EXPLANATORY MEMORANDUM TO

THE BREAD AND FLOUR (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2024

S.R. 2024 No. 196

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Food Standards Agency (FSA) to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under powers conferred by Articles 15(1), 17(1)(c), 25(1)(a) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991. and is subject to the negative resolution procedure.

2. Purpose

2.1. This Statutory Rule will amend the Bread and Flour Regulations (Northern Ireland) 1998 to:

- provide for the mandatory addition of folic acid to non-wholemeal flour to reduce the number of Neural Tube Defects (NTD) affected pregnancies.
- introduce definitions of "common wheat" and "wholemeal flour" to clarify the scope of the regulations and ensure a consistent understanding across the bread and flour supply chain and local enforcement.
- change to the required quantities of calcium carbonate, iron and niacin and replace the criteria for the calcium carbonate specification to ensure consistency with other food legislation and to assist understanding and compliance.
- provide exemptions for small mills to reduce regulatory burden for businesses where public health outcomes of the policy are not compromised.
- provide for improvement notices, including the offence of failing to comply with an improvement notice, as an effective and proportionate approach to enforcement.
- allow flour millers to place unfortified flour on the market, subject to it being destined for countries outside the UK or used in products destined to be sold outside of the UK; and
- provide a transition period for businesses to adjust.

3. Background

3.1. The Bread and Flour Regulations (Northern Ireland) 1998 cover specific rules on the labelling and composition of bread and flour, including the compulsory fortification of non-wholemeal wheat flour manufactured with added calcium, iron, thiamin and niacin to protect against

nutrient deficiencies within the Northern Ireland population. Equivalent legislation in Great Britain is the Bread and Flour Regulations 1998.

3.2. The Scientific Advisory Committee on Nutrition (SACN) published an updated report in 2017 recommending mandatory fortification of flour with folic acid to improve the folate status of women most at risk of neural tube defect (NTD) affected pregnancies.

3.3. Following public consultation in 2019, the UK Government and the Devolved Governments announced in 2021 their intention to mandate the fortification of non-wholemeal wheat flour with folic acid.

3.4. The Bread and Flour regulations were considered an appropriate vehicle for implementation as the regulations already mandate the fortification of flour with calcium, iron, thiamin and niacin.

3.5. The FSA holds policy responsibility for the Bread and Flour Regulations (Northern Ireland) 1998. Under the arrangements within the UK's Food Composition Standards and Labelling provisional Common Framework, the FSA in Northern Ireland and Wales, Department for Environment, Food and Rural Affairs (Defra) and Food Standards Scotland (FSS) conducted a four-nation review of the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 to ensure they remained fit for purpose. The review was in conjunction with the Northern Ireland Department of Health, Department of Health and Social Care, Welsh Government and Scottish Government who have responsibility for matters of public health, including the policy to fortify non-wholemeal wheat flour with folic acid.

3.6. The review aimed to implement the UK wide commitment for the mandatory addition of folic acid to non-wholemeal wheat flour, update the regulations to ensure consistency with other overlapping legislation, provide clarity on the scope of the regulations, introduce specific exemptions, provide an adjustment period for industry and replace the current offences and penalties provisions with improvement notices as an effective and proportionate approach to enforcement. The proposals are to ensure the regulations lead to improved public health, support industry, assist enforcement authorities and protect consumers.

4. Consultation

4.1. In 2019, the UK Government and devolved administrations launched a 12-week public consultation (13 June 2019 - 9 September 2019) on the proposed policy of mandatory fortification of flour with folic acid to help prevent NTDs in foetuses. In total, the consultation received 1,438 responses from a range of individuals, organisations and businesses including those across the food industry and non-government organisations. Proposal to add folic acid to flour: consultation response - GOV.UK (www.gov.uk)

4.2. The proposal to allow flour millers to place unfortified flour, subject to it being destined for countries outside the UK or used in products destined to be sold outside of the UK, was consulted upon between September 2021 – December 2021.

4.3. A UK-wide consultation on proposals to update and amend the Bread and Flour Regulations was held between 1 September – 23 November 2022. There were 369 responses to the consultation, with 6% (23) of respondents based in Northern Ireland.

4.4. A summary of responses was published in January 2024 and further detail can be accessed through the government website - Summary of responses and government response - GOV.UK (www.gov.uk).

4.5. Respondents were asked to indicate their views on 'raising the minimum level of added nutrients', with 29% supporting, 50% not supporting and 22% stating don't know or no comment. The majority of those responding from academia (4 out of 7 responses), campaign group/NGO (7 out of 12 responses), and public sector bodies (6 out of 7 responses) supported the change whereas the majority of responses from individuals (133 out of 264 responses) and industry representatives (16 out of 29 responses) were against the proposal. Respondents were asked to explain opposition to the proposal and while the removal of mandatory fortification requirements was not in scope of the consultation a significant proportion of respondents voiced opposition to fortification more generally. Several further responses (mainly from individual consumer respondents) raised concerns around adverse health risks related to the proposals. The majority of health professionals who responded supported the change. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) found change to the proposed levels of fortification would not result in any material increase in risk of adverse health effects particularly when considering the entire diet and consumption of supplements. Many responses that opposed mandatory fortification did so on the basis that it removed consumer choice. Limiting the scope of mandatory fortification to non-wholemeal flour derived from common wheat and exempting small-scale mills will address aspects of this concern.

4.6. A significant proportion (42%) of respondents supported the proposal to remove the calcium carbonate specification from the Regulations and replace it with the specification criteria established in food additives legislation compared to 18% who opposed this amendment.

4.7. The proposal to amend the compositional requirements of wholemeal flour rectifies a technical barrier to compliance and introducing a new definition provides consumer protection, ensuring wholemeal flour must consist of the whole product from the milling and grinding of cleaned cereal. Many responses were deemed to be out of scope on the basis that respondents

mistakenly thought the proposal involved the mandatory addition of nutrients to wholemeal flour.

4.8. Respondents were asked for their views on a small mill exemption and majority of responses (84%) were in favour of this proposal. The majority of respondents agreed that the proposal to exempt small-scale mills would be unlikely to have a significant impact on the nutrient intake levels of consumers.

4.9. Respondents were asked for their views on allowing unfortified flour to be sold for use as an ingredient in a product where it makes up less than 10% of the final product and most respondents (63%) supported the proposal. Out of the responses received from academic institutions, three out of four did not support the proposed exemption. Out of the responses received from retailers, three out of four did not support the proposed exemption. Several responses to the open questions in this section of the consultation raised concerns that the proposal would lead to added complexity in terms of compliance with the law as well as enforcement. The complexity of complying, monitoring and enforcing this exemption may compromise the ability to meet desired objectives. Therefore, following the consultation this proposal was not progressed and is not included in the legislation.

4.10. Many responses welcomed the introduction of a requirement to add folic acid to flour with several responses encouraging this to be implemented as soon as possible. Of the 170 responses, just over half were broadly characterised as being against the government policy to require fortification of flour with folic acid more broadly. The most common reason for this was the perceived removal of consumer choice.

4.11. Of those who responded to the open questions in this section, many called for an increase to the proposed level of folic acid added to flour from 250mcg to 1mg per 100g of flour. These responses predominantly came from health care professionals responding in an official capacity for academic institutions, public health organisations and charities.

4.12. Many responses from industry representatives of manufacturers, retailers, and trade associations raised concerns around the consequential labelling costs for products containing non-wholemeal flour as an ingredient and challenges related to synchronising the timings of composition and labelling changes together.

4.13. The consultation proposed an overall 24-month transition period to allow businesses to adjust their processes and adapt to changes in both the composition and labelling and spread the cost into their natural relabelling cycles.

4.14. Non-wholemeal wheat flour will be required to contain 250 micrograms of folic acid per 100 grams of flour. The level of fortification will be kept under review as part of the monitoring and evaluation of the policy, which will assess both positive and postulated negative impacts.

4.15. Respondents were asked to what extent they agreed or disagreed that a move to improvement notices to address non-compliance is a more proportionate approach to enforcement than the existing enforcement regime, which only provides for criminal sanctions. The use of improvement notices to address non-compliance within the Bread and Flour Regulations a more proportionate approach to enforcement was either strongly agreed or agreed upon by 37% of respondents, compared to 11% who either strongly disagreed or disagreed. Notably, of the six responses received from enforcement authorities, five either strongly agreed or agreed compared with one who disagreed.

4.16. Respondents were asked an open question about whether the 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. Of the 77 responses received, approximately half of respondents agreed that enforcement should extend to manufacturers of flour-based products, and approximately a quarter of responses disagreed.

4.17. The proposal to add folic acid to non-wholemeal wheat flour requires time for industry to adapt premixes and make subsequent labelling changes which will impact a wide range of products. There is a 24-month transition period to accommodate this. Around half of respondents expressing an opinion felt the proposed period was reasonable (27% of responses overall), with the views of others split between those who felt it was too long (12% of responses overall) and those who felt it was too short (16% of the responses overall) with 46% answering ‘don’t know’ or ‘no comment’.

5. Equality Impact

5.1. This Statutory Rule has been screened for any possible impact on equality of opportunity affecting the groups listed in Section 75 of the Northern Ireland Act 1998 and no adverse or differential impacts were identified.

6. Regulatory Impact

6.1. The implementation of all proposals was considered the best option as it best meets the policy objectives of the intervention. Implementing all proposals means that these changes will happen at the same time which makes familiarisation with these changes simpler for businesses and enforcement authorities.

6.2. The monetised benefits are considered to far outweigh the monetised costs (£24.31m vs £5.25m in the central estimates. The main costs of the policy for businesses are transitory, arising from initial relabelling (estimated total present value of £1.4m) and packaging waste (estimated at a total present value of £3.85m). Familiarisation costs equate to £784 across millers in Northern Ireland (central estimate) and while there is a recurring cost for folic acid, the cost of this is considered low and on a per product basis is considered negligible.

6.3. The impact on the public sector will primarily fall on the FSA and district councils, who will be responsible for enforcing the legislation. This main cost will be a one-off familiarisation cost (average £354 based on one officer from each of the 11 councils).

6.4. The full Impact Assessment is published alongside this Explanatory Memorandum.

7. Financial Implications

7.1. None.

8. Section 24 of the Northern Ireland Act 1998

8.1. Consideration has been given to the human rights implications of these Regulations. They are considered compatible with Section 24 of the Northern Ireland Act 1998.

9. EU Implications

9.1. The EU does not have harmonised community provisions for the fortification of bread and flour. Regulation (EC) 1925/2006 set out rules on the addition of vitamin and minerals to foodstuff and provides an ability to adopt national measures. In accordance with this Regulation and Directive (EU) 2015/1535, the FSA in Northern Ireland notified the EU of the proposed new national provisions. The EU provided a positive opinion on the notification.

10. Parity or Replicatory Measure

10.1. While this legislation is exclusive to Northern Ireland, it parallels equivalent legislation in England, Scotland, and Wales.

11. Additional Information

11.1. Not applicable.