to comply with an improvement notice will attract a criminal sanction.

How has the law changed?

The Bread and Flour Regulations 1998 establish minimum compositional and labelling requirements for bread and flour. This instrument amends provisions on the mandatory fortification of non-wholemeal wheat flour by adding folic acid to the list of required substances. It updates existing requirements for the mandatory addition of calcium carbonate, iron, niacin, and thiamin, considering legislative and technological developments. These changes will come fully into force in December 2026, allowing the industry time to implement them responsibly and effectively, thereby mitigating costs associated with labelling changes and packaging waste.

The instrument also introduces several additional amendments, including exemptions for flour produced by small mills, definitions for 'common wheat' and 'wholemeal flour,' and the removal of impractical compositional requirements for natural nutrient levels in wholemeal flour. Enforcement will now be carried out through improvement notices, with the creation of an offence for failing to comply with such notices, in line with other, recent, food standards legislation. These changes will come into effect in January 2025.

Why was this approach taken to change the law?

This is the only viable method to implement the necessary changes. The decision to revoke and replace the regulations, rather than amend the existing Bread and Flour Regulations, aligns with Welsh Government policy to ensure legislation is clear and accessible. This approach allows the regulations to be available bilingually for the first time.

5. Consultation

A formal consultation ran from 1 September 2022 to 23 November 2022 to gather views on proposed amendments to the rules on the composition of Bread and Flour products. The consultation was drawn to the attention of a wide audience of key stakeholders including businesses manufacturing, exporting, importing and selling flour or flour products, Local authorities/District Councils, trade bodies, health and nutrition professionals and consumers.

369 responses were received to the UK wide consultation, reflecting a broad range of views. After carefully considering these responses, the UK government and devolved administrations have agreed to proceed with the proposed amendments to the Bread and Flour Regulations 1998. This includes the

mandatory addition of 250 micrograms of folic acid per 100 grams of non-wholemeal wheat flour. The only exception to the proposals was the decision not to exempt flour used as a minor ingredient (less than 10% of the final product). This exemption was not included primarily due to the added complexity it would introduce, potentially compromising the effectiveness and enforceability of the regulations.

The full summary of responses can be found on Department for Environment Food & Rural Affairs website, at:

<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>

The consultation pack is available at:

<https://consult.defra.gov.uk/food-compositional-standards/bread-and-flour-consultation-2022>

6. PART 2 – REGULATORY IMPACT ASSESSMENT

1 Introduction

This Regulatory Impact Assessment (RIA) covers a number of proposed measures relating to the Bread and Flour Regulations. These regulations lay down specific labelling and compositional rules for bread and flour in Wales. Under these rules, white and brown non-wholemeal wheat flour is required to have added to it specified quantities of calcium carbonate, iron, thiamin and niacin. The regulations also lay down chemical specifications on the composition of those added nutrients.

The fortification of non-wholemeal wheat flour is one small part of the flour production process, that in itself fits into a wider flour milling industry, linked to the markets for both milling wheat and bakery products.

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

1.1 Justification of analytical approach in the IA

The pre-consultation IA focused on the qualitative costs and benefits of the shortlisted options identified. Following the consultation on the proposed measures, monetised estimates of the cost and benefits associated with the respective options will be provided.

It is necessary to demonstrate impact on both a measure-by-measure basis and within groups of different measures (with similar policy objectives), which form the options formally assessed in this document. This is important, to maintain a manageable number of options to be considered, whilst providing sufficient detail on the costs of benefits of each specific potential intervention.

For this reason, the sections that follow in this assessment will often provide comment on overall impact or the impact of a group of intervention measures before commenting further on a case-by-case basis.

1.2 Key regulation references

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

- i. **The Bread and Flour Regulations (BFR)**: The Bread and Flour Regulations 1998 which laid down specific rules on the labelling and compositional standards of bread and flour in Great Britain.

- ii. **Regulation 1925/2006:** This lays down rules for the addition of vitamins and minerals and of other substances to food. In Great Britain, this Regulation has been retained in domestic law under the European Union (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- iii. **Regulation 1333/2008:** This lays down the rules on food additives: definitions, conditions of use, labelling and procedures. In Great Britain, this Regulation has been retained in domestic law under the European Union (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- iv. **Regulation 231/2012:** This lays down specifications for food additives. In Great Britain, this Regulation has been retained in domestic law under the European Union (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- v. **Regulation 1169/2011:** This lays down rules on the provision of food information to consumers. In Great Britain, this Regulation has been retained in domestic law under the European Union (Withdrawal) Act 2018 (the Withdrawal Act) and amended by secondary legislation made under that Act. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.
- vi. **Food Information (Wales) Regulations 2014:** the Food Information (Wales) Regulations 2014 provide enforcement provisions for rules on the provision of food information to consumers in Wales.

2 Problem under consideration

Key points

- There is a need to make further progress in reducing the number of Neural Tube Deficiency (NTD) affected pregnancies.
- There are disparities between the Bread and Flour Regulations and wider food legislation that have arisen prior and following EU exit.
- Alongside UK Government, Welsh Government have also committed to reviewing other issues which have been raised by stakeholders.

2.1 Issue to be addressed

The current BFRs could be improved to be more favourable to industry, resolve ambiguity in legislation, and more clearly interact with wider food policy. This will

support the fulfilment of wider policy objectives, such as supporting the productivity and resilience of the bread and flour industry (and the wider food industry) through updated legislative arrangements and achieving public health outcomes.

More specifically, ambiguity exists in the legislative arrangements covering the fortification criteria of nutrients, calcium carbonate and the definition of wheat. The regulations can be potentially disproportionately burdensome for small scale millers. Consequently, amendments to the BFR are required, in order to reduce the burden to businesses, confusion in enforcement criteria, and the disproportionate challenge to small scale millers. In addition, the introduction of folic acid into flour is seen to bring further benefits for businesses, consumers Welsh Government and the public as a whole.

More details on the problems under consideration for each potential measure covered within this assessment can be found below.

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

Government advice is for women who could become pregnant to take a daily folic acid supplement of 400 micrograms (μg) before conception and up until the 12th week of pregnancy. With some women, for example, those with a family history of NTDs and those with certain conditions or taking some medications, advised to take a daily supplement of 5 milligrams until the 12th week of pregnancy.

Around half of pregnancies in the UK are unplanned. Those planning a pregnancy are advised to follow Government recommendations regarding folic acid supplementation, to reduce the risk of NTDs. However, for unplanned pregnancies, these messages may not have reached the women in time to increase their folate intake before conception, hence the call for intervention to improve folate intake to achieve a reduction in NTD-affected pregnancies, and the resulting impact on families and the NHS.

NTDs are often serious in nature and can significantly affect both the life expectancy and quality of life in those affected by the conditions. By fortifying non-wholemeal wheat flour with folic acid, the blood folate levels of women who could become pregnant across the population should increase through dietary consumption, therefore reducing the number of NTD-affected pregnancies.

The three main NTDs in order of frequency are Spina Bifida, Anencephaly and Encephalocele. Given the relative severity of NTDs, even a small number of cases carry a large cost to the individuals themselves, the NHS, and the wider economy due to reductions in labour productivity.

Given the existing inclusion of four fortificants in non-wholemeal wheat flour (Niacin, thiamin, 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.

2.1.2 Minimum Level of Nutrients Added to Flour

The regulatory framework governing non-wholemeal wheat flour fortification requirements for Welsh businesses can be improved by providing clarity on the interaction of overlapping legislation. The BFR sets minimums for the addition of calcium, iron, niacin and thiamin in non-wholemeal wheat flour produced in the UK. There are also minimums that would apply to these nutrients when they are added to food controlled by Regulation 1925/2006 on the addition of vitamins, minerals and other substances to foods. As the two minimum levels differ in some cases, there may be ambiguity around which takes precedence, resulting in confusion in terms of compliance.

Article 6(6) of Regulation No 1925/2006 requires that where nutrients are added to food, it must be at a significant amount – defined in Regulation 1169/2011 as 15% of the NRVs. The minimum fortificant requirements of the BFR compared with NRVs is illustrated in Table 1.

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

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

2.1.3 Calcium Carbonate Specification

In relation to calcium purity, the misalignment relates to the additive specification applied by regulation 6 on purity criteria for calcium carbonate (in Regulation 231/2012, applied by Regulation 1925/2006) and the current requirements of the

BFR. As Regulation 1925/2006 Article 5 states that purity criteria for vitamins and minerals “for other purposes than those covered by this Regulation” apply, this would indicate that Regulation No 231/2012 (which lays down specifications for food additives listed in Annexes II and III of Regulation 1333/2008) also applies. This contains a criterion for calcium which is stricter in some instances than that currently prescribed in the BFR, creating challenges in terms of compliance and enforcement. ^[OBJ]

Calcium carbonate composition is determined by the natural geological makeup and is therefore unvarying and very difficult to change. Industry has predominantly moved to using calcium imported from France, which enables them to meet the specifications in both the BFR and Regulation 231/2012 to supply both the domestic market and export to the EU without using different calcium carbonate sources for different markets.

2.1.4 Scope of the Regulations

The BFR currently refers to the need to fortify “flour derived from wheat.” The scientific taxonomy for “common wheat” is ‘Triticum aestivum’ but there are several more subspecies of the Triticum genus, including spelt and other ancient grains, which are gaining more use in milling processes, and all are derived from “wheat”. There is hence an opportunity to provide greater clarity to facilitate compliance and consistency in enforcement approaches.

Currently, the levels of consumption of wheat flour made with grains other than “common wheat” are comparably very low. Whilst industry have been taking the view that BFR fortification requirements apply only to ‘common wheat’ or ‘bread wheat’ (and this was believed to be the original policy intention), some local enforcement officers/trading standards have previously considered that spelt flour could be captured by the regulations given they only specify “wheat”. Therefore, there is an interpretation issue and a need to provide clarity for businesses to facilitate compliance and consistency in enforcement approaches.

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

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

Traditional and small mills are often charitable bodies, where the sale of flour for commercial purposes (normally to local/regional markets) is a significant aspect of the enterprise. There are only a small number of such mills in Wales (for

example, there are only three admitted to the Traditional Corn millers Guild) and not all will produce non-wholemeal wheat flour.

The regulatory burden placed on small-scale millers would also potentially increase with the introduction of folic acid fortification to flour and increased levels of other fortificants required. Stakeholders also argue that the impact on human health (or loss of potential benefit when considering potential fortification of flour with folic acid) from introducing this exemption would be very small, given that output accounts for such a small proportion of overall flour production. Fortification is seen to be impractical and more burdensome for small-scale millers because:

- The technology used in small scale mills means it is not possible to dose flour accurately with fortificants in consistent amounts, especially the small proportions required by the BFR.
- To install the machinery required is impractical given the Listing restrictions in the buildings that many traditional mills are housed in (Grade 2*, Grade 1, Scheduled Ancient Monuments). The costs involved with purchasing and installation are also viewed to be prohibitive when compared to the revenue of most small-scale mills.
- Small-scale mills typically have restricted space for storage of grain meaning that millers purchase small tonnages at any one time. The requirements of the BFR entail that each “parcel” of flour would need to be tested for calcium, thiamine, niacin etc to ensure that the fortificants have been sufficiently mixed in and demonstrate that the flour has been fortified to the required levels. Small-scale mills argue that they cannot afford the additional cost overhead of testing every parcel of flour once produced. The argument is hence that there would be a much lower per-unit cost of testing (using dedicated technology) in larger, industrial-scale mills where throughput is much more significant.
- Income derived from selling non-wholemeal flour is seen to be a vital part of the turnover of the mills that produce it, in turn safeguarding the future of the listed buildings they operate from and the tradition of small-scale milling. Should the cost and impracticality of compliance with the new requirements lead small-scale millers to focus their output on unfortified flour (e.g. wholemeal), their future income could be severely restricted given consumer preference for non-wholemeal flours.

2.2 Rationale for Government Intervention

Government intervention is required to improve existing legislation in the following respects:

- **Mandatory Fortification of UK-milled non-wholemeal wheat flour with Folic Acid:** Folate levels in women of all age groups have been falling over time despite public health advice. This trend is likely to increase the risk of NTD-affected pregnancies in pregnant women or women who

could become pregnant if it continues unabated. Voluntary fortification is already permitted, and supplements are available, but current data suggests these approaches are unlikely to deliver an outcome that sees folic acid intakes increase.

- Interaction with wider food regulations: To address the inconsistencies between the Bread and Flour Regulations and other overlapping food regulations. This will mitigate some of the ambiguity over how legislation is applied.
- Scope of the regulations: To clarify the scope of fortification requirements for wheat flour. This will allow consistent understanding across the flour supply chain and local enforcement of what types of flour are subject to these fortification requirements.
- Exemptions: To address regulatory burdens disproportionately affecting some businesses where public health outcomes of the policy are not compromised to the same extent.

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

2.2.1 Minimum Level of Nutrients Added to Flour

Government intervention is required to improve existing legislation to make it clearer for businesses and enforcement authorities. The objective of the intervention would be to update and align BFR legislation covering fortificant levels with the principle of fortification requirements set out in Regulation 1925/2006 where the addition of vitamins and minerals to food are to be added at a significant amount. This will provide greater clarity for all and make it easier for industry to be compliant, as well as ensuring consistent enforcement.

2.2.2 Calcium Carbonate Specification

Government intervention is required to improve existing legislation to make it clearer for businesses and enforcement authorities. The objective of the intervention would be to ensure coverage of calcium carbonate purity in the BFR legislation is not at odds with wider food additive rules, as well as providing greater clarity and thereby making it easier for industry to be compliant and help enforcement authorities to be consistent.

2.2.3 Scope of the Regulations

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

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

Government intervention is required to ensure the future viability of small-scale mills by addressing potentially significant challenges presented by existing and proposed fortification requirements, due to the practical and technological limitations of small-scale operations.

6. Options

Options considered

Five main options have been investigated in detail to keep the number of options manageable. The grouping of measures chosen for individual options are designed to reflect the similarities in terms of policy objectives and consultation structure. The options are:

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

The individual measures proposed – described in more detail later – which sit under the categories specified in Option 3, 4 and 5 above are:

- i. Interaction with wider food regulations
 - Amend BFRs to raise required fortificant levels to the 15% NRV level required by overlapping legislation, Regulation 1925/2006 on the addition of vitamins and minerals to food.
 - Amend BFRs to remove existing calcium carbonate criteria, requiring millers to comply with the specification in Regulation 231/2012 instead.
- ii. Clarifying scope of the regulations with respect to fortification requirements for wheat flour
 - Provide clarity on the type of wheat which falls within the scope of the fortification requirements in the regulations so that the fortification requirements apply to “common wheat” *Triticum aestivum* only.
- iii. Introduce specific exemptions to reflect industry feedback
 - Introduce exemptions from all fortification requirements for small-scale millers.

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

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

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

Non-regulatory Options

Finding a non-regulatory option that achieves the policy objectives of the proposed interventions is extremely difficult. For instance, it might be possible for government to produce marketing material to encourage industry to produce flour as per the requirements of EU legislation relating to fortification – but this would not tackle issues with the BFR being seen to be disproportionately burdensome for some businesses. The differentiated nature of the various proposed measures hence means that any non-regulatory options that were designed to try to apply to all of them would need to be suitably generic – which in turn limits the effectiveness of those options to the various specific policy objectives of each proposed measure individually.

For folic acid, non-regulatory options were considered as part of the pre-consultation impact assessment carried out in 2019, which included conducting folic acid supplement awareness campaigns and encouraging voluntary fortification of flour with folic acid. These options were not quantified in detail as they were not seen as being effective at addressing the number of NTD-affected pregnancies. Please see the folic acid pre-consultation impact assessment¹ for further details.

Shortlisted options

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

Option 1 – Do Nothing

This involves making no changes to the existing BFRs at all.

Option 2 – Introduce folic acid fortification of flour only

This option would entail amending the BFRs to allow the fortification of flour with folic acid (250 µg of folic acid per 100g flour).

¹ [Fortification of flour with folic acid: impact assessment \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/421111/fortification_of_flour_with_folic_acid_impact_assessment.pdf)

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

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

- Amend BFRs to raise required fortificant levels to 15% of the NRV in line with overlapping legislation on the fortification of foods, to give businesses in Wales clarification on fortification requirements.
- This option would involve raising the minimum levels of calcium, iron, and niacin so that they are all level with the 15% NRV threshold specified in Regulation 1925/2006.
- Amend BFR’s to remove existing calcium carbonate criteria, requiring millers to comply with specification in 231/2012 instead – this option would remove misalignment with the overlapping regulations on additives.

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

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

- Amend the regulations so that the fortification requirements apply to “common wheat” *Triticum aestivum* only. This option would remove ambiguity for industry and enforcement authorities in terms of what flour requires fortification.

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

This option would build on option 4 above but also involves:

Introducing exemptions from all fortification requirements for small-scale millers, meaning that any type of mill producing less than 500t per year would not be exempt from the requirement to fortify.

Proposed changes to enforcement regime – improvement notices analysis

This measure is being analysed separately to the main proposed changes to the BFRs because the changes relate to the enforcement of the regulations rather than the regulations themselves.

These changes are supported by enforcement authorities and were well received in the consultation. See below for a summary of the benefits of the proposed changes

Benefits

A more proportionate enforcement procedure for businesses

There is a benefit to industry in terms of moving from prosecution as the only enforcement sanction to improvement notices. It is anticipated that the gains will originate from reduced costs and the time saved to businesses in resolving the issues more quickly. This is because most cases will be resolved through compliance with the improvement notice, only appeals and those not complied with, will need to be escalated to court and prosecution for non-compliance with the notice. Persons served with an improvement notice can appeal that notice to a magistrate's court. We do not expect there to be an increase in enforcement action, the main effect of the BFR legislation is the fortification of flour, and this responsibility rests in the hands of a small number of players, i.e. flour millers, 99% of whom are members of the UK Flour Millers Association.

Simpler enforcement procedures for enforcement officers

The introduction of improvement notices will bring BFR legislation in line with other similar legislation that is enforced by local authorities.

Improvement notices

Improvement notices will enable a more proportionate approach to enforcement to be taken.

The only current sanction under the BFR's is prosecution for non-compliance. If a business does not meet the requirements in the regulation, it is breaking the law and can be fined. This approach is seen to be inconsistent with modern enforcement measures in place in other food standards legislation – for instance, the Food Information Regulations, the Honey Regulations and the Fruit Juices & Fruit Nectars Regulations. In addition, continuing to classify all breaches of fortification requirements as a criminal offence would retain costly court cases as the only way of addressing non-compliance, when compliance could be achieved via use of a simpler and more proportionate enforcement option.

As is the case currently, food manufacturers and small mills (unless Option 5 is taken forward) would need to ensure they are using the flour as it is intended (for example, that unfortified flour is not used in UK products). Failure to do so would result in action being taken against them.

There have been no previous prosecutions for failing to comply with the BFRs. With the introduction of improvement notices however, any breaches may be easier to take action on. The likelihood of this happening is very low, for a number of reasons.

Firstly, businesses have little incentive to circumvent the rules and misuse flour intentionally, and responsibility only lies with flour millers – the cost savings from doing so will be small. Secondly, breaches of the BFRs are very difficult to detect. The presence of unfortified flour on a business premises does not necessarily

indicate the business intends to use it for products that will be placed on the domestic market. Businesses have the option of using unfortified non-wholemeal wheat flour in products that they export themselves or sell to another business who then exports the products. Therefore, sampling would be required to confirm that products made in the UK using unfortified flour have been placed on the market, or confirmation sought that such products have not been or are not destined for export.

Therefore, moving to the use of improvement notices is expected to have very little impact on the food industry in Wales, particularly as there are no commercially producing flour mills in Wales. However, this change ensures there is a more proportionate approach to enforcement should any issues arise.

7. Costs and benefits

Option 1 - Do Nothing

This option would involve no changes to the BFRs and it is the baseline to which we measure all of the following options against. In this option it is assumed that:

- a) In the absence of folic acid fortification, there will be no changes to the current level of NTDs and the associated health costs will remain the same.
- b) Interpretation issues regarding how the BFR's interact with overlapping food regulations would remain and therefore there would still be legal ambiguities for businesses and enforcement authorities.
- c) BFRs would continue to apply to all milling businesses regardless of size or scale.

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

This option would entail amending the BFRs to require the fortification of flour with folic acid to include 250ug per 100g flour.

Table 2 outlines the costs and benefits captured in the analysis of the policy.

Table 2: Costs and Benefits of Option 2

Monetised costs	Transition costs of redesigning packaging to adhere to the new regulations
	Transition costs of wasted packages because the product contains flour that has been fortified with folic acid but the current label doesn't contain

	folic acid on the ingredients list
	Transition costs associated with enforcement authorities becoming familiar with the new regulations on folic acid fortification
Non-monetised costs	Possible loss in profits due to consumer preference/choice to consume products which do not contain folic acid
	Loss of choice for consumers that do not wish to consume additional folic acid
	Possibility of small number of people exceeding recommended daily folic acid intake levels, and associated low health risks
Monetised benefits	Health benefits of reduced NTD cases – fewer NTD births, miscarriages and terminations.
	NHS treatment cost savings due to fewer NTD cases
	Increased labour productivity in would-be NTD patients and parents or carers of NTD patients
Non-monetised benefits	Reduction in the psychological harm and distress caused by NTD related miscarriages, terminations and stillbirths.
	Wider benefits of an increase in folic acid intake beyond the benefits in reducing NTDs
	Social care cost savings

The net present value of the policy is assessed over a period of 10 years, in line with Green Book guidance. The health benefits of those annual cohorts born during that period are assessed over their whole lifetime. The benefits of avoided NTDs will last throughout an individual's lifetime due to the severe and lasting impact of the condition. The main costs are transitional in nature, so the duration of the appraisal period has little impact on the cost estimates.

Key Assumptions

The costs estimated here are derived using the best available data and evidence. However, where data is not available, reasonable assumptions are made, which are clearly signposted in the assessment below.

In modelling the health benefits derived from the policy, it is assumed that the baseline risk of NTDs remains constant throughout the assessment period and that the birth rate remains stable, in line with projections from the Office for National Statistics².

Costs of Option 2

Costs to business

Data from the ONS' Interdepartmental Business Register shows that there are no grain milling businesses in Wales. There are some small producers using traditional heritage milling methods to produce non-wholemeal wheat flour in Wales, who will incur additional familiarisation and fortification costs under Option 2. These millers are thought to be very small in number and therefore, the aggregate costs to businesses will be very low in Wales. As such, these costs have not been monetised.

The main costs to businesses are expected to fall on manufacturing companies who use flour as an ingredient in their products. These are expected to fall into 2 main categories: relabelling costs and package wastage costs

Relabelling costs

A transitional cost for manufacturers 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.

Information from the 2010 Campden BRI study "Developing a framework for assessing the costs of labelling changes in the UK³" looks at the total cost of all stages of the labelling cycle, from familiarisation of new legal requirements, re-design and auditing through to printing. It also provides estimates based on the magnitude of change, which are used in this analysis. It provides an average cost of relabelling per Stock Keeping Unit (SKU), which are unique codes used to identify products and track inventory⁴.

This is used to represent a cost per SKU basis for relabelling and later

²

<https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections/datasets/tablea11principalprojectionuksummary>

³ Developing a framework for assessing the costs of labelling changes in the UK, May 2010, <https://webarchive.nationalarchives.gov.uk/20110318121117/http://www.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf>

⁴ <https://www.investopedia.com/terms/s/stock-keeping-unit-sku.asp>

multiplied by the number of SKUs requiring relabelling. The study concluded that the following costs would be incurred by businesses depending on whether the labelling change was ‘minor’ or ‘major’, shown in Table 3.

Table 3: Relabelling costs

Extent of change	Average cost (£/Stock Keeping Unit)
Minor	1,810
Major	3,800

Source: Developing a framework for assessing the costs of labelling changes in the UK⁵

The estimates have been updated to account for inflation by multiplying the values in the paper by 1.36, the change between 2010 prices and 2024 prices calculated using the GDP deflators⁶ at market prices, shown in Table 4.

Table 4: Relabelling costs updated for inflation, 2024 prices

Extent of change	Average cost per SKU (2024 prices)
Minor	£2,400
Major	£5,100

As the relabelling change is simply adding ‘folic acid’ to the list of fortificants within flour, the average cost for a minor change is used. A minor change is defined as a change to the text on a single face of a label with no packaging size modification. This means a relabelling cost of £2,400 per affected SKU.

To estimate the number of products that would require a labelling change Kantar data provided by the UK Flour Millers’ Association⁷ is used, which showed the number of SKUs containing non-wholemeal wheat flour in the largest four UK supermarkets by market share.

The data showed that there were 10,184 individual SKUs containing non-wholemeal wheat flour in the biggest 4 UK supermarkets (Tesco, Sainsbury’s, Asda, Morrisons). This figure includes own-label products as well as branded products, some of which would be common across different supermarkets.

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

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

⁶<https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-march-2023-quarterly-national-accounts>

⁷ This data was provided as a bespoke request.

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

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

The Kantar data showed that the big 4 supermarkets' total individual own label SKUs (including non-flour products) were 17,786. Applying the evidence, we have on the percentage of own label SKUs that contain non-wholemeal wheat flour, suggests that there are 5,585 products in this category.

Combining the 10,184 branded individual NWWF containing SKUs from the largest four supermarkets with the 5,585 own label products and 2,738 products in this category from other retailers gives an estimated total of 18,507 SKUs in the UK. Many of these are likely to be imported so are out of scope of the cost estimates in this impact assessment⁸.

Data collected by the Department for Environment, Food and Rural Affairs⁹ showed that in 2021 (the latest year for which data is available) 39% of the food consumed in the UK is imported. Taking this as a proxy for the proportion of SKUs imported suggests that 11,300 UK produced SKUs will be affected by the legislation. Data from the ONS' Interdepartmental Business Register suggests that 5% of UK food manufacturers are based in Wales¹⁰. Under the assumption that the number of SKUs produced in Wales is proportionate to this, this suggests around 564 different non-wholemeal wheat flour-containing SKUs are produced in Wales each year. This is then multiplied by the inflation adjusted unit cost of relabelling to give the central estimate for total relabelling costs.

Given the uncertainty in some of the assumptions used to calculate this estimate, a range is produced around the central value, by assuming that the number of SKUs affected is 10% lower/higher than the data suggests, as shown in Table 5.

Table 5: Total Relabelling Cost by Number of Affected SKUs

Number of Affected SKUs	Total Relabelling Cost, £m 2024
493 – Lower Estimate	£1.2m

⁸ Page 40 of the 'Green Book'
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/106333/0/Green_Book_2022.pdf

⁹ Available at: [AUK-Chapter14-14jul22.ods \(live.com\)](https://www.uktradeandinvestment.com/~/media/1/4/14jul22.ods)

¹⁰ Source, Office for National Statistics.

564 – Central Estimate	£1.4m
636 – Upper Estimate	£1.6m

These costs are likely to be an overestimate, as some manufacturers will have planned to make labelling changes anyway. Therefore, the cost of making the change for folic acid will be much lower for those manufacturers who can align their relabelling cycle with changes to comply with these regulations.

Package Wastage Costs

Food manufacturers will incur one off package wastage costs where they're not able to coordinate the relabelling of products with the transition in the flour they receive to include folic acid. Millers supply multiple manufacturers and it's unlikely that they'll be able to coordinate an optimal date with all of them. Some manufacturers will therefore be unable to fully run-down stock of old packaging and will need to discard some, thus incurring a cost.

The Food and Drink Federation contacted their members to provide evidence on the package wastage costs if they had to change their packaging at short notice - 4 responded. A number of these stated that they order 12 weeks' worth of packaging at a time so in a worst-case scenario, they would need to discard 12 weeks' worth. On average, it is assumed that each company has 6 weeks' worth in stock at the point they must change to the new packaging.

Taking the average of the industry estimates suggests that the package wastage cost per SKU would be around £7,000 (2024 prices). The lowest central estimate received was around £2,000 per SKU and the highest central estimate received was around £13,000. Multiplying this range by the range of estimated SKUs that contain non-wholemeal wheat flour that are produced in Wales (493 to 636) gives the total wastage costs in Table 6:

Table 6: Estimated package waste costs, in 2024 prices

Total package wastage costs	Low central cost per SKU	Average Central Cost of SKUs	High central cost of SKUs
Low no. of SKUs	£1.0m	£3.4m	£6.7m
Central no. of SKUs	£1.2m	£3.8m	£7.6m
High no. of SKUs	£1.3m	£4.3m	£8.6m

Non-Monetised Costs to Industry

Industry may face reduced profits, as a result of some consumers being unwilling or unable to purchase products containing folic acid. This has not been quantified due to a lack of evidence about 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.

Manufacturers producing products containing non-wholemeal wheat flour will need to understand the changes in fortification requirements and the implications for their packaging. As these are minor (manufacturers are used to using fortified flour) this should be easily absorbed into existing operations. These costs are likely to be negligible and have not been estimated.

Non-Monetised Costs to Consumers

There will be a small cost to consumers from a reduced choice of products that do not contain folic acid. Some may choose not to consume products containing folic acid. Alternatives such as wholemeal wheat flour or non-wheat-based flour which will not require fortification, may be more expensive.

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

Overconsumption of folic acid

There will be a small increase in the risk of people exceeding the recommended level of folic acid consumption as a result of the policy (Food Standards Scotland (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.¹¹

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 7).

Table 7: 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,

¹¹ cotfolicacidstatement.pdf (food.gov.uk)

		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 7 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.

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

The Scientific Advisory Committee on Nutrition (SACN) has considered¹⁴ the potential risks associated with sustained high doses of folic acid. The risks considered were masking/exacerbation of low vitamin B12 status; cognitive decline in older individuals, cancer (prostate, breast, colorectal and overall risk); and the long-term effects of unmetabolized folic acid in the body. The Committee found that there was limited evidence to suggest that overconsumption would lead to serious health risks.

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.

Cost pass through

Producers may pass-on any additional costs to consumers. However, these costs are mainly transitory in nature and are spread across a large number of products. Katar data obtained by the Department for Health and Social Care in England suggests that around 11bn items containing non-wholemeal wheat

flour are produced in England and sold in Great Britain each year. Therefore, any price increase is expected to be minimal.

Non-Monetised Costs to 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. It is assumed that adding folic acid to the fortificants will not create a significant additional burden on the trading standards officers that enforce the current laws. No additional products or premises would require inspection.

Benefits of Option 2

Health Benefits

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

One of the modelling scenarios used in this analysis from FSS accounted for variation in individuals' folate intake including women who take the recommended daily 400 micrograms folic acid supplement. Table 8 shows the results of the modelling.

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

The best performing model was deemed to be one that accounted for variation in folate status across the population, as well as assuming that 30% of women take the recommended daily 400 micrograms/d folic acid supplementation. This model is known as 'Model C'. There are 2 variants of this: Daly and Crider

Table 8: Percentage reduction in NTD risk from fortification of all non-wholemeal wheat flour, assuming 30% of women planning to become pregnant also take 400 mcg folic acid supplement (FSS modelling)

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

As shown in Table 8, fortifying with 250micrograms/100g NWWF would lead to between a 15.4% and 22.4% reduction in NTD risk, using the equations from Daly and Crider respectively. The Daly prediction is based on an Irish population which is likely to be more similar in diet and genetics to a UK population but is older, with the study having been carried out in 1995.

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

The Daly and Crider prediction equations lead to different results, and as stated in the FSS report it is unclear which is more relevant. As a result, an average of the two, 19%, is used in this analysis. The FSS analysis also reports an uncertainty range of +/- 20%¹² around these modelled values. A range around the central estimate of the risk reduction is constructed by subtracting 20% from the Daly estimate (net risk reduction:12%) and adding 20% to the Crider estimate (net risk reduction: 27%).

If a foetus develops an NTD, there are 3 possible outcomes:

- i. Pregnancy goes to term and the baby is born with an NTD
- ii. Foetus is aborted
- iii. Mother has a miscarriage or stillbirth

A risk reduction of 19% from folic acid fortification is applied equally across all 3 outcomes. The FSS analysis did not look at the risk reductions for different pregnancy outcomes.

The section below monetises the individual health benefits in terms of the reduction of NTD affected live births. However, there may also be 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, it is not 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 these benefits have not been taken into account.

Reduction in the number of NTD affected live births

Data from Public Health Wales (PHW) shows that there was an average of nine live NTD births per year, in Wales between 1998 and 2022. The FSS report suggests that a fortification level of 250micrograms/100g NWWF would lead to

¹² Page 37 of

https://www.foodstandards.gov.scot/downloads/STOCHASTIC_MODELLING_TO_ESTIMATE_THE_POTENTIAL_IMPACT_OF_FORTIFICATION_OF_FLOUR_WITH_FOLIC_ACID_IN_THE_UK_-_FINAL_REPORT_-_July_31_2017.pdf

an estimated 19% reduction in NTD risk, meaning that around two fewer NTD births, on average, are anticipated each year in Wales. The number of live birth cases and cases prevented, by NTD type, is shown in Table 9.

Table 9: Split of NTD Cases and Estimated Prevented Cases

NTD	Annual Cases, Wales, (1998 – 2022 average)	Estimated Cases Prevented per year, 250ug/100g	Estimated cases prevented over a 10-year time horizon
Spina Bifida	6	1.22	12
Anencephaly	1	0.1	1
Encephalocele	2	0.33	3
Total	9	1.7	16

The health benefits of a reduction in NTD cases are monetised by calculating 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. This loss would be considered prevented if an NTD case was avoided, assuming that the individual would instead be born and live with average health throughout their life. The monetised health benefits for that individual would be the QALYs that would have been lost had they been born with an NTD.

The lifetime health profile of a typical individual without an NTD is taken from McNamara *et al* (2023)¹³ as expressed by EQ5D scores in different age bands. These are converted into discounted QALYs using the standard Green Book¹⁴ discount rate of 1.5% for health factors¹⁵. It is assumed that individuals live for 81 years which was the average life expectancy of a newborn in 2020¹⁶. The resulting expected QALYs of a typical new-born when discounted was 41.9.

The above process was repeated for new-borns with Spina Bifida and Anencephaly. The average life expectancies for new-borns with these NTDs are 43 years¹⁷ and less than 1 day¹⁸ respectively. No data exists on the life expectancy or quality of life of children born with Encephalocele, so this analysis assumes this is the same as Spina Bifida. This is likely to understate the benefits of fortification as Encephalocele is a more serious condition. The standard deviation of the EQ5D score was 0.24¹⁹ and this is used when constructing the range of health benefit estimates in Table 11 below.

When converted to discounted QALYs using different weighted QALY utility

¹³ <https://www.sciencedirect.com/science/article/pii/S1098301522021015#tbl1>

¹⁴ [The Green Book \(publishing.service.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/100000/green-book-2015.pdf)

¹⁵ [Health discount factors: 1.5% for years 1 – 30; 1.286 for years 31 – 75; 1.071 for years 76 to 125](#)

¹⁶ ONS Life Tables (https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesunitedkingdomreferencetables)

¹⁷ [Cost-Effectiveness of Mandatory Folic acid Fortification in Australia | The Journal of Nutrition | Oxford Academic \(oup.com\)](#)

¹⁸ [Anencephaly: information for parents - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/100000/green-book-2015.pdf)

¹⁹ Tilford, JM et al 2005, <https://link.springer.com/article/10.1007/s11136-004-3305-2>

values from literature²⁰ (Anencephaly is assumed to have a QALY utility of 0), the figures for Spina Bifida and Encephalocele become 17.6 QALYs. The discounted QALY figures were then subtracted from the QALY life expectancy for a new-born in typical health to calculate the QALY loss for an individual with each of the NTDs. The process is summarised in Table 10.

Table 10: Discounted Lifetime QALY Loss of NTDs

NTD	Life Expectancy (Years)	QALY Adjustment (Utility)	Discounted Lifetime QALYs	Disc. Lifetime QALY Loss	Discounted Value of Loss, Individual (£2024)
Spina Bifida	43	0.55	17.6	24.2	£1.9m
Anencephaly	0	0	0	41.9	£3.2m
Encephalocele	43	0.55	17.6	24.2	£1.9m

A single QALY is valued at £70,000 as per standard Green Book²¹ practice. Multiplying each of the NTDs discounted lifetime QALY loss produces the monetised health benefit for an individual prevented case, £1.9m, £3.2m, and £1.9m for Spina Bifida, Anencephaly and Encephalocele respectively.

Preventing cases of Anencephaly produces the largest monetised health benefits because the majority of cases lead to death soon after being born, meaning each prevented case is essentially a full life of QALYs gained. In line with cross government impact assessment guidance the ‘policy lifetime’ used to assess the costs and benefits is 10 years. As a result, there are 10 annual cohorts of new-borns that stand to benefit from reduced cases of NTDs.

Health benefits are estimated over each cohort’s whole lifetime due to the severity and lasting nature of the conditions. There is the possibility that some women giving birth in the first year will not have seen increased blood folate levels as the preconception period and the first 12 weeks of their pregnancy occurred before the introduction of folic acid fortification. For the sake of simplicity these cases are not factored into the analysis, but it should be noted that the first cohort may be an over-estimation as a result.

The total live-birth health benefits from the 10 cohorts born over the 10-year policy period for fortifying non-wholemeal wheat flour with folic acid at 250ug/100g are estimated to be £29.7m in the central scenario. Table 11 shows the total health benefits for each NTD under the low, central and high scenarios.

Table 11: Monetised Health Benefits by NTD (250 ug/100 g flour), £2024

NTD	Low Monetised	Central	High
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²⁰ [Health state preference scores of children with spina bifida and their caregivers | SpringerLink](#)

²¹

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063330/Green_Book_2022.pdf

	QALY Loss Prevented,	Monetised QALY Loss Prevented,	Monetised QALY Loss Prevented
Encephalocele	£2.5m	£5.7m	£10.7m
Spina Bifida	£9.2m	£21.0m	£39.5m
Anencephaly	£2.0m	£3.1m	£4.4m
Total	£13.7m	£29.7m	£54.5m

Wider Economic Benefits

There would also be wider economic benefits arising from the policy. These stem from:

- i. lower costs to the NHS due to fewer people living with NTDs
- ii. lower health and social costs from NTD related miscarriages
- iii. lower healthcare costs from NTD related terminations
- iv. increased lifetime earnings for would-be NTD sufferers
- v. Increased labour market participation by parents and carers of children with NTDs

NHS Treatment Cost Savings

A review of the academic literature on NTDs found a number of estimates of the treatment costs. Many of these are US based and differences in their healthcare system meant that it is not appropriate to use their figures in a UK context. There was only one study from Europe (and none from the UK) that offered a reasonably comprehensive account of the treatment costs of NTDs both in and out of hospital.

The Economic burden of Neural Tube Defects in Germany²² (Bowles *et al*, 2014) found that the average net additional annual healthcare expenditure per person with Spina Bifida was 3,032 Euro (or £3,375 in 2024 prices). This is over and above normal healthcare expenditure and includes the cost of additional inpatient and outpatient care, GP care, rehab, drugs and medical aids. No European studies looked at the cost of Encephalocele so the costs for Spina Bifida are used as a proxy for those cases.

For the treatment cost of Anencephaly, the findings from a US study reported in Yi *et al* (2011)²³ are used, that found that the average annual cost was £3,659 (2024 prices). This was the only study found that had details of the cost of this NTD. The cost is scaled to £933²⁴ to account for systematic differences in the cost of the US vs English health system. The treatment costs for Anencephaly are lower because patients who are born with the condition typically die within

²² [Economic burden of neural tube defects in Germany - ScienceDirect](#)

²³ <https://pubmed.ncbi.nlm.nih.gov/21594574/>

²⁴ The scaling is done 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

minutes or hours of being born.

Applying the annual cost to the number fewer NTD cases in each cohort born during the 10-year policy period, gives a total cost saving from fewer live NTD births of £1.04m. A breakdown of these costs is given in Table 12

Table 12: Cost savings to the NHS from fewer babies born with NTDs

NTD	Number fewer live births per year	Annual treatment costs per person (£ 2024)	Total, discounted lifetime cost savings
Spina Bifida	1.22	£3,400	£817,000
Encephalocele	0.33	£3,400 ²⁵	£221,000
Anencephaly	0.1	£900	£822
Total	1.7		£1,039,000

Given the uncertainty in the risk reduction that will be gained from fortification, and hence the reduction in the number of NTD births, a range of NHS cost reductions has been estimated around the central value, using the range in NTD risk reduction identified previously (12% - 27%), as shown in Table 13.

Table 13: NHS cost savings from the reduction in incidence of all 3 NTDs (2024 prices, present value)

	Number fewer live NTD births per year	Present value of lifetime cost savings
Low	1.08	£677,000
Central	1.7	£1,039,000
High	2.4	£1,480,000

Lower health and social costs from fewer NTD related miscarriages

The cost savings from fewer miscarriages are calculated by multiplying the number fewer miscarriages by the health care and wider cost of miscarriages.

Data on the prevalence of NTD related miscarriages comes from NHS Wales' Congenital Anomaly Register and Information Service for Wales (CARIS). The number of fewer cases is then estimated using the FSS risk reduction figure of 19%.

²⁵ Spina Biffida figure used because of lack of Encephalocele specific data

The cost of miscarriage comes from a study by Sagili and Divers (2007)²⁶ who find that the average cost is £2,317 (2024 prices). This includes hospital care, drugs and medical products, community health and social services, and work absences.

The total, discounted cost saving over the 10-year evaluation period is £7,600. A summary of the figures is given in Table 14.

Table 14: NHS cost savings resulting from fewer NTD related miscarriages

Average annual number of NTD related miscarriages	Average annual reduction due to 19% reduced risk	Cost of miscarriage (2024 prices)	Total annual cost saving, undiscounted (£2024)	Total discounted cost over 10-year evaluation period
2	0.4	£2,317	£880	£7,600

Given the uncertainty in the risk reduction gained from fortification, and hence the reduction in the number of NTD births, a range of cost reductions has been estimated around the central value, using the range in NTD risk reduction identified previously (12% - 27%). These are shown in Table 15.

Table 15: Cost savings from the reduction in incidence of NTD related miscarriages

	Average number fewer NTD related miscarriages per year	Present value of cost savings
Low	0.2	£4,900
Central	0.4	£7,600
High	0.5	£10,800

Lower healthcare costs from fewer NTD related terminations

Another consequence of fewer NTD affected pregnancies will be fewer NTD related terminations.

Again, it is assumed that fortification will reduce the NTD risk and number of pregnancies that result in termination by 19% in line with the evidence in the FSS report.

The average annual number of NTD related terminations over the period 1998-2022 in Wales is 43, from CARIS. Termination is the most common outcome for

²⁶ <https://pubmed.ncbi.nlm.nih.gov/17233871/>

NTD affected pregnancies.

The costs of termination are taken from NHS Tariff data²⁷ and there are different costs depending on whether a medical or surgical procedure is used, and the point during the pregnancy at which the foetus is aborted. This normally depends on the point at which the NTD is detected.

Data on the split between medical and surgical terminations comes from UK government statistics²⁸. In 2021 the proportion of all termination that were medical was 87% with the rest being surgical. It is assumed this same distribution applies to NTD related terminations. The total present value of the cost savings over the 10-year evaluation period is £61,000, with a summary of the key figures provided in Table 16.

Table 16: Savings from fewer NTD related terminations

NTD	Average annual number of NTD related terminations (Wales, 1998-2022)	Number prevented (assuming 19% reduction)	Cost of medical termination	Cost of surgical termination	10 year discounted present value
Anencephaly	19	4	£514	£1,124	
Encephalocele	5	1	£1,020	£1,620	
Spina Bifida	18	3	£1,020	£1,620	
Total	43	8			£61,000

Given the uncertainty in the risk reduction that will be gained from fortification, and hence the reduction in the number of NTD affected pregnancies a range in this value (12% - 27%) is used to create a range of cost reduction estimates around the central value. These are shown in Table 17.

Table 17: Cost savings from the reduction in incidence of NTD related terminations

	Average annual reduction in number of NTD related terminations	Present Value of Cost saving (£)
Low	5	£40,000
Central	8	£61,000

²⁷ <https://www.england.nhs.uk/publication/national-tariff-payment-system-documents-annexes-and-supporting-documents/>

²⁸ <https://www.gov.uk/government/statistics/abortion-statistics-for-england-and-wales-2021/abortion-statistics-england-and-wales-2021>

High	11	£87,000
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Lifetime earning gains of would-be NTD sufferers

People with Spina Bifida and Encephalocele are more likely to be out of work and have shorter life expectancy than those without. They are also likely to earn less due to poorer health. Reducing the incidence of NTDs will therefore have a positive impact on the lifetime earnings of would-be NTD sufferers.

A range of studies exist that estimate the employment rate of NTD sufferers. Values range from 19%²⁹ to 63%³⁰. The average of the studies is 39% which is the value used here for the central estimate. This is much lower than the average employment rate of adults in the UK aged 16 – 64 which is 76%³¹.

Data on the wages of people with NTDs is not available, but disabled people in general have lower median wages than non-disabled people - £13.37 vs £15.51³².

Accounting for the higher wages, employment rates and longer life expectancy of non-NTD sufferers suggests that the total discounted earnings gains experienced by the cohorts born during the 10-year policy period would be £2.9m.

Given the uncertainty in the risk reduction that will be gained from fortification, and hence the reduction in the number of NTD affected pregnancies the range in this value (12% - 27%) is used to create a range of increased earnings estimates around the central value. This is shown in Table 18.

Table 18: Increased earnings as a result of a decrease in the number of would be NTD-sufferers

	Reduction in number of would be NTD sufferers	Total PV benefits
Low	10	£1.93m
Central	15	£2.96m
High	22	£4.22m

²⁹ Lonton et al., 1984 See NZ 2019 IA <https://www.mpi.govt.nz/dmsdocument/37230-Folic-acid-fortification-both-society-and-individuals-benefit>

³⁰ Van Mechelen et al., See NZ 2019 IA <https://www.mpi.govt.nz/dmsdocument/37230-Folic-acid-fortification-both-society-and-individuals-benefit>

³¹ ONS [A05 SA: Employment, unemployment and economic inactivity by age group \(seasonally adjusted\) - Office for National Statistics \(ons.gov.uk\)](https://www.ons.gov.uk/economy/employment/unemploymentandeconomicinactivity)

³² Office for National Statistics, Disability pay gaps in the UK: 2021. Figures inflated to 2024 prices using the GDP deflator.

Lifetime earnings gains of would-be parents of children with NTDs

NTD cases lead to reduced labour participation in the parents and/or carers of the patient. A literature review by Yi et al.³³ states that on average, parents of Spina Bifida patients have between a 21% and 27% lower labour participation rate. In the absence of data for Encephalocele it is assumed this is the impact for that condition as well. It is also assumed that all individuals with a would-be NTD come from two-parent/carer households.

According to ONS data³⁴, 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 £29k. The ONS do not publish separate data for Wales. It is estimated that there will be on average, 1.55 fewer live Spina Bifida and Encephalocele births per year at the 250micrograms/100g NWWF fortification level. This figure is then doubled to 3.1 to account for both parents, under the assumption that both parents work, and household labour participation is distributed equally between them.

The aggregated average annual income for 3.1 people is £69,000. Using a central value from the literature review of a reduction of 24% in labour participation, the aggregated average annual income for 3.1 parents of Spina Bifida patients is £52,000, implying an annual income loss of £16,600 owing to Spina Bifida and Encephalocele cases.

Following the cohort approach used in the health benefits and NHS treatment cost analyses, the total labour market participation gain owing to the policy over the 10-year policy period is estimated to be £1.9m. This assumes that parents/carers look after their NTD affected children until the age of 18 years.

Given the uncertainty in the risk reduction that will be gained from fortification, and hence the reduction in the number of NTD affected pregnancies we use the range in this value (12% - 27%) to create a range of increased earnings estimates around the central value, shown in Table 19.

Table 19: Increased earnings as a result of a decrease in the number of would be NTD-sufferers

	Reduction in number of parents and carers of would be NTD sufferers each annual cohort	Total PV benefits
Low	2.0	£1.3m
Central	3.1	£1.9m

³³ [Economic burden of neural tube defects and impact of prevention with folic acid: a literature review | SpringerLink](#)

³⁴ [A05 SA: Employment, unemployment and economic inactivity by age group \(seasonally adjusted\) - Office for National Statistics \(ons.gov.uk\)](#)

High	4.1	£2.8m
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Non- monetised benefits

Those affected by NTDs often require lifelong health and social care³⁵. As a result of a reduction in cases of NTDs, the overall social care burden created by these conditions will fall, meaning a reduction in the opportunity cost (separate to a labour productivity increase), as well as a reduced social cost of those that have to give up time to care without pay for those suffering with NTDs.

This benefit has not been quantified due to a lack of evidence and available data on which to base an estimate. Abortion, miscarriage and stillbirth cause considerable psychological harm and distress to the mothers and families of those involved and its impact is likely to be significant.

Summary of Costs and Benefits

The monetised benefits of the policy far outweigh the monetised costs - £35.7m vs £5.24m in the central estimate. The main costs of the policy are transitory - relabelling and packaging waste. While there is an annual cost involved in adding folic acid to the fortificants that are put into NWWF, the cost of this is low compared to most of the other costs and benefits and on a per product basis is negligible (for example the cost of the folic acid would add 0.008p to the cost of a standard 800g loaf of bread). Table 20 summarises the central estimate costs and benefits of the policy.

Table 20: Central estimate of present value of costs and benefits

<u>Central Estimate of Costs</u>	
Relabelling	£1.39m
Package wastage costs	£3.85m
Total Costs	£5.24m
<u>Central Estimate of Benefits</u>	
Live births without NTDs	£29.69m
NTD related miscarriage costs prevented	£0.01m
NTD related termination costs prevented	£0.06m
Higher wages and labour market	£2.96m

³⁵ [Neural tube defects in Australia: prevalence before mandatory folic acid fortification, Summary - Australian Institute of Health and Welfare \(aihw.gov.au\)](http://www.aihw.gov.au)

participation	
Parents prevented from leaving the labour market	£1.95m
NHS cost savings	£1.04m
Total Benefits	£35.7m
Net Benefit (Present Value)	30.46m

Sensitivity Analysis

To test the conclusion that the benefits outweigh the costs it's possible to compare the low end of our range of benefit estimates with the upper bound of our range of costs as set out in the cost and benefit sections above. The result of this analysis is shown in Table 21.

Table 21: Low net present value sensitivity – upper end of range of costs, compared to lower bound of range of benefits

<u>High Costs</u>	
Relabelling	£1.57m
Package wastage costs	£8.59m
Total	£10.15m
<u>Low Benefits</u>	
Live births without NTDs	£13.71
NTD related miscarriage costs prevented	£0.005m
NTD related termination costs prevented	£0.4m
Higher wages and labour market participation	£1.93m
Parents prevented from leaving the labour market to care for NTD afflicted children	£1.27m

NHS cost savings	£0.68m
Total	£17.63m
Low Net Benefit (Present Value)	£7.47m

Even under this pessimistic scenario, benefits are larger than costs.

Conversely if the lower bound of the estimated costs is compared with the upper bound of estimated benefits this gives the results shown in Table 22.

Table 22: High Net Present Value sensitivity – lower end of range of costs, compared to upper end of range of benefits

<u>Low Costs</u>	
Relabelling	£1.22m
Package wastage costs (placeholder TBC)	£1.02m
Total	£2.24m
<u>High Benefits</u>	
Live births without NTDs	£54.54m
NTD related miscarriage costs prevented	£0.01m
NTD related termination costs prevented	£0.09m
Higher wages and labour market participation	£4.22m
Parents prevented from leaving the labour market to care for NTD afflicted children	£2.77m
NHS cost savings	£1.48m
Total	£63.09m
High Net Benefit (Present Value)	£60.85m

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

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

Costs – option 3

Costs to businesses

As there are no grain milling businesses in scope of the policy change in Wales and only a very small number of small, traditional millers, no direct costs to businesses have been calculated as these are likely to be minimal.

Indirect

This option could make it difficult for UK based calcium manufacturers to provide food grade calcium for fortification purposes in future. Since Regulation 231/2012 would now apply, UK supplied calcium would not be able to meet these standards unless the composition was changed, which is very difficult to do as it would involve changing the chemical makeup of the calcium carbonate. However, there are currently no UK based manufacturers of food grade calcium carbonate. This is an unmonetised indirect cost.

Costs to consumers

Indirect

As there are no grain milling businesses in scope of the policy change in Wales and only a very small number of small, traditional millers, no direct costs to consumers have been calculated, as these are likely to be minimal. They will only apply to customers of small millers under Option 3 and the price of the flour they sell will be influenced by a number of factors, not least the quantity and quality of the local grain harvest.

Costs to Government

Direct

As there are no grain milling businesses in Wales and only a small number of traditional mills, any additional costs to enforcement authorities in Wales in Option 3 are likely to be minimal and therefore, have not been monetised.

Benefits – Option 3

Benefits to businesses

As there are no grain milling businesses in scope of the policy change in Wales and only a small number of traditional mills, no benefits to businesses have

been calculated. However, Option 3 will provide legal clarity for the small number of mills that would be required to fortify under this option.

Benefits to consumers

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

Benefits to government

Direct

Like the impact on businesses this option also offers legal clarity to enforcement authorities as it makes it easier for them to enforce the calcium criteria rules. This is an unmonetised benefit because this would only apply to a very small number of traditional mills in Wales and any additional benefits are likely to be small.

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

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

Costs – Option 4

Costs to businesses

As there are no grain milling businesses in scope of the policy change in Wales and only a small number of traditional mills, no costs to businesses have been calculated.

Costs to consumers

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

Costs to government

As there are no grain milling businesses in Wales and only a small number of traditional mills, any additional costs to enforcement authorities in Wales in Option 3 are likely to be minimal and therefore, have not been monetised.

Benefits – Option 4

Benefits to businesses

Direct

As there are no grain milling businesses in scope of the policy change in Wales, no benefits to businesses have been calculated.

Benefits to consumers

Indirect

This option would improve consumer choice by providing unfortified alternative options alongside non-wheat-based flour. This should be taken into consideration for those with particular dietary requirements where avoiding fortificants like calcium and iron is sometimes advised. This is an unmonetised benefit.

Benefits to government

Direct

This option would provide greater clarity to the industry and enforcement authorities and resolve the ambiguities over which grains are required to be fortified. Because of the small number of traditional/small mills in scope in Wales, this cost has not been monetised.

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

This option would include all of the costs and benefits of Option 4 in addition to the costs and benefits included below.

Costs – Option 5

Costs to businesses

Familiarisation costs

Small millers in Wales will be required to familiarise themselves with the changes, which will exempt them from fortification requirements. As there are few small millers in scope and the time required to familiarise themselves with the changes is small, this cost has not been monetised.

Pre-mix sales

If qualifying millers are not required to fortify, this will result in a reduction of pre-mix sales to those millers. This cost has not been monetised, due to the small number of millers involved and the relatively low cost of premix, given the millers' output levels.

Relabelling costs for small scale millers who take up the exemption

If millers who qualify for the exemption decide that they want to no longer fortify the flour that they produce, then they will need to produce new labelling. This would involve remove the fortificants from the labelling on the flour they produce. These are stated in brackets after flour on the ingredients list.

The analysis undertaken for Option 2 suggests that the average cost for a minor labelling change as estimated at £2,106 per Stock Keeping Unit (SKU), in 2024 prices.

However, estimating the number of SKUs affected by the change is very difficult. The number of mills in scope is very small, as is the amount of non-wholemeal wheat flour produced. Furthermore, production can vary significantly from year to year, depending on demand, the power source (which may also depend on the weather), the availability of grain locally and staffing.

Therefore, due to the difficulty of monetising this cost accurately, this is an unmonetized cost in this Impact Assessment.

Costs to consumers

Reduction in fortificant intake

A small proportion of consumers may experience a marginal decrease in fortificant intake as a result of the exempted products they consume no longer containing fortified flour. However, the impact on health outcomes is expected to be negligible given the small amounts of flour no longer being fortified³⁶. In addition, this only applies to flour sourced from the small number of exempted small mills in Wales, all other non-wholemeal wheat flour products purchased from elsewhere will be fortified.

Costs to government

Direct

Familiarisation costs

Enforcement authorities will need to familiarise themselves with the change in regulations. However, due to the small number of mills in scope, this will only apply to a small number of authorities and the time required to do so is expected to be minimal. Therefore, this cost has not been monetised.

Additional compliance costs

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

Benefits – Option 5

Benefits to business

Direct

Reduction in fortification costs

Qualifying millers would no longer be required to fortify their flour. The cost savings arising from this are very difficult to estimate accurately, due to the

³⁶ Traditional Corn Miller's Guild estimates that around 300 tonnes of non-wholemeal wheat flour is produced by small scale millers.

difficulty in estimating the amount of flour that is produced in small mills, in Wales. However, this is likely to be a relatively small saving overall, due to the small number of mills in scope and the relatively low cost of fortification (estimated at £1.20 per tonne³⁷). This cost would imply a maximum saving per mill of £600 per year.

Indirect

Viability of small-scale millers

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

Benefits to consumers

Direct

If millers took up the exemption this would offer consumers more choice when buying unfortified non wholemeal flour-based products. This should be taken into consideration for those with particular dietary requirements, where avoiding significant intakes of nutrients like calcium and iron is sometimes advised. This is an unmonetised benefit.

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

Benefits to government

Direct

There are no additional direct benefits to government resulting from this option.

Indirect

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

Conclusion

Option 5 is the preferred option as it best meets the policy objectives of the intervention. Although there are currently no large milling businesses in Wales, Option 5 will ensure that any future large milling businesses will help to deliver an improvement in public health outcomes via the fortification of flour with folic acid. It will also align the BFRs with wider food rules and provide future clarity

³⁷ Pre assessment information request from premix manufacturer.

to businesses and enforcement authorities.

Exempting small mills producing less than 500 tonnes per year will help to ensure the viability of what are small, often heritage mills with historical and cultural value.

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

8. Competition Assessment

A competition assessment has been carried out, below. The legislation is not expected to have a detrimental effect on competition.

Question	Answer (Yes/No)
<i>Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?</i>	Unknown, but possible.
<i>Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?</i>	Unknown, but possible.
<i>Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?</i>	Unknown, but possible.
<i>Q4: Would the costs of the regulation affect some firms substantially more than others?</i>	Yes, as small millers are exempt.
<i>Q5: Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?</i>	No
<i>Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?</i>	No
<i>Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?</i>	No
<i>Q8: Is the sector characterised by rapid technological change?</i>	No
<i>Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?</i>	No

9. Post implementation review

What is the approach to monitoring and reviewing this legislation?

To monitor the impact of this legislation at a UK-wide level, we will use data from the National Congenital Anomaly and Rare Disease Registration Service

(NCARDRS), which registers NTDs, and the National Diet and Nutrition Survey (NDNS). This will allow us to track the prevalence and incidence of NTDs, as well as folate and vitamin B12 status, folate and folic acid intakes, and folic acid supplement use.

This data will be evaluated to assess the policy's impact in three key areas: 1) the reduction in the incidence and prevalence of NTDs compared to model estimates; 2) improvements in folic acid intake and status across the population, particularly among women of child-bearing age; and 3) any increase in the proportion of the population, especially older adults, exceeding the upper guidance level for folic acid.

We plan to conduct surveys and workshops with stakeholders to evaluate the experiences of industry and enforcement officers with the regulations, ensuring they remain current and effective. Additionally, we will seek consumer feedback to confirm that marketing controls are appropriate. Sampling data will be used to measure compliance and identify any barriers that may need to be addressed.

We will evaluate policy outcomes once we have reliable data. Monitoring the health impact of the policy will need to consider the 2-year period for industry to implement the policy before it becomes mandatory, as well as the availability of outcome data from the NCARDRS (and equivalent registers) and the NDNS.

The instrument does not include a statutory review clause. However, the FSA plans to monitor and evaluate the policy as outlined above to ensure it achieves its intended effect and to determine if any revisions are necessary.