



Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998

Date: 1st September 2022

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Executive Summary

The UK Government and devolved administrations are seeking views on proposals to update and amend The Bread and Flour Regulations 1998 and The Bread and Flour Regulations (Northern Ireland) 1998 which cover specific rules on the labelling and composition of bread and flour. The regulations primarily mandate the compulsory fortification of milled white and brown non-wholemeal wheat flour that are manufactured and sold in the UK for public health reasons with added calcium, iron, thiamin and niacin to protect against nutrient deficiencies within the UK population.

Calls for a review into the regulations arose due to the legislative changes which were made following the UK's departure from the EU.¹ Requests for a review were largely due to a disparity between the Bread and Flour Regulations and other pieces of food legislation on the levels and specifications of vitamins and minerals added to foods. While we have set out to ensure the Bread and Flour Regulations are consistent with other food standards legislation, we have also committed to reviewing a range of other issues regarding some of the provisions of the regulations which have been raised by stakeholders. The proposals included in this consultation look at ways to ensure that the regulations lead to improved public health, support UK industry, assist enforcement authorities and protect consumers.

[Following a UK-wide public consultation](#), the UK Government and devolved administrations announced in September 2021 their intention to proceed with arrangements to require the mandatory fortification of non-wholemeal wheat flour with folic acid to help prevent neural tube defects in fetuses. To minimise the impact of this requirement on industry, where possible, multiple changes should be incorporated under one set of amendments. Thus, the addition of folic acid to the list of nutrients which must be added to non-wholemeal wheat flour is being co-ordinated as part of this wider review of the regulations.

¹ The Food (Amendment and Transitional Provisions) (England) Regulations 2021; The Food (Withdrawal of Recognition) (Miscellaneous Amendments) (Scotland) Regulations 2021; The Food (Withdrawal of Recognition) (Miscellaneous Amendments and Transitional Provisions) (Wales) (EU Exit) Regulations 2022; ended the mutual recognition arrangements for flour from EU/EEA member states, meaning wheat flour imported from the EU and EEA to GB will need to comply with Bread and Flour Regulations fortification requirements from October 2022. Under the terms of the Protocol on Ireland/Northern Ireland, mutual recognition continues to apply to flour imported from EU member states into Northern Ireland meaning flour imported from EU member states to Northern Ireland is exempt

from the requirements of the Bread and Flour Regulations. At the same time changes were made to allow the sale of unfortified flour for export or use in a product destined for export.

Over 99% of British households buy bread and [one quarter of all groceries in the four biggest UK supermarkets contain flour](#). Hence, the proposals to amend the legislation will impact a wide range of stakeholders including flour millers, food manufacturers, wholesalers, retailers, importers, food enforcement authorities, and the majority of consumers within the UK. We would like to hear from anyone with an interest.

The Department for Environment, Food and Rural Affairs (DEFRA) alongside the Food Standards Agency in Northern Ireland, Food Standards Agency in Wales (FSA) and Food Standards Scotland (FSS) have agreed to work on this review together under the Food Compositional Standards and Labelling provisional common framework in efforts to align UK policy as far as possible. This consultation is also being held in conjunction with the Department of Health and Social Care (DHSC), Welsh Government, Scottish Government and Department of Health Northern Ireland who have responsibility for matters of public health. The addition of folic acid to flour will be 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.

Consultation Details

Why we are consulting

Consultation on changes to food law in the UK is required by both the Food Safety Act 1990 retained EU food law Regulation (EC) 178/2002 and EU food law Regulation (EC) 178/2002 as applied in Northern Ireland. We are seeking views on policy options presented in this consultation which have been developed following discussions with a range of relevant stakeholders.

The purpose of the consultation is to ensure that the Bread and Flour Regulations are fit for purpose and support UK industry, while protecting consumers.

The objectives of the consultation are to:

1. Understand the preferences and views from interested parties on the policy proposals presented.
2. Assess whether the new proposals are suitable and reflective of the needs of UK industry, consumers and enforcement authorities.
3. Explore any unintended consequences of the new proposals that have not been considered.

The consultation has been split into five areas which the proposals aim to address:

- **Interaction with wider food legislation** – Policy proposals in this section primarily look at ways to update the regulations to ensure consistency with other food standards legislation enabling understanding and compliance.
- **Folic acid** – As folic acid fortification has already been subject to a public consultation; this part of the consultation focuses on the implementation of the UK-wide commitment to introduce the mandatory addition of folic acid to non-wholemeal wheat flour. This outlines the technical aspects related to the policy including the proposed level at which folic acid should be added to flour in line with public health aims to reduce incidence of neural tube defect affected pregnancies and consideration of a suitable transition period necessary for businesses to adjust.
- **Scope of the Regulations** – This part of the consultation clarifies potential differing interpretations over the scope of fortification requirements for wheat flour. The policy proposals set out to ensure a consistent understanding across the bread and flour supply chain and local enforcement.
- **Exemptions from fortification requirements** – This section covers proposals to reduce regulatory burden for businesses where public health outcomes of the policy are not compromised. Proposals consider exempting small-scale mills from requirements to fortify, taking into account practical and technological limitations of this section of the industry. The proposals also look at exempting flour which is to be present as an ingredient in a final food product at less than 10% recognising that these products make a negligible contribution to the dietary intake of these added nutrients.
- **Enforcement** – The final section of the consultation covers proposals to move to a more proportionate enforcement regime, adding improvement notices as a first step in addressing non-compliance.

The consultation offers stakeholders a chance to share their preferences and views on the policy options presented. This consultation is expected to be of interest to millers, food manufacturers, enforcement authorities, consumers and consumer groups as well as health professionals and public bodies. We are also seeking additional information to further our assessment of the impacts of policy options, ensuring proposals brought forward are suitable for meeting the policy objectives and check against potential unintended consequences. Responses to the consultation will be used to help refine proposals and inform policy decisions on how the UK government and devolved administrations proceed with any subsequent legislative changes.

Audience

While some of the matters discussed here are about the technical aspects of producing flour, anyone may reply. We would like to hear from any individual or organisation with an interest in this issue, including industry, enforcement authorities, consumer organisations, health practitioners, academics, charities, and consumers.

Geographical Scope

This consultation is being carried out as part of a UK-wide review of The Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 under the UK's Food Composition Standards and Labelling provisional common Framework. This approach recognises that the bread and flour supply chains throughout the UK are interlinked and much of the relevant data on the milling industry is collected on a UK-wide basis. The addition of folic acid to flour will be considered by officials under the Nutrition Labelling and Composition Standards (NLCS) framework. This will help facilitate a common approach to any policy changes resulting from this consultation across the UK, while recognising food and health matters are devolved issues and that each devolved administrations will need to form their own judgements on any potential change to policy, including enforcement.

Responding to this consultation

The consultation will be open for 12 weeks from 1st September to 23rd November 2022. Responses should be received by 23:59 on 23rd November. Our preferred way of receiving responses is through the Citizen Space platform.

If you are unable to use Citizen Space, you can download the consultation documents and return your response via email to [breadandflour2022@defra.gov.uk]

Campaign responses

We recognise that respondents may choose to use some standard text to inform their response. Campaigns are when organisations (or individuals) coordinate responses across their membership or support base, often by suggesting a set of wording for respondents to use. Campaign responses are usually very similar or identical to each other. For this consultation, campaign responses may be analysed separately to other responses to ensure the breadth of views received can be summarised effectively and efficiently. All campaign responses will be taken into account in the final analysis of public views and campaigns help provide an indication of the strength of feeling on an issue. The preferred route for all respondents to provide their views (including where a response is based on a campaign) is via the Citizen Space platform.

Confidentiality and data protection information

1. A summary of responses to this consultation will be published on the UK Government website at: www.gov.uk/defra. An annex to the consultation summary will list all organisations that responded but will not include personal names, addresses or other contact details.

2. Defra may publish the content of your response to this consultation to make it available to the public without your personal name and private contact details (for example, home address, email address, etc).
3. If you click on 'Yes' in response to the question asking if you would like anything in your response to be kept confidential, you are asked to state clearly what information you would like to be kept as confidential and explain your reasons for confidentiality. The reason for this is that information in responses to this call for evidence may be subject to release to the public or other parties in accordance with freedom of information law (these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA)). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances. In view of this, your explanation of your reasons for requesting confidentiality for all or part of your response would help us balance these obligations for disclosure against any obligation of confidentiality. If we receive a request for the information that you have provided in your response to this call for evidence, we will take full account of your reasons for requesting confidentiality of your response, but we cannot guarantee that confidentiality can be maintained in all circumstances.
4. If you click on 'No' in response to the question asking if you would like anything in your response to be kept confidential, we will be able to release the content of your response to the public, but we won't make your personal name and private contact details publicly available.
5. This is a joint UK-wide consultation any responses to this consultation will be shared with the FSA in England, Wales, Northern Ireland, the FSS, DHSC, Scottish Government, Welsh Government and Department of Health Northern Ireland.
6. This consultation is being conducted in line with the [Cabinet Office "Consultation Principles"](#).
7. Please find our latest privacy notice uploaded as a related document alongside our consultation document.

About you

1. Would you like your response to be confidential? (Select one option only)
 - Yes
 - **No**
 - If you answered yes, please give your reason (Open text)
2. Who are you responding as? (Select one option only)

- Individual – You are responding with your personal views, rather than as an official representative of a business / business association / other organisation
- Public sector body - In an official capacity as a representative of a local government organisation / public service provider / other public sector body in the UK or elsewhere
- Industry - In an official capacity representing the views of a business
- Campaign group/NGO - In an official capacity as the representative of a non-governmental organisation / trade union / other organisation
- Academia - In an official capacity as a representative of an academic institution
- **Royal Medical College**

3. Which of the following best described the role or field you belong to? (If you have multiple roles, please select the one which best represents your interests in this consultation response) (select one option only)

- Flour miller
- Premix supplier
- Retailer
- Food manufacturer
- Enforcement authority
- Health care professional
- Consumer
- **Professional membership organization and standard setting organization.**

3a) if you are responding on behalf of a business, please indicate below the size of the business² you are responding on behalf of?

- Sole proprietorship (a business run by one self-employed person)
- Ordinary partnership (a business run by two or more self-employed people)
- Small and medium-sized enterprises (SMEs) (businesses with 0 to 249 employees)
- Large business (250 or more employees)

4. What is the name of your organisation?

Royal College of Physicians of Edinburgh (RCPE)

² For the purposes of this consultation, [official government business size classifications](#) were used to distinguish categories.

5. Please select where you or your organisation is based (select all that apply):

- England
- Scotland
- Wales
- Northern Ireland

Overview of Relevant Food Regulations and National Differences

As food is a devolved policy area, any legislative changes following consultation will be implemented through separate statutory instruments for England, Scotland, Wales and Northern Ireland.

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

The Bread and Flour Regulations: The Bread and Flour Regulations 1998 and The Bread and Flour Regulations (Northern Ireland) 1998 lay down specific rules on the labelling and compositional standards of bread and flour in Great Britain and Northern Ireland respectively.

Regulation 1925/2006: This lays down rules for the addition of vitamins and minerals and of certain 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 the relevant legislation. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.

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 the relevant legislation. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.

Regulation 231/2012: This lays down specifications for food additives listed in Annex II and III of Regulation 1333/2008. In Great Britain, this Regulation has been retained in domestic law under the European (Withdrawal) Act 2018 (the Withdrawal Act) and

amended by the relevant legislation. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.

Regulation 1169/2011: This lays down rules on the provision of food information to consumers. In Great Britain, this Regulation has been retained in domestic law under the European (Withdrawal) Act 2018 (the Withdrawal Act) and amended by the relevant legislation. In Northern Ireland, the EU Regulation applies under the current terms of the Northern Ireland Protocol.

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

The Bread and Flour Regulations

The Bread and Flour Regulations lay down specific labelling and compositional rules for bread and flour in the United Kingdom. Under these rules non-wholemeal wheat flour is required to include the addition of specific quantities of calcium carbonate, iron, thiamin and niacin. The regulations also lay down chemical specifications for those added nutrients.

There are several specific cases for exemption detailed in the regulations concerning the addition of nutrients for wholemeal flour, self-raising flour, wheat malt flour. Manufacturers and importers cannot import or sell flour for the UK market which does not comply with the Bread and Flour Regulations unless used for communion wafers, matzos, gluten, starch or any concentrated preparation that assists flour fortification. Under the current terms of the Protocol on Ireland/Northern Ireland, mutual recognition continues to apply to flour imported from EU member states into Northern Ireland meaning flour imported from EU member states to Northern Ireland is not subject to the requirements of the Bread and Flour Regulations.

Many of the original rules on additives and treatment agents which were referred to in the Bread and Flour Regulations have been revoked and replaced by other legislation that apply to food in general. However, the use of any bleaching agent in the preparation of bread and flour is still prohibited in the regulations. The Bread and Flour Regulations also define terms such as 'wholemeal' and 'self-raising'. They require that bread advertised as: "wholemeal" must contain 100% wholemeal flour; "wheat germ" must have at least 10% added processed wheat germ.

Legislative measures mandating the addition of vitamins and minerals to flour were introduced during the 1940's and 1950's to address concerns surrounding nutrient

deficiency amongst the public. The requirement to add calcium was introduced in the 1940s as a means of providing more calcium in the diet at a time when dairy products (a major source of calcium) were limited. From 1940 until the end of food rationing in Great Britain in 1954, legislation enforced the milling of flour up to 80% extraction or higher in order to retain the nutritional value of the wheat grain (extraction rate is a measure of the percentage of the grain that is made into flour during the milling process).³ In 1953 controls on the milling of white flour were lifted and bread could again be made from flour of approximately 70% extraction rate, and it was considered that restoration of nutrients removed by milling was required in order to maintain the nutritional value of a staple food.

Calcium is the most abundant mineral in the human body and is important for a range of functions in the body including muscle contraction, nerve functions and for the activity of several enzymes. It is a key component of bones and teeth. Deficiency of calcium is linked to the bone conditions rickets, osteomalacia and osteoporosis.

Iron is a component of haemoglobin (in red blood cells) and is essential for transportation of oxygen throughout the body. Iron is also a component of a number of enzymes involved in a range of the body's metabolic processes. Progressive iron deficiency can lead to iron deficiency anaemia.

Niacin is an important factor in the utilisation of food energy and deficiency is rare in the UK.

Thiamin is necessary for the release of energy from carbohydrate; deficiency is rare in the UK.

In 2013, [DEFRA in conjunction with Department of Health and Social Care consulted](#) on whether to remove the fortification requirements enforced by the Bread and Flour Regulations in order to reduce regulatory burden for businesses. This took into account the [Scientific Advisory Committee on Nutrition's \(SACN\)](#) assessment of the potential implications of removing the requirement to add nutrients to non-wholemeal wheat flour. SACN concluded that the case for maintaining the mandatory addition of calcium to non-wholemeal wheat flour is strongest, followed by iron.⁴ The report found evidence that withdrawing calcium fortification would increase the proportion of consumers in the UK with intakes below the LRNI (lower reference nutrient intake) and the corresponding risk of inadequate calcium intakes in the population particularly for women and low-income

³ Extraction refers to the amount of flour made as a percentage of total wheat ground. For example, wholemeal flour uses the whole wheat meaning the extraction rate should be close to 100%.

⁴ Scientific Advisory Committee on Nutrition: Nutritional Implications of Repealing the UK Bread and Flour Regulations 2012

groups. This implies an increased risk of deficiency which has been associated with poor bone health and subsequent osteoporotic fracture. The report also found that removing the current requirement to add iron to wheat flour (other than wholemeal) would decrease iron intakes in the population and increase the proportion of the population with intakes less than the LRNI. In the case of niacin and thiamine clinical deficiency is rare, however, a single averted case of deficiency could save more than the additional cost of fortification.⁵

The consultation response showed that overall, most health professionals were against removing the rules on the fortification of flour on the basis that it would have a negative impact on public health. On balance industry appeared content with the current requirements and consumer groups who responded felt there was a significant public health benefit in keeping the mandatory fortification of flour with the four nutrients. [The Government published its decision in August 2013 which concluded that the Regulations should be retained intact and in their existing format.](#)

Prior to EU exit, flour imported from other EU and EEA member states was exempt from the regulations, this was to ensure the free movement of goods within the EU's single market. Changes made following EU-exit ended the mutual recognition arrangements for flour imported from EU and EEA member states to GB, meaning wheat flour imported from the EU and EEA to GB will need to comply with Bread and Flour Regulations fortification requirements from October 2022. Under the terms of the Protocol on Ireland/Northern Ireland, mutual recognition continues to apply to flour imported from EU member states into Northern Ireland meaning flour imported from EU member states to Northern Ireland is not subject to the requirements of the Bread and Flour Regulations. At the same time changes were made to allow the sale of unfortified flour for export or use in a product destined for export (pending in Northern Ireland).

Minimum Level of Nutrients Added to Flour

The Bread and Flour Regulations set minimum levels at which the nutrients added to flour must be present for every 100g of flour (Calcium carbonate – 235-390mg, iron - 1.65mg, nicotinic acid or nicotinamide – 1.60mg and thiamine – 0.24mg). These were set at levels which represented restoration to the natural levels present in wheat prior to the milling process, except for calcium where there was a clear public health policy to supplement the diets of the UK population with a minimum level of calcium via flour fortification.

Since the introduction of the Bread and Flour Regulations, general rules on the addition of vitamins and minerals to foods have been introduced and these requirements are laid out

⁵Bread and Flour Regulations 1998: A summary of responses to the consultation and Government Reply 2013

in Regulation 1925/2006. These rules stipulate when foods are fortified, that the nutrients must be present in a “significant amount”. This is defined for each added nutrient in Regulation 1169/2011 as 15% of the NRV (nutrient reference values are established guidelines for the recommended daily energy and nutrient consumption). This is higher than minimum levels laid out in the Bread and Flour Regulations for three of the four added nutrients (calcium 11.75%, iron 12% and niacin 10%) as illustrated in table 1 below.

This has brought into question the interaction between the Bread and Flour Regulations and overlapping legislation. General rules on the addition of vitamins and minerals to foods in Regulation 1925/2006 set the minimum level of nutrients added to food at 15% NRV to ensure there is a nutritional benefit to consumers. Setting minimum levels in the Bread and Flour Regulations that are consistent with general rules would ensure this principle applies equally to flour fortification.

It is our understanding that the majority (over 90%) of industry have already moved to adding the nutrients at higher levels than the minima required in the Bread and Flour Regulations in order to have one production line of flour which can be marketed on both domestic (GB) and export markets (nutrients must be present at least at 15% of the NRV when exporting to EU member states).⁶ All non-wholemeal flour produced in the UK is currently fortified late in the milling process via a premix which has been proven to be the most straightforward approach to fortification. The indicative costings of using a premix which is compliant with the higher levels is compared to the premix compliant with the minimum levels of nutrients as stated in the Bread and Flour Regulations in Table 2 below.

Table 1: Compositional requirements of the Bread and Flour Regulations compared with Nutrient Reference Value.

Nutrient	Current Minimum Levels Amount per 100g Flour in BFR's	NRV per 100g	15% of the respective NRV per 100g	Form added to flour
Calcium*	235-390mg (calcium carbonate) Or equivalent of 94-156mg (calcium)	2000mg (calcium carbonate) 800 mg (calcium)	300mg (calcium carbonate) (120mg calcium)	Calcium Carbonate

⁶This estimate is based on sales figures of the vitamin and mineral premix which is added to flour 2020-21.

	As percentage of NRV (per 100g): 11.75%-19.5%			
Iron	≥1.65mg As percentage of NRV (per 100g): 12%	14 mg	2.1mg	Any or a combination of: - ferric ammonium citrate - green ferric ammonium citrate - ferrous sulphate - dried ferrous sulphate - iron powder
Thiamin*	≥ 0.24mg (thiamine hydrochloride) Or equivalent of 0.21mg (thiamine) As percentage of NRV (per 100g): 19%	1.26mg (thiamine hydrochloride – rounded to 2 dp) 1.1 mg (thiamin)	0.165mg	Thiamine hydrochloride
Niacin	≥ 1.60mg As percentage of NRV (per 100g): 10%	16 mg	2.40mg	Nicotinic acid or nicotinamide

Table 2: Indicative costs of added nutrients to flour (per tonne of flour)⁷

⁷ Industry contact.

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

Calcium Carbonate Specification

The Bread and Flour Regulations specify certain compositional criteria that the added nutrients must meet. The criteria set out for calcium carbonate in the Bread and Flour Regulations differ from the specification laid out for calcium carbonate (E170) in Regulation 231/2012 on food additives.

Previously, the supply of calcium used in UK flour fortification was sourced from a single quarry in England, Steeple Morden. It met the specification (pharmacopeia) in the Bread and Flour Regulations but did not meet the Regulation 231/2012 purity criteria (E170) on two variables (acid insoluble matter and fluoride). Calcium carbonate composition is determined by the natural geological makeup and is therefore unvarying and very difficult to change. The quarry producing the calcium carbonate in England is no longer producing calcium carbonate for human consumption. Our understanding is industry have now all moved to using calcium compliant with Regulation 231/2012 for both the exports and the domestic market.

Table 3: Calcium Carbonate Criteria

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

While it remains possible to be compliant with the calcium carbonate criteria in both the Bread and Flour Regulations and Regulation 231/2012, we recognise that consistency across overlapping food standards regulations would help improve the legislation and regulatory framework.

Policy proposals summary

Minimum Level of Nutrients Added to Flour

Baseline – Do nothing

The Bread and Flour Regulations would retain existing minimum levels for calcium, iron, thiamin and niacin, remaining at odds with overlapping legislation regarding the minimum level at which nutrients should be added to foods. Further action will need to be taken to provide clarification on the interaction of the rules for operability purposes.

Proposed change - Raise the set minimum level of nutrients present in flour

Raising minimum levels of added nutrients so that they are consistent with the requirements covering the addition of vitamins and minerals to food at a minimum 15% of the NRV per 100g of flour is something industry stakeholders have said they would welcome. This option would involve moving the minimum required level of iron present in flour from 1.65mg to 2.1mg, niacin from 1.6mg to 2.4mg and calcium carbonate from 235-390mg to 300-390mg per 100g of flour. The minimum amount of thiamin required to be present in flour would remain the same as this currently sits at above 15% of the nutrient reference value. This option would update the regulations in line with the wider rules for the fortification of foods for nutritional benefit. Making this amendment would reflect changes which have already been made on a voluntary basis by the majority of industry ensuring a level playing field in the market. Greater clarity on regulatory requirements would facilitate compliance and assist enforcement. Millers currently fortifying at lower levels (accounting for an estimated 9% of non-wholemeal wheat flour) would need to change to a premix with higher levels of nutrients.

Unlike the other added nutrients calcium carbonate has a maximum level as well as a minimum level provided for in the regulations. This is largely to protect the authenticity of flour to avoid the potential use of calcium carbonate in excessive amounts as a “filler”. Thus, we are not proposing to change this maximum level in order to protect food standards for consumers. Some industry stakeholders have raised concerns that the new narrower range will be difficult to comply with as there is a wide natural variation of calcium levels found in flour prior to the addition of the premix which may lead to variation in levels. The regulations stipulate levels of calcium carbonate which must be present in flour rather than levels of calcium which must be present. Since the natural levels of calcium would not be found in the form of calcium carbonate this should not impact compliance. There are tests which can measure the level of calcium carbonate rather than levels of calcium and we will provide updated guidance to clarify this for enforcement purposes alongside any regulatory changes brought in following this consultation.

Currently, the regulations state that wholemeal flour shall naturally contain iron, thiamin and niacin in at least the minimum levels (iron - 1.65mg, niacin – 1.60mg and thiamine – 0.24mg) per 100g. This is linked to the composition of wholemeal flour which is made

using the whole grain of wheat and thus, wholemeal flour should retain the nutritional value of the wheat used. Some industry stakeholders have raised concerns around the existing wording, as nutritional characteristics of wheat are subject to natural variability and can be affected by external factors such as climatic conditions. The way the regulations are worded presently prohibits the addition of nutrients to meet the minimum levels required, hence this may be vulnerable to causing non-compliance beyond the control of flour millers. Hence, it may be necessary to refine this requirement at the same time as addressing the levels for non-wholemeal flour.

The National Diet and Nutrition Survey (NDNS) Rolling Programme would be used to monitor the impact of this policy. The NDNS Rolling Programme is a continuous cross-sectional survey of diet and nutritional status of the UK population which has been running since 2008, covering adults and children from 18 months upwards living in private households. It provides detailed, quantitative information on food consumption, nutrient intakes, nutritional status, and related characteristics in the general population by age and sex. Dietary intake of iron, calcium, niacin, and food supplement intake is recorded and reported through the dietary data collection method.

Calcium Carbonate Specification

Baseline – Do nothing

Millers would still be able to use calcium carbonate which meets the criteria laid out in the Bread and Flour Regulations and Regulation 231/2012 to ensure they are compliant with the law. However, the Bread and Flour Regulations would retain a calcium specification which is at odds with overlapping regulations. This complicates industry compliance and makes consistent enforcement of food standards law more difficult.

Proposed change - Remove calcium carbonate criteria from the regulations

This option would involve removing the criteria on the composition of calcium carbonate added to flour from the Bread and Flour Regulations. Calcium carbonate added to flour would be required to meet the specification as laid out in Regulation 231/2012 which lays down the rules on the wider use of additives in foods. The amendment would correct misalignment between the Bread and Flour Regulations and overlapping legislation providing clarity for business and update the Bread and Flour Regulations with criteria consistent with the wider use of calcium carbonate in other foods. Industry have made us aware that calcium carbonate being added to flour is already meeting this criterion, and therefore we wouldn't expect any additional significant costs for industry resulting from this change. This option would protect against future legislative changes being needed if the criteria in Regulation 231/2012 was updated.

Questions

An assessment of the cost and benefits of each of the possible options has been provided in the accompanying consultation stage Impact Assessment (IA). A short summary of cost and benefit analysis of the proposed changes versus the do-nothing options for the minimum level of nutrients added to flour and the calcium carbonate specification is summarised in the table below.

Policy Proposal	Consumers	Industry	Government/Local Enforcement
<p>Raise the minimum level of added nutrients to flour in line with wider rules on fortified foods and remove the calcium carbonate criteria from the Bread and Flour Regulations</p>	<p>Cost:</p> <p>No significant price change for consumers anticipated from this intervention.</p> <p>Benefit:</p> <p>Consistency with wider food additive rules and vitamins and minerals rules.</p>	<p>Cost:</p> <p>Familiarisation costs for millers as a result of the changing regulations. Combined estimated cost across sector: £4,600</p> <p>Minor increased in fortification costs for millers who were not already fortifying flour to the levels required in Regulation 1925/2006</p> <p>May make it harder for UK calcium producers to provide calcium carbonate for fortification in the future.</p> <p>Benefit:</p> <p>Greater regulatory clarity for industry stakeholders.</p>	<p>Cost:</p> <p>Familiarisation costs for enforcement and compliance authorities because of the changing regulations. Combined estimated costs for all 408 enforcement authorities: £19,000</p> <p>Benefit:</p> <p>Great regulatory clarity provided to law enforcement authorities.</p>

6. Does the summary above accurately represent the main costs for industry, consumers and government/enforcement authorities (please see section 4.5 of the accompanying Impact Assessment for a more detailed breakdown of the cost and benefit analysis and calculations p.34-37)?

	Agree	Neither agree nor disagree	Disagree	Don't know/no comment
The cost and benefits of the proposed policy changes to <u>industry</u> are accurately represented				X
The cost and benefits of the proposed policy changes to <u>consumers</u> are accurately represented				X
The cost and benefits of the proposed policy changes to <u>government/enforcement</u> authorities are accurately represented	X			

6a. Please detail which costs or benefits you feel have not been accurately represented and provide any evidence you have to support your views.

7. Please indicate your views on the following options (select one option per proposal):

	Yes, I support this	No, I don't support this	I don't know/no opinion
Do nothing		X	
Raise the minimum level of added nutrients to flour in line with wider rules on fortified foods	X		
Remove the calcium carbonate criteria from the Bread and Flour Regulations	X		

7a. If you do not support any element of the proposal (to raise the minimum level of added nutrients to flour in line with wider rules on fortified foods and remove the calcium carbonate criteria from the Bread and Flour Regulations), please explain why and provide any evidence you have in support of your views.

8. (For millers and premix suppliers to respond) We understand that precise distribution of added nutrients can be difficult. If the minimum level for calcium carbonate present in flour is increased, this would narrow the range in which it must be present in flour to 300mg-390mg per 100g. Provided that millers add calcium carbonate at 345mg per 100g of flour, this would allow for a variation of 15% higher or lower to be in compliant with the rules.

To what extent do you agree or disagree that calcium carbonate levels are consistently within the proposed range per 100g of flour is realistic? (Select one answer)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

9. Should the requirement for wholemeal flour to contain 1.65mg of iron, 1.60mg of niacin and 0.24mg of thiamine (per 100g) be revised?

The RCPE would support the appropriate rewording of regulations so that they do not prohibit the addition of nutrients to meet the minimum levels required.

10. If you would like to add any further comments on your responses to questions 1-9 above or any other comments relevant to the proposals discussed, please do so here:
(Open text)

Folic Acid

Background and previous consultation

[Following a UK-wide public consultation](#) in 2019, the UK Government and devolved governments announced in September 2021 that they would [proceed with the mandatory fortification of non-wholemeal wheat flour and legislate on this basis](#). The consultation covered public health protection benefits as well as consideration of any negative consequences on population groups and the impact for businesses and trade. The proposal aimed to ensure the policy is proportionate, effective and ultimately enforceable.

Consumption of folic acid in the pre-conception period and up to the 12th week of pregnancy has been shown to reduce the population risk of Neural Tube Defect (NTD) affected pregnancies.⁸ NTDs arise in the first few weeks of pregnancy, often before a woman knows that she is pregnant. NTDs can have a significant impact on life expectancy and quality of life and there are approximately 1000 NTD-affected pregnancies each year in the UK.

Therefore, all women who could become pregnant are advised to take a daily 400-microgram folic acid supplement before conception and up to the 12th week of pregnancy. However, as pregnancies may be unplanned or women in the first few weeks of pregnancy may not know they are pregnant, many women do not or cannot follow this recommendation. Further details on NTD-affected pregnancies are provided in the [folic acid fortification policy proposal consultation response](#).

In [2017](#), the Scientific Advisory Committee on Nutrition (SACN)⁹ confirmed that its previous recommendations on folic acid ([2006](#) and [2009](#)) remained unchanged and recommended mandatory folic acid fortification to improve the folate status of women most at-risk of NTD-affected pregnancies. SACN recommended ensuring mandatory fortification does not lead to an increase in the proportion of the population with folic acid intakes above the Guidance Level.

Since discussion on whether to proceed with the fortification of non-wholemeal flour has already been subject to public consultation, this consultation specifically focuses on the technical aspects of implementing this policy.

Policy proposal summary

Level

The proposal is to introduce into the Bread and Flour Regulations the legal requirement to add 250 micrograms folic acid per 100g of non-wholemeal wheat flour.

This proposed level was determined following modelling by Food Standards Scotland (FSS), [Stochastic modelling to estimate the potential impact of fortification of flour with folic acid in the UK | Food Standards Scotland](#) (2017). The modelling exercise explored the potential

⁸NTDs are major birth defects of the brain, spine or spinal cord of the foetus, the most common are spina bifida and anencephaly.

⁹SACN advises on nutrition and related health matters. It advises the Office for Health Improvement and Disparities (OHID) and other UK government organisations.

impact of fortification of non-wholemeal wheat flour with folic acid and estimated the effectiveness and safety of different options on levels of folic acid for the purpose of dietary intakes of folate (ensuring no decrease in current average folate intakes and no increase in numbers of people consuming too much folic acid) and reducing the number of NTD affected pregnancies in the UK. It should be noted that the calculations used in the modelling applied an average 25% production loss to folic acid added to flour. This means that the same modelled effect is found when folic acid is **added to flour at** 250 micrograms or **present at** 187.5 micrograms in the final product.

Choosing a set level at which to fortify non-wholemeal wheat flour (the addition of 250 micrograms per 100g non-wholemeal flour), rather than a range of values, supports a standard approach to fortification across industry and allows enforcement authorities to assess compliance with legislation. Choosing to fortify non-wholemeal wheat flour only, which is already subject to mandatory fortification allows an element of consumer choice as wholemeal flour and other milled grains and flours including those that are 'gluten free' are not currently subject to other fortification as per the current Bread and Flour Regulations.

Impact of level on NTDs

The FSS modelling indicates that mandatory fortification of non-wholemeal flour with folic acid would be expected to reduce prevalence of low folate intakes, resulting in a reduction in the number of NTD-affected pregnancies. According to the modelling, 250 micrograms of folic acid added to every 100g of non-wholemeal flour would see a reduction in the rate of NTDs by 15-22% a year (based on an estimated production loss at an average of 25%)¹⁰ (FSS modelling provides further details on the calculations used to model this reduction).¹¹

Impact on Guidance Level

Tolerable Upper Limits (TUL) for vitamins and minerals are set on the basis of safety. In the absence of evidence for a TUL for folic acid, a Guidance Level of 1 milligram (mg) per day supplemental folic acid was set by the [Expert Group on Vitamins and Minerals \(EVM\) in 2003](#).

¹⁰ An estimated production loss of 25% results in the folic acid content of non-wholemeal wheat flour at 187 micrograms per 100g

¹¹ 15-22% NTD reduction a year is dependent on the prediction equations used as shown in the FSS modelling. At 300 micrograms, the risk is reduced by 17-25%, at 350 micrograms, risk is reduced by 19-28% and at 450 micrograms, risk is reduced by between 23 and 32%, however the modelling shows this would increase the number of people estimated to exceed the GL, 0.8%, 1.1% and 1.8% respectively.

In February 2019, the [Chemicals in Food, Consumer Products and the Environment \(COT\)](#)¹² reaffirmed the [Guidance Level for supplemental folic acid of 1 mg/day in 2019](#). This assessment followed a reconsideration of the evidence on the safety of folic acid (taking into account further evidence produced since the 2003 EVM report), on the basis that folic acid intakes above this level may mask presence of pernicious anaemia caused by vitamin B₁₂ deficiency. Pernicious anaemia may lead to progressive damage to the nervous system.

Impact on Cost

It is considered that the proposed change will levy a cost of approximately £6.5m for industry in sourcing and adding folic acid to flour, £4,600 for industry and £19,000 for enforcement respectively in familiarisation with the legislation, plus one-off re-labelling costs for products made from flour as the legislation which set the requirements on food labelling (Regulation 1169/2011) requires the fortificants to be shown in the ingredients listing. The proposed implementation period for the addition of folic acid is 24 months, therefore it is anticipated costs which are involved with re-labelling of flour to include folic acid as a fortificant should be mitigated as part of the natural labelling cycle (see question 35 on transition period). The cost to businesses of re-labelling of flour is estimated to be limited and will primarily relate to adding folic acid to the list of fortificants already added to non-wholemeal wheat flour. However, aligning with the natural labelling cycle is dependent on when the millers choose to reformulate and how much advance notice they provide their customers. If there is poor communication between millers and customers there may be re-labelling costs to businesses which do not align with the natural labelling cycle. The 24-month implementation period is proposed to mitigate this risk. Industry will need to relabel all products which use non-wholemeal wheat flour to reflect the composition of the new flour immediately after this is introduced in the product. Further details on costs associated with re-labelling are provided in the impact assessment which accompanies this consultation.

By fortifying only non-wholemeal wheat flour, which is already mandatorily fortified with calcium, iron, thiamin and niacin, it is unlikely that there will be a significant cost in identifying which flour must be fortified. Similarly, it is unlikely that new machinery would be required by industry as existing machinery used for the addition of already mandated fortificants can also be used for the addition of folic acid. Introduction of the new requirement would result in an additional quality assurance cost to industry (i.e., product sampling tests to ensure compliance with the legislation), including engaging and connecting with enforcement by the Local Authorities / District Councils.

¹²The COT is a committee of independent experts that provides advice to the Food Standards Agency, the Department of Health and Social Care and other Government Departments and Agencies on matters concerning the toxicity of chemicals in food, consumer products and the environment.

Amending the legislation imposes costs on both industry and enforcement colleagues associated with familiarisation of the legislation, that is, the total wage costs of relevant employees within the company or enforcement authority taking the necessary time to understand the changes and how they will affect business.

There may be potential inconvenience to consumers who cannot or do not wish to consume folic acid. Existing labelling legislation provides a requirement for accurate and honest labelling with regards to the sale of food. This ensures that consumers will be aware of the inclusion of folic acid when they purchase non-wholemeal wheat flour and pre-packed products containing non-wholemeal wheat flour. This proposal excludes wholemeal flour and other milled grains and flours including those that are 'gluten free' from mandatory fortification, providing an alternative "non-fortified" option for consumers.

As shown in the [impact assessment](#) which accompanied the folic acid consultation, the cost of fortification on a per loaf (or other food item) basis is expected to be very low, such that no significant change is expected in retail prices for flour and flour-based products.

Risk management

Since folic acid is already added to some foods via voluntary fortification and consumed through dietary supplements in the UK, mandatory fortification of non-wholemeal flour may push some high consumers over the Guidance Level. As shown in the [impact assessment](#) which accompanied the consultation, approximately 0.4% of the population already exceed the Guidance Level for folic acid. Analysis of NDNS data indicates that individuals who are likely to exceed the Guidance Level for folic acid are likely to be taking food supplements. The relatively low levels of folic acid currently in most fortified foods, or which have been modelled in flour as part of this policy proposal shows that increasing folate intakes may push more of the population (from 0.4% to 0.6%) above the Guidance Level (1 milligram per day).

After consideration of the burden on businesses, the projected impact on folate intakes and the timeline for the delivery of the policy a pragmatic decision has been agreed that mandatory fortification with folic acid will not be accompanied by a restriction on voluntary fortification of foods. This decision will be kept under review as part of the policy monitoring and evaluation.

The four UK Chief Medical Officers support both the recommendation not to restrict voluntary fortification and for non-wholemeal flour to be fortified with the addition of 250 micrograms of folic acid per 100g.

As shown by the FSS modelling the proposed level for the addition of 250 micrograms of folic acid per 100g non-wholemeal wheat flour (which accounts for an estimated production loss at an average of 25%) would result in a reduction in NTD risk of 15-22%, while producing a minimal increase in the number of people exceeding the Guidance Level for

folic acid increasing from 0.4% to 0.6%. Without limits on voluntary fortification, mandatory fortification of non-wholemeal wheat flour at higher levels than the proposed 250 micrograms folic acid per 100 grams of flour would further increase the number of people at risk of exceeding the Guidance level. Further detail is provided in the [impact assessment](#) and [FSS modelling](#) which accompanied the consultation on the folic acid policy proposal.

Monitoring

At present, it is the intention for any proposed monitoring strategy to include measures of both positive and potential negative impacts of the policy on the UK population health. This will require pre- and post-implementation collection and is likely to include analysis of data on:

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

Details of how this policy will be monitored are included in the impact assessment which accompanies this consultation.

Questions

An assessment of the cost and benefits of each of the possible options has been provided in the accompanying consultation stage Impact Assessment. Possible effects on industry, local authorities and wider society have been outlined. We would welcome further input from stakeholders on the costs and benefits associated with the options discussed in this consultation. This section of the consultation is specifically focused on the implementation of the addition of folic acid to non-wholemeal flour, hence this is reflected in the questions below.

Policy Proposal	Consumers	Industry	Government/Local Enforcement
Requirement to add 250mcg of folic acid per 100grams of wheat flour (excluding exemptions)	Costs: No significant changes to retail prices for flour or flour-based products.	Costs: Added cost of fortification: £6.5m over the next 10 years.	Costs: Familiarisation costs: £19,000.

		<p>Familiarisation costs: £4,600.</p> <p>Re-labelling cost of up to a £27.3m we would expect most of this cost to be assumed within the natural re-labelling cycle for businesses.</p>	
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11. Does the summary above accurately represent the main costs of implementing folic acid fortification at a level of 250mcg per 100g of flour for 1) industry, 2) consumers and 3) government/enforcement authorities (please see section 4.41 of the accompanying Impact Assessment for a more detailed breakdown of the costs of implementation p.30-33)?

	Agree	Neither agree nor disagree	Disagree	Don't know/no comment
The cost to <u>industry</u> of the proposed implementation of flour fortification with folic acid are accurately represented				X
The cost to <u>consumers</u> of the proposed implementation of flour fortification with folic acid are accurately represented				X
The cost to <u>government/enforcement authorities</u> of the proposed implementation of flour fortification with folic acid are accurately represented	X			

11a. Please detail which costs you feel have not been accurately represented and provide any evidence you have to support your views.

12. There are two options for how the Bread and Flour regulations could be drafted. We propose that they should specify how much folic acid must be added to flour, not how much folic acid must be present in flour (except where there are explicit exemptions for example for wholemeal). Do you agree or disagree with this proposal?

- I agree, the regulation should require that folic acid must be added at 250mcg/100g wheat flour
- I disagree, the regulations should require that “folic acid must be present at 187.5mcg/100g wheat flour” (accounting for the anticipated 25% production loss in the fortification process).
- Don't know or no comment

13. Do you have any further comments or supporting evidence on the proposed implementation of mandatory fortification of flour with folic acid?

The RCPE is strongly in favour of mandatory fortification from a public health perspective. The academic evidence in favour, as referred to in this document, is substantial and robust. The new fortification has the potential to raise levels of folic acid amongst women whose pregnancies are unplanned sufficiently to have a substantial impact on neural tube defects. The clinical consequences of NTD can be extremely serious and may lead to decisions to terminate pregnancy, requirement for neonatal surgery, physical disability, bowel and bladder dysfunction, recurrent catheter related UTIs, renal damage and the need for life long high tariff healthcare.

In terms of the risk of excess intake of folic acid, our Fellows suggested that many of those taking folate supplements to reduce their risk of NTD in pregnancy may choose not to do so once folic acid is added to flour and assuming medical recommendations are updated.

Scope of Mandatory Fortification

The Bread and Flour Regulations stipulate that “flour derived from wheat” is subject to the fortification requirements laid out in the legislation aside from certain specified exemptions around wholemeal, wheat malt flour and self-raising flour. There are differing interpretations of what this means for the type/species of wheat which are considered in scope of the regulations. Industry stakeholders have taken the view that the requirements apply to flour which is derived from the wheat species *Triticum aestivum* usually referred to as “common wheat” or “bread wheat”. However, there are other grains of wheat that are species of the *Triticum* genus, including *Triticum Spelta* (used for spelt flour) as well as other ancient grains which could be considered to be included.

When the fortification requirements for non-wholemeal flour were introduced, flour from alternative ancient grains of wheat such as *Triticum Spelta* weren't commonly used for food

production in the UK. The intention of introducing mandatory fortification measures was to prevent nutrient deficiencies by increasing the populations dietary intake of the required nutrients through targeting a food which was part of the staple diet, “common wheat” flour. Therefore, wheat flour produced with other grains which are less commonly available and consumed and not part of the populations staple diet could be considered to fall outside the intent of the regulations. Hence, our understanding is that flour derived from other grains, such as spelt flour, is currently not being fortified by industry on this basis.

However, given that the regulations currently don’t specify further than “flour derived from wheat” some enforcement officials have taken the view that spelt flour which is derived from a wheat grain is caught under the regulations.

The naturally occurring levels of nutrients in flour made from other species of wheat differ to those of “common wheat” and therefore the amount of nutrients which would need to be added to restore these nutrient levels to the amount lost during the milling process would be different. The fact only one set of values are provided in the regulations supports the argument that fortification of flour was primarily introduced to restore the nutritional value of “common wheat” specifically.

Currently, the levels of consumption of wheat flour made with grains other than “common wheat” are comparably very low. In the UK approximately, 5 million tonnes of wheat is milled each year for human consumption.¹³ Alternative grains to “common wheat” account for around 1.8% of this.¹⁴ Hence, it can be argued that requiring the fortification of these flours would put unnecessary burden on business while the impact on public health would not be significant.

Making clear that the fortification requirements apply only to “common wheat” would also ensure consumers are provided with alternative options to fortified flour beyond non-wheat-based flours. This may be considered particularly appropriate given that some population groups have certain specific dietary requirements which necessitate lower intakes of some nutrients.

In formulating policy options, we have looked to consider these points recognising it would be beneficial to provide clarity on this issue to facilitate compliance and enforcement approaches.

Policy proposal summary

Baseline – Do nothing:

Taking no action would likely see the continuation of current industry practice whereby only flour derived from “common wheat” is fortified. We may miss the chance to bring greater clarity to the regulations.

¹³ Facts and Figures UK Flour Millers.

¹⁴ Industry contact.

Proposed Change - Add clarification on the scope of the regulations limiting fortification requirements to flour derived from “common wheat”

This option would see clarification on the scope of compositional requirements of flour regarding the level of nutrients (currently: calcium, iron, thiamin and niacin) making it clear within the regulations that this applies to “flour derived from *Triticum aestivum* (common wheat)” rather than flour derived from alternative grains. This would provide greater clarity and ensure a consistent understanding of the regulations across industry and enforcement authorities. This option would continue to allow flour produced from other grains of wheat to be sold without being fortified avoiding any additional burden on industry and reflects the original intention of the policy to improve dietary intake of these nutrients by targeting a food that is part of the staple diet. It is clear from the consumption figures that flour made from wheat other than *Triticum aestivum* (common wheat) does not fall into this category.

This option allows for greater consumer choice, providing unfortified alternative options alongside non-wheat-based flour. This should be taken into consideration for those population groups or individuals with particular dietary requirements where avoiding calcium and iron is sometimes advised. It should be noted that where consumers could previously choose unfortified flour imported from EU member states this will no longer be available in GB from October 2022 (while remaining available in Northern Ireland due to the mutual recognition arrangements in accordance with the Northern Ireland Protocol).

There is a small risk that limiting the scope of the fortification requirements in this way might hinder the future public health benefit of the policy for example if the use of alternative grains in the production of flour rises and the use of “common wheat” falls. However, given the current disparity in consumption figures of flour derived from “common wheat” compared to other grains this seems unlikely to have a significant impact.

Questions

Policy Option	Consumers	Industry	Government/Local Enforcement
Add clarification on the scope of the regulations limiting	Cost: No significant costs.	Cost:	Cost:

fortification requirements to flour derived from “common wheat.	Benefit: Greater choice of flour for consumers with dietary requirements.	Familiarisation costs for millers as a result of the changing regulations. Combined estimated cost across sector: £4,600. Benefit: Clarity on fortification requirements for different types of flour.	Familiarisation costs for enforcement and compliance authorities because of the changing regulations. Combined estimated costs for all 408 enforcement authorities: £19,000. Benefit: Clarity on fortification requirements for different types of flour.
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An assessment of the cost and benefits of each of the possible options has been provided in the accompanying consultation stage Impact Assessment. Possible effects on industry, consumers and local authorities have been identified. A short summary of cost and benefit analysis of the preferred options against the do-nothing options is summarised in the table below.

14. Does the summary above accurately represent the main costs for industry, consumers and government/enforcement authorities (please see section 4.6 of the accompanying Impact Assessment for a more detailed breakdown of the cost/benefit analysis and assumptions p.36-39)?

	Agree	Neither agree nor disagree	Disagree	Don't know/no comment
The cost and benefits of the proposed policy changes to industry are accurately represented				X
The cost and benefits of the proposed policy changes to consumers are accurately represented				X

The cost and benefits of the proposed policy changes to government/enforcement authorities are accurately represented	X			
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14a. Please detail any costs or benefits you feel have not been accurately represented and provide any evidence you have to support your views.

15. Please indicate your views on the following options (please select one option per row):

	Yes, I support this	No, I don't support this	I don't know/ no opinion
Do nothing		X	
Add clarification on the scope of the regulations limiting fortification requirements to flour derived from "common wheat" (proposed option)	X		

15a. If you do not support any element of the proposal (to add clarification on the scope of the regulations limiting fortification requirements to flour derived from "common wheat"), please explain why and provide any evidence you have in support of your views.

16. (For millers) Are you aware of any millers adding nutrients to flour made from alternative grains of wheat to *Triticum aestivum* "common wheat"? (Select one option only)

- Yes
- No

17. Do you agree or disagree that limiting the fortification requirements to flour made from *Triticum aestivum* "common wheat" provides greater choice for consumers? (Select one option only)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

18. How likely is it that there will be decreased use of *Triticum aestivum* “common wheat” in the production of flour? (Select one option only)

- Highly likely
- Likely
- Neither likely nor unlikely
- Unlikely
- Highly unlikely
- Don't know

19. If you would like to add any further comments or supporting evidence to your responses to questions 14-18 above or any other comments relevant to the proposal to explicitly limit flour fortification requirements to flour derived from “common wheat”, please do so here:

While the RCPE strongly supports the proposed regulation in relation to mandatory fortification of flour derived from common wheat, a number of our Fellows expressed concerns at the exclusion of gluten free and non-wheat flour and the fact that this may lead to discrimination against, for example, those with coeliac disease, gluten intolerance or wheat allergy. RCPE is concerned that without the flexibility to cater for other populations such as those with gluten intolerance, which has a prevalence of up to 6% in the UK and is more common in women, the guidelines are not in line with equity diversity and inclusivity.

The RCPE considers that government should keep this issue under consideration going forward and should monitor matters with a view to revisiting if the use of alternative grains in the production of flour rises.

Exemptions

Small Scale Mills

In the UK flour is sometimes milled in relatively small volumes compared with standard

industrial scale milling which makes up the vast majority of the overall UK flour production. This part of the industry is made up mainly by mills using traditional milling methods, producing flour using horizontal millstones in historic mill buildings powered by wind and water energy. The methods adopted by these mills make it difficult to ensure accurate distribution of vitamins and minerals added to flour. Installing the machinery needed to ensure consistent dispersion of nutrients is not feasible for many of these small mills due to space constraints within which the often-listed buildings the mills are housed. Equally, many smaller mills are restricted by funds available to finance installation of such machinery. Thus, compliance with the regulations places a disproportionate burden on these mills compared against standard industrial scale mills. The policy options below consider ways government

intervention can address these concerns without compromising the wider public health outcomes of the Bread and Flour Regulations.

Products with Minimal Flour Content

Some industry stakeholders have raised concerns about some of the requirements laid out in the Bread and Flour Regulations. This has been largely attributed to the changes to labelling rules in 2014 (under Regulation 1169/2011) which required that the vitamins and minerals which are added to flour be declared in the ingredients list of the label. It has been suggested that this has led to a competitive disadvantage when exporting products to certain EU member states who do not currently legislate for mandatory fortification of flour. EU member states thereby can opt for an alternative unfortified flour product which is readily available from GB competitors from other countries.

Steps have been taken to address this already with legislative changes allowing unfortified flour to be sold (or imported) if destined for export or for use in a product destined for export. However, manufacturers have argued the costs which come from having two separate production lines for the export and domestic markets often outweigh the benefit of using unfortified flour in products containing a minimal amount of flour for export.

This issue has been of particular concern for sectors of industry using flour in small quantities as an ingredient in their products. This issue could be mitigated by allowing the production and sale (or import) of unfortified flour destined for use as an ingredient which is present at a low level in a product without compromising public health objectives. We have looked at this option in the past and sought views on this possibility in a public consultation in 2013 (this considered the proposed labelling changes Food Information Regulations would bring in to force) but it was generally not supported because it was felt too challenging logistically. Millers argued they didn't know how the flour would be used and could therefore unknowingly find themselves committing an offence. Following the labelling changes coming into force this issue was raised again. We looked at alternative ways to mitigate including using CN (Combined Nomenclature) codes, but the list of products grew and there was a lack of consensus over which products should be exempt.

As we are reviewing the Bread and Flour Regulations, we are now revisiting the option of introducing an exemption for flour for use in products where flour is present as an ingredient at a minimal amount of the overall product composition. Prior to the UK's exit from the EU flour imported from EU member states was not subject to the requirements laid out in the Bread and Flour Regulations as a result of the mutual recognition arrangements to ensure free movement of goods within the EU single market. This will no longer be the case following EU exit and with changes coming into force from October 2022 which means that flour imported from EU member states to GB will be subject to

requirements laid out in the Bread and Flour Regulations.¹⁵ Thus, in GB, manufacturers of products containing minimal amounts of flour no longer have access to unfortified flour coming from imports to use in these products for the domestic market. Some industry stakeholders who were previously against having an exemption for flour used in these products have recognised that this change gives greater weight to the argument for an exemption for flour used in these products. While unfortified flour imported from EU member states will still be available in Northern Ireland it remains important to keep a level playing field across all of the UK. We would want to avoid a scenario whereby millers based in Northern Ireland are unable to produce unfortified flour for exempt products while millers based in GB are. Hence, despite the continued availability of unfortified flour imported from the EU in Northern Ireland this exemption is being considered on a UK-wide basis.

Industry stakeholders have highlighted that having these nutrients listed in the ingredients list of products containing minimal amounts of flour in the final product could be considered misleading, given the trace amounts of these nutrients that would be found in the product.

In light of these points, we have deemed it sensible to revisit the option of introducing an exemption for products with low flour content where the health benefits to consumers are minimal and the wider public health objectives of the regulations aren't compromised.

Policy proposals summary

Small scale mills

Baseline – Do nothing:

No legislative change.

Small-scale mills would continue to be required to fortify non-wholemeal wheat flour. There is a risk that this would lead to closures of some mills due to the higher relative burden of fortification for smaller mills compared to large industrial scale mills. If the mills were able to continue production, there may be technical barriers to consistent compliance due to the difficulties in distributing nutrients as outlined above. Consequently, there is a greater chance consumers would be misled as to nutrients present in the flour.

¹⁵ Under the terms of the Protocol on Ireland/Northern Ireland, Mutual Recognition continues to apply for products from EU member states sold in Northern Ireland.

Proposed Change - Exempt small scale-mills producing less than 500 metric tonnes of flour per annum from fortification requirements:

This regulatory change would allow mills producing less than 500 metric tonnes of non-wholemeal wheat flour per annum to opt not to add the required nutrients to flour, taking into account the disproportionate burden compliance with the fortification requirements places on these small-scale mills. We have reviewed available data on flour mill production output in arriving at the proposed 500 metric tonnes threshold, it's estimated that mills falling under this category contribute to less than 0.05% of UK flour production. Thus, we would expect the impact on the policy's public health objectives to be negligible. Following conversations with stakeholders we have assessed this threshold to be sufficient in applying to small-scale mills where the fortification requirements place a disproportionate burden on their business.

There is a risk that applying this exemption may result in a small number of consumers missing out on the nutritional benefits of fortified flour. However, further choice would be provided for consumers who have particular dietary requirements.

Businesses selling flour under this exemption would need to ensure that labels were updated removing the mandatory added nutrients from the label of the flour to ensure consumers aren't being misled on the composition of the flour. For this option to work millers falling under the exemption would need to keep accurate monitoring of flour output which could be checked by enforcement officials to demonstrate they are in compliance with the regulations.

Products with Minimal Flour Content

Baseline – Do nothing:

The introduction of folic acid to the mandatorily added nutrients to flour may put manufacturers of products containing minimal amounts of flour at a further disadvantage when exporting to EU member states compared to importers from other countries.

However, businesses already have an option to use unfortified flour in products for export, albeit with extra costs attached to having separate lines of production for domestic and export production.

Proposed change - Exempt flour to be used in a product when it is present as an ingredient at <10%

This proposal would allow unfortified flour to be sold for use as an ingredient in a product (where it makes up less than 10% of the final product) enabling businesses to use one

production line for both domestic and international markets and providing a level playing field for UK businesses in international markets. This suggested level has been proposed as products under this threshold are not deemed to be the key vehicles which contribute to the dietary intakes of these added nutrients. It is therefore expected that exempting these products would have negligible impact on the effectiveness of the policy as a public health measure. This assumption is consistent with previous modelling exercises carried out by the Scientific Advisory Committee on Nutrition (SACN) which excluded contribution of flour intakes of products estimated to contain less than 10% flour.¹⁶ [FSS modelling on the impacts of folic acid fortification](#) exempted products containing less than 4% non-wholemeal wheat flour, this implies that the modelled impact of folic acid fortification could be achieved if products containing less than 4% non-wholemeal wheat flour are exempt. Analysis of data from 2016-19 of the UK-wide National Diet and Nutrition Survey suggests that the contribution of products which contain 4-9% non-wholemeal wheat flour (bringing total exemption to less than 10%), to overall intakes of non-wholemeal wheat flour is less than 5g/day. Therefore, intake of folic acid from products containing 4-9% non-wholemeal wheat flour is likely to be small.

This proposed exemption alongside the proposal to exempt small-scale mills would likely increase the volume of unfortified flour produced in the UK. This creates a need for millers to clearly specify the terms of use to manufacturers of flour-based products to ensure unfortified flour sold under this exemption (for use in products containing under 10% flour) or the exemption for flour products destined for exports is only used applicable products. Currently the Bread and Flour Regulations place the direct obligation regarding the fortification of flour on manufactures of flour and importers. Specific obligations may need to be extended to manufacturers of products containing flour to allow for enforcement actions to be taken against the responsible party if flour purchased under one of these exemptions was used in a non-applicable product (see question 34).

Questions

An assessment of the cost and benefits of each of the possible options has been provided in the accompanying consultation stage Impact Assessment. Possible effects on industry, consumers and local authorities have been identified. A short summary of cost and benefit analysis of the proposed changes against the do-nothing options is summarised in the table below.

¹⁶ Scientific Advisory Committee on Nutrition: Nutritional Implications of Repealing the UK Bread and Flour Regulations 2012

Policy Proposals	Consumers	Industry	Government/Local Enforcement
<p>Exempt small scale-mills producing less than 500 metric tonnes of flour per annum from fortification requirements.</p> <p>Exempt flour to be used in a product as a minimal ingredient <10%</p>	<p>Cost:</p> <p>Marginal decrease in nutrient intake for some consumers.</p> <p>Benefit:</p> <p>More choice for consumers when buying unfortified flour-based products.</p> <p>Small-scale miller exemption</p> <p>Consumers place a value on these small-scale mills and will continue to benefit from them.</p>	<p>Cost:</p> <p>Small-scale miller exemption:</p> <p>Familiarisation costs for small-scale millers Combined estimated cost across sector: £7,800</p> <p>Labelling costs.</p> <p>Potential reduction in pre mixer sales.</p> <p>Potential reduction in flour output at millers producing marginally over 500t per year.</p> <p>Products with low flour content exemption:</p> <p>Familiarisation costs</p> <p>Potential for additional production costs if mills produce both fortified and unfortified flour.</p> <p>Compliance costs.</p> <p>Benefit:</p> <p>Small-scale miller exemption</p> <p>Reduction in fortification costs for millers who qualify for the exemption.</p> <p>Viability of small-scale millers would be supported.</p> <p>Products with low flour content exemption</p> <p>Trade: increase competitiveness in European markets where mandatory fortification is viewed unfavourably.</p>	<p>Cost:</p> <p>Familiarisation costs for enforcement and compliance authorities because of the changing regulations. Combined estimated costs for all 408 local authorities: £19,000.</p> <p>Benefit:</p> <p>Products with low flour content exemption</p> <p>Exchequer benefits: increased tax revenue due to increased trade.</p> <p>Reduced risk of businesses relocated abroad.</p> <p>Small-scale miller exemption</p> <p>Savings related to enforcement authorities no longer having to enforce regulations.</p> <p>'Future proofing' for areas where there are zero or very few 'small scale' millers.</p>

		Potential for reduced input costs, if unfortified flour is less costly to produce.	
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20. Does the summary above accurately represent the main costs for 1) industry, 2) consumers and 3) government/enforcement authorities for the proposal to exempt mills producing less than 500 tonnes of flour (please see section 4.7 of the accompanying Impact Assessment for a more detailed breakdown of the cost/benefit analysis and calculations p.39-43)?

	Agree	Neither agree nor disagree	Disagree	Don't know/no comment
The costs and benefits to <u>industry</u> of the proposed exemption from fortification for mills producing less than 500 tonnes of flour are accurately represented				X
The costs and benefits to <u>consumers</u> of the proposed exemption from fortification for mills producing less than 500 tonnes of flour are accurately represented				X
The cost and benefits to <u>government/ enforcement authorities</u> of the proposed exemption from fortification for mills producing less than 500 tonnes of flour are accurately represented				X

20a. Please detail which costs or benefits you feel have not been accurately represented and provide any evidence you have to support your views (Open text).

21. Does the summary above accurately represent the main costs for 1) industry, 2) consumers and 3) government/enforcement authorities for the proposal to exempt flour to be used in a product as a minimal ingredient (please see section 4.7 of the accompanying Impact Assessment for a more detailed breakdown of the cost/benefit analysis and calculations p.39-43)?

	Agree	Neither agree nor disagree	Disagree	Don't know/no comment
The costs and benefits to industry of the proposed exemption for flour to be used in a product as a minimal ingredient <10% are accurately represented				X
The costs and benefits to consumers of the proposed exemption for flour to be used in a product as a minimal ingredient <10% are accurately represented				X
The costs and benefits to <u>government/ enforcement</u> authorities of the proposed exemption for flour to be used in a product as a minimal ingredient <10% are accurately represented				X

The RCPE has no specific comments on the remaining questions in this section.

21a. Please detail which costs or benefits you feel have not been accurately represented and provide any evidence you have to support your views. (Open text)

22. Please indicate your support for the following options (select one option per row):

	Yes, I support this	No, I don't support this	I don't know/no opinion
Do Nothing			
Exempt small scale-mills producing less than 500 metric tonnes of flour per annum from fortification requirements			
Exempt flour to be used in a product as a minimal ingredient <10%			

23. In your opinion, is setting a threshold for fortification requirements at an annual production of 500 metric tonnes: (select one option only)

- About right
- Too high
- Too low
- Don't know/no comment

24. Do you agree or disagree that the proposal to exempt small-scale mills would be unlikely to have significant impact on the nutrient intake levels of consumers? (Select one option only)

- I agree - it is unlikely to have a significant impact on nutrient intake levels
- I disagree – it is likely to have a significant impact on nutrient intake levels
- Don't know/No comment

25. (For Enforcement Authorities) Do you have any major concerns around monitoring mills producing less than 500 metric tonnes per annum under the proposed exemption? (Select one option only)

- Yes, I have major concerns
- No, I do not have major concerns
- Don't know/no comment

25a. If you answered yes, which of the reasons below, if any, explain your answer? (Select all that apply)

- Lack of resource
- Lack of time
- Lack of clear process
- Other (please provide details)

B): Questions on the proposal to exempt flour to be used as a minor ingredient of a final product

26. How far do you agree or disagree that the proposal to exempt flour that is less than 10% of a product, is reasonable? (Select one option only)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

27. (For Industry Stakeholders) To what extent do you agree or disagree that this proposed exemption would support UK business to compete on a more equal footing with international competition in export markets? (Select one option only)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

28. How far do you agree or disagree that the proposal to exempt flour that is less than 10% of a product would be unlikely to have a significant impact on nutrient intake levels of consumers? (Select one option only)

- Strongly agree
- Agree

- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/no comment

29. (For Enforcement Authorities) Do you have any major concerns around the enforcement of the regulations if the proposal to exempt flour in products where it makes up <10% of the final product were to go ahead? (Select one option only)

- Yes
- No
- Don't know/no comment

29a. If you answered yes, which of the reasons below, if any, explain your answer? (Select all that apply)

- Lack of resource
- Lack of time
- Lack of clear process
- Other (please provide details)

30. If you would like to add any further comments or supporting evidence to your responses to questions 20-29 above or any other comments relevant to the exemption proposals above, please do so here:

Enforcement

Enforcement of the Bread and Flour Regulations is carried out by trading standards officers and environmental health officers from local authorities and district councils (See list of local authorities and district councils for England, Wales, Northern Ireland when clicking on the link to food standards data [here](#) and [here](#) for the local authorities in Scotland).

The existing Bread and Flour Regulations only provide for criminal sanctions to address non-compliance. This is not in keeping with similar food standards legislation in England, Wales and Northern Ireland i.e. The Food Information Regulations, The Honey Regulations and the Fruit Juice and Fruit Nectars Regulations which adopt a more proportional and targeted approach with a move to improvement notices as an initial

enforcement option.¹⁷ An improvement notice can be served by an authorised officer if an enforcement authority has reasonable grounds for believing that an FBO (Food Business Operator) is failing to comply with the legislative requirements. The notice outlines the matter which constitutes the failure to comply and specify measures, which in the officer's opinion, the proprietor must take in order to secure compliance within a specified time period. Any person who fails to comply with an improvement notice shall be guilty of an offence.

Currently, improvement notices are not used in the enforcement of food standards regulations in Scotland. However, Scotland are considering the introduction of compliance notices as a similar enforcement measure for food standards legislation.

A move towards using improvement notices as part of the enforcement regime is seen as a means to correct non-compliance efficiently while reducing cost and time for businesses in resolving issues more quickly. This approach has also been viewed as a way of reducing excessive costs associated with court time when criminal proceedings are brought.

In England, businesses would have the opportunity to appeal against an improvement notice to the First-tier Tribunal. The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 can be found [here](#)

In Wales & Northern Ireland, businesses would have the opportunity to appeal against an improvement notice to the Magistrates Court.

Proposal

A separate consultation was held on the introduction of compliance notices for food standards requirements in Scotland. Hence, the proposal and following questions below apply to potential changes to The Bread and Flour Regulations in England, Wales and Northern Ireland only.

We are planning to change the existing enforcement regime which only provides for criminal sanctions to address non-compliance, to a more proportionate and targeted regime allowing the use of improvement notices. Businesses would have the opportunity

¹⁷ The Food Information (England) Regulations 2014; The Food Information (Wales) Regulations 2014; The Food Information (Northern Ireland) Regulations 2014; The Fruit Juice and Fruit Nectars (England) Regulations 2013; The Fruit Juice and Fruit Nectars (Wales) Regulations 2013; The Fruit Juice and Fruit Nectars (Northern Ireland) Regulations 2013; The Honey (England) Regulations 2015; The Honey (Wales) Regulations 2015; The Honey (Northern Ireland) Regulations 2015.

to appeal against an improvement notice. A failure to comply with an improvement notice would be a criminal offence for which a fine may be imposed.

Questions

31. How far do you agree or disagree that introducing improvement notices to address non-compliance a more proportional approach to enforcement than the existing enforcement regime which only provides for criminal sanctions? (Select one option only).

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/no comment

32. How far do you agree or disagree that using improvement notices would resolve issues with non-compliance efficiently? (Select one option only)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/no comment

33. Do you agree or disagree that enforcement of the regulations should extend to manufacturers of flour-based products where unfortified flour is purchased under the condition it is to be used in an exempt product or to be exported outside the UK? (Open text)

The RCPE has no specific comments on this question.

34. Do you have any further comments on the proposed change to the enforcement of the Bread and Flour Regulations?

The RCPE looks forward to seeing further details of how the new regulations will be enforced in Scotland in particular and whether it will move forward with compliance notices.

General Questions on Implementation of Policy Changes

35. The proposal to add folic acid to non-wholemeal flour requires time for industry to adapt premises and make subsequent labelling changes which will impact a wide range of products. A 24-month transition period before proposals brought forward come into force is proposed to accommodate for this. In your opinion, is the proposed transition period of 24 months for the new requirements to come into force? (Select one option only).

- Reasonable
- Too short
- Too long
- Don't know/no comment

35a. If you disagree with the proposed transition period, please explain why?

Next Steps

We will be carefully reviewing all responses to the consultation taking into account views expressed, as well as any additional information provided which will be used to further refine proposals and inform the impact assessment. A summary of responses is due to be published on the gov.uk website within 12 weeks of the consultation closure.

Following the consultation relevant Ministers from the UK Government and devolved administrations will make the final decision on any legislative changes, taking into account responses received.