EXPLANATORY MEMORANDUM TO

THE BREAD AND FLOUR (AMENDMENT) (ENGLAND) REGULATIONS 2024

2024 No. 1162

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food & Rural Affairs and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Daniel Zeichner, Minister of State for Food Security and Rural Affairs at the Department for Environment Food & Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

2.2 Karen Lepper (SCS) for Food Standards at the Department for Environment Food & Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Miles Healy at the Department for Environment, Food and Rural Affairs email: foodcstandards@defra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

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

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England only.

5. Policy Context

What is being done and why?

5.1 NTDs affect approximately 800 pregnancies a year in England and around 1,000 pregnancies in the UK as a whole. NTD risk is associated with low levels of blood folate among pregnant women and women who could become pregnant. In the UK, women who could become pregnant are advised to take a daily supplement of 400 micrograms of folic acid (synthetic form of folate) prior to conception and up until the 12th week of pregnancy. However as approximately half of pregnancies are unplanned, many women do not take folic acid supplements during this period.

5.2 The instrument introduces the compulsory addition of folic acid to non-wholemeal wheat flour, which is expected to reduce incidences of NTD affected pregnancies by 15-22% per year preventing around 100-210 potentially life-threatening spinal conditions in England and 150-220 in the UK as a whole. This policy is supported by recommendations from the Science Advisory Committee on Nutrition[1], and research modelling the potential impact of fortification of flour with folic acid.[2] Analogous changes are being made in Scotland, Wales and Northern Ireland.

5.3 This amendment also makes technical changes to:

- Take account of legislative developments ensuring consistency with other food standards regulations controlling the conditions for the addition of vitamins and minerals to food, enabling understanding and compliance.
- Improve clarity of requirements and definitions facilitating common interpretation, avoiding future areas of dispute.
- Introduce both a new definition and changes to the compositional rules of wholemeal flour, removing barriers to compliance while maintaining consumer protection.
- Minimise regulatory burdens by introducing an exemption for small-scale producers.
- Update enforcement provisions by introducing improvement notices allowing more proportionate and efficient enforcement action to be taken and reduce risk of excessive costs associated with court time when criminal proceedings are brought.

What was the previous policy, how is this different?

5.4 The Bread and Flour Regulations 1998 set out provisions requiring minimum levels of calcium carbonate, iron, thiamin and niacin to be present in non-wholemeal wheat flour as well as chemical specifications for these substances which need to be added to meet the required levels. This amendment adds folic acid to the list of substances required to be added to non-wholemeal wheat flour at a level of 250 micrograms per 100g of flour.

5.5 Previous minimum levels set out for the addition of three of the nutrients, calcium carbonate, iron and niacin to non-wholemeal wheat flour were not aligned with general rules on the addition of vitamins and minerals to food which requires that

[1] Folic acid: updated SACN recommendations, 2017

[2] Food Standards Scotland: Stochastic Modelling to Estimate the Potential Impact of Fortification of Flour with Folic Acid, 2017

vitamins and minerals added to food result in the presence of a "significant amount" [3] of the nutrient in the food to ensure there is sufficient benefit to consumers. This amendment aligns the minimum levels of these substances to equate to 15% of the Nutrient Reference Value (NRV) for these nutrients, which brings it into line with the accepted definition of 'significant'. It also updates the specification criteria for the specified vitamins and minerals which must be present, providing consistency with other food standards legislation and ensuring high standards which take account of the latest specifications and analytical techniques.

5.6 The amendment removes the requirements which sets minimum natural levels of the specified nutrients in wholemeal flour but introduces a legal definition of wholemeal flour to ensure the natural nutritional value found in wheat is retained.

5.7 The amendment clarifies that the intended scope of the legislation applies to flour made from common wheat only and not flour made from other wheat species. This ensures a consistent interpretation of requirements across industry and enforcement, avoids placing disproportionate burdens on industry and helps maintain an element of choice for consumers.

5.8 The amendment now exempts flour produced by mills producing less than 500 metric tonnes of flour per year. This mitigates the disproportionate burden that the requirements place on smaller scale producers without compromising the public health outcomes of the policy.

5.9 Previously any non-compliance with The Bread and Flour Regulations 1998 was a criminal offence. This amendment introduces the use of improvement notices to address non-compliance, with criminal sanctions only used as a backstop if improvement notices are ignored or not complied with.

6. Legislative and Legal Context

How has the law changed?

6.1 The Bread and Flour Regulations 1998 lay down minimum compositional and labelling requirements for bread and flour. This instrument amends provisions on the mandatory fortification of non-wholemeal wheat flour, adding folic acid to the list of added substances. The instrument updates existing requirements on the conditions for the mandatory addition of calcium, carbonate, iron, niacin, and thiamin, taking account of legislative and technological developments. These changes will come into force from December 2026 allowing industry time to implement changes in a responsible and effective manner, mitigating costs associated with labelling changes and packaging waste. The instrument makes a number of additional amendments including exempting flour produced by small mills, introducing definitions for "common wheat" and "wholemeal flour", and removing compositional requirements on natural levels of nutrients in wholemeal flour which are impractical and present barriers to compliance. Enforcement by way of improvement notices is now provided by the amending instrument, with the creation of an offence for failing to comply with an improvement notice in line with other food standards legislation. These changes will come into force from December 2024.

Why was this approach taken to change the law?

6.2 This is the only possible approach to make the necessary changes.

[3] A "significant amount" is defined as 15% of the Nutrient Reference Value (NRV) per 100g. NRVs are established guidelines for the recommended daily energy and nutrient consumption of an average person.

7. Consultation

Summary of consultation outcome and methodology

7.1 The UK government and devolved governments held a 12-week public consultation between 13 June and 9 September 2019 seeking views on the proposal to introduce the mandatory addition of folic acid to flour to help prevent NTDs in foetuses. The consultation received 1,438 responses from a range of individuals (88%), organisations and businesses including those across the food industry and non-government organisations. The consultation asked respondents for their views on the overall proposal for the mandatory fortification of non-wholemeal wheat flour with folic acid in the UK. 53% of respondents overall supported the proposal with 85% of health sector respondents who had an opinion being supportive. The consultation included additional questions including on products that should be fortified, alternative ways to reduce NTDs, population groups and businesses that might be negatively affected by the policy and how to mitigate this. A range of answers were received from different stakeholders. Following careful consideration of the responses received, the UK and devolved governments confirmed their intent to proceed with the mandatory fortification of non-wholemeal wheat flour.

7.2 The consultation summary and responses published on 21 September 2021 can be found here: Proposal to add folic acid to flour: consultation response - GOV.UK[4]

7.3 The UK government and devolved governments held an additional UK-wide 12-week public consultation between 1st September and 23rd November 2022 on proposals to amend The Bread and Flour Regulations 1998 including the implementation of the mandatory addition of folic acid to flour, as well as other proposals resulting from a wider review of the regulations. We received 369 responses to the consultation representing a broad range of views from different stakeholders. Some respondents used the consultation to voice opposition to mandatory fortification on the basis that it limits freedom of choice, while most health professionals were strongly supportive of mandatory fortification, and some called for higher levels of folic acid to be added and a broadening of the scope of fortification requirements. Removing mandatory fortification of flour was not in scope of this consultation as this policy continues to be viewed as an important vehicle for improving the population's nutrient intake. The UK government and devolved governments agreed to proceed with the proposed level of folic acid addition of 250 micrograms per 100g of flour on the basis that adding at a higher level could result in a greater proportion of the population exceeding the guidance level for intake. The UK government and devolved governments agreed to maintain an element of consumer choice by limiting the scope of mandatory fortification requirements to non-wholemeal flour made from common wheat, leaving wholemeal flour and flour made from other grains as alternatives.

7.4 The Consultation Summary of Responses and Government Response published on 17th January 2024 can be found here: Summary of responses and government response - GOV.UK (www.gov.uk)[5].

[4] https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/outcome/proposal-to-add-folic-acid-to-flour-consultation-response#:~:text=After%20considering%20feedback%20to%20the,folic%20acid%20(baseline%20option)

[5] https://www.gov.uk/government/consultations/amending-the-bread-and-flour-regulations-1998-and-the-bread-and-flour-northern-ireland-regulations-1998/outcome/summary-of-responses-and-government-response#chapter-4-exemptions

7.5 The World Trade Organisation Committee on Technical Barriers to Trade was notified of our intention to amend the Bread and Flour Regulations 1998 on 9th February 2024. No comments were received from members.

8. Applicable Guidance

8.1 Updated guidance is being developed and will be published prior to new requirements coming into force.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A De-Minimis Assessment is published alongside the Explanatory Memorandum on legislation.gov.uk. The Department estimates total costs of the policy at approximately £85million over the 10-year appraisal period. This is mainly due to indirect one-off packaging write-off costs of up to £60million, plus direct costs of relabelling flour containing products at around £20million, and additional costs of folic acid itself of around £5million for industry (15p per tonne of flour, less than a penny per standard 800g loaf of bread). The costs are spread across a high volume of products hence the cost per product is expected to be minimal with no significant impact on retail prices anticipated. The cost to the public sector is estimated to be £8,000 related to familiarisation with the updated Regulations. The net benefit of the policy is estimated to be close to £600million, centrally related to health benefits and care cost benefits associated with the estimated reduction in Neural Tube Defects.

Impact on businesses, charities and voluntary bodies

9.2 There is no anticipated impact to charities and voluntary bodies. There are costs to business associated with one-off relabelling costs and the addition of vitamins and minerals to flour as outlined in para 9.1.

9.3 The legislation does impact small or micro businesses as milling is highly automated and not a labour-intensive sector, exempting all businesses with less than 50 employees would have compromised the health outcomes of the policy due to the proportion of flour produced by businesses of this size. Thus, some small businesses will be required to adhere to the changes in mandatory fortification of flour requirements. However, there is a subset of small businesses in the milling industry that operate on a fundamentally different scale of production and have different production processes on whom compliance with these provisions would place a disproportionate burden. Hence, an alternative exemption based on production capacity has been provided to mitigate this.

9.4 There is no significant impact on the public sector because there are existing routines in place to enforce the current laws regarding mandatory fortification of non-wholemeal wheat flour with calcium carbonate, iron, thiamin and niacin. We assume that the amendments will not create any new significant burdens on the trading standards officers that enforce the existing regulations beyond the initial familiarisation costs set out above.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation will be to monitor the impact of the policy at a UK-wide level where possible by utilising data from the existing National

Congenital Anomaly and Rare Disease Registration Service (NCARDRS), which registers NTDs and the National Diet and Nutrition Survey (NDNS) This will enable us to monitor the prevalence and incidence of NTDs, folate and vitamin B12 status and folate and folic acid intakes and folic acid supplement use. There are also plans to monitor the trends of prostate, breast, colorectal and overall cancer through existing prospective cancer registries. However, it may be difficult to attribute a specific cause for these cancers given cancer's multiple causes and the long latency period for many cancers.

10.2 This data will be evaluated to assess the impact of the policy in relation to 1) the reduction in incidence and prevalence of NTDs in comparison with estimates in the modelling; 2) improvements in folic acid intakes and status of the population but in particular in women of child-bearing age and 3) any increase in the proportion of the population (especially older adults) exceeding the upper guidance level of folic acid.

10.3 It is planned to undertake surveys and workshops with stakeholders to test industry and enforcement officers experience of the regulations, testing whether the measures remain up to date and fit for purpose. As well as this consumer views will be sought to ensure marketing controls remain suitable. Sampling data will be drawn upon to measure compliance and identify any barriers which may need to be addressed.

10.4 We will evaluate policy outcomes once we have reliable data from which to do so. Time points for monitoring the health impact of the policy will need to take into account the 2-year period for industry to implement the policy before it becomes mandatory and when outcome data will become available through the NCARDRS (and equivalent registers) and the NDNS.

10.5 The instrument does not include a statutory review clause as the measure does not have an impact greater than £10 million (net annualised) on business. However, the government intends to carry out monitoring and evaluation of the policy as indicated above to ensure it has its intended effect and consider if revisions to the policy are needed.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 Daniel Zeichner, Minister of State for Food Security and Rural Affairs at the Department for Environment Food & Rural Affairs has made the following statement regarding Human Rights:

"In my view the provisions of the Bread and Flour (Amendment) (England) Regulations 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").