

Health, Social Care and Sport Committee  
28 January 2025  
3rd Meeting, 2025 (Session 6)

## Note by the Clerk on Subordinate legislation

### Background

1. At this meeting, the Committee will consider the following Scottish Statutory Instrument (SSI), which is subject to annulment by resolution of the Parliament until 13 February 2025. The Committee is invited to consider the instrument and decide what, if any, recommendations to make.
2. More information about the instrument is summarised below:

**Title of instrument:** [Bread and Flour Amendment \(Scotland\) Regulations 2024](#)  
(SSI 2024/387)

**Laid under:** sections 16(1)(a) and (e), 18(1)(c), 26(1)(a) and 48(1) of the [Food Safety Act 1990](#).

**Laid on:** 20 December 2024

**Procedure:** Negative

**Deadline for committee consideration:** 10 February 2025 (Advisory deadline for any committee report to be published)

**Deadline for Chamber consideration:** 13 February 2025 (Statutory 40-day deadline for any decision whether to annul the instrument)

**Commencement:** 3 February 2025 and 13 December 2026

### Procedure

3. Under the negative procedure, an instrument is laid after it is made, and is subject to annulment by resolution of the Parliament for a period of 40 days beginning on the day it is laid.
4. Once laid, the instrument is referred to:
  - the Delegated Powers and Law Reform (DPLR) Committee, for scrutiny on various technical grounds, and
  - a lead committee, whose remit includes the subject-matter of the instrument, for scrutiny on policy grounds.
5. Any MSP may propose, by motion, that the lead committee recommend annulment of the instrument. If such a motion is lodged, it must be debated at a meeting of the Committee, and the Committee must then report to the Parliament (by the advisory deadline referred to above).

6. If there is no motion recommending annulment, the lead committee is not required to report on the instrument.

## Delegated Powers and Law Reform Committee consideration

7. The DPLR Committee considered the instrument on 14 January and reported on it in its [4th Report, 2025](#). The DPLR Committee made no recommendations in relation to the instrument.

## Purpose of the instrument

8. The instrument amends the Bread and Flour Regulations 1998 (“the 1998 Regulations”) in Scotland:
  - to introduce the mandatory requirement for non-wholemeal wheat flour to be fortified with folic acid,
  - to amend the required quantities of fortificants which are currently added to flour,
  - to introduce an exemption from these fortification requirements for small mills, and
  - to make some other technical amendments.
9. The policy notes further state that the purpose of the instrument is to:
  - Introduce the mandatory fortification of non-wholemeal wheat flour with folic acid as a public health intervention to work alongside other public health measures to help to reduce the incidence of foetal neural tube defects in Scotland by increasing the dietary intake of folic acid, and therefore blood folate levels in women of child-bearing age. The amendments specify that mandatory flour fortification will take place by requiring that non-wholemeal wheat flour be fortified with folic acid in the specified quantities.
  - Update and improve the Regulations by aligning the existing fortification requirements with overlapping assimilated Regulation (EC) No 1925/2016 on the addition of vitamins and minerals and of certain other substances to foods which can be accessed at <https://www.legislation.gov.uk/eur/2006/1925> and assimilated Regulation (EU) No 1169/2011 on the provision of food information to consumers which can be accessed at <https://www.legislation.gov.uk/eur/2011/1169>.
  - to provide consistency and understanding across industry and enforcement authorities. This in turn will help improve public health outcomes, support UK Industry, assist enforcement authorities, protect consumer interests and support trade with the EU.
10. The Policy Note accompanying the instrument is included in **Annexe A**. It includes a summary of consultation undertaken on the instrument, impact assessments carried out, and the anticipated financial effects.
11. The Minister for Public Health and Women’s Health wrote to the Committee on 20 December 2024 in relation to the instrument. This correspondence is included in **Annexe B**.

## **Committee consideration**

12. So far, no motion recommending annulment has been lodged.
13. Members are invited to consider the instrument and decide whether there are any points they wish to raise. If there are, options include:
  - seeking further information from the Scottish Government (and/or other stakeholders) through correspondence, and/or
  - inviting the Minister (and/or other stakeholders) to attend the next meeting to give evidence on the instrument.
14. It would then be for the Committee, at the next meeting, to consider the additional information gathered and decide whether to make recommendations in relation to the instrument.
15. If Members have no points to raise, the Committee should note the instrument (that is, agree that it has no recommendations to make).
16. However, should a motion recommending annulment be lodged later in the 40-day period, it may be necessary for the Committee to consider the instrument again.

**Clerks to the Committee**  
**January 2025**

## Annexe A: Scottish Government Policy Note

### POLICY NOTE

#### THE BREAD AND FLOUR AMENDMENT (SCOTLAND) REGULATIONS 2024 SSI 2024/387

The Scottish Ministers make the following Regulations in exercise of the powers conferred on them by sections 16(1)(a) and (e), 18(1)(c), 26(1)(a) and 48(1) of the Food Safety Act 1990, and all other powers enabling them to do so. The instrument is subject to negative procedure.

#### Summary Box

The purpose of the instrument is to amend the Bread and Flour Regulations 1998 (“the 1998 Regulations”) in Scotland:

- to introduce the mandatory requirement for non-wholemeal wheat flour to be fortified with folic acid,
- to amend the required quantities of fortificants which are currently added to flour,
- to introduce an exemption from these fortification requirements for small mills, and
- to make some other technical amendments.

#### Policy Objectives

The purpose of the Bread and Flour Amendment (Scotland) Regulations 2024 is to amend the 1998 Regulations to:

- Introduce the mandatory fortification of non-wholemeal wheat flour with folic acid as a public health intervention to work alongside other public health measures to help to reduce the incidence of foetal neural tube defects in Scotland by increasing the dietary intake of folic acid, and therefore blood folate levels in women of child-bearing age. The amendments specify that mandatory flour fortification will take place by requiring that non-wholemeal wheat flour be fortified with folic acid in the specified quantities.
- Update and improve the Regulations by aligning the existing fortification requirements with overlapping assimilated Regulation (EC) No 1925/2016 on the addition of vitamins and minerals and of certain other substances to foods which can be accessed at <https://www.legislation.gov.uk/eur/2006/1925> and assimilated Regulation (EU) No 1169/2011 on the provision of food information to consumers which can be accessed at <https://www.legislation.gov.uk/eur/2011/1169>.
- to provide consistency and understanding across industry and enforcement authorities. This in turn will help improve public health outcomes, support UK Industry, assist enforcement authorities, protect consumer interests and support trade with the EU.

A transitional period from December 2024 to December 2026 is provided by these regulations. This is in relation to the new fortification requirements and will allow businesses a period of time to act to phase the changes in, and coordinate changes

as far as possible with their own labelling and packaging update cycles. This will be of most benefit to those businesses with multiple product lines which are affected by the new legal requirements.

## **UN Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 Compatibility**

The Scottish Ministers have made the following statement regarding children's rights:

- In accordance with section 23(2) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024, the Scottish Ministers certify that, in their view, the Bread and Flour Amendment (Scotland) Regulations 2024 are compatible with the UNCRC requirements as defined by section 1(2) of the Act.

## **EU Alignment Consideration**

Across the EU there is variation in the requirements concerning the fortification of food and more generally across a range of domestic legislation. The Regulations provide for longstanding domestic measures in Scotland on the fortification of flour and as such will not have an impact on the Scottish Government's policy to maintain alignment with the EU. However, revising the levels of calcium carbonate, iron, and niacin to align with the requirements set out in both EU and assimilated EU law supports the Scottish Government's policy to maintain alignment with the EU.

## **Consultation**

A full UK wide public consultation was held from 1 September 2022 to 23 November 2022 on the proposed amendments to the Regulations, including the fortification of non-wholemeal wheat flour with folic acid. The full summary of responses received from the UK wide consultation is available in the publication at <https://www.gov.uk/government/consultations/amending-the-bread-and-flour-regulations-1998-and-the-bread-and-flour-northern-ireland-regulations-1998/outcome/summary-of-responses-and-government-response#executive-summary>

A separate Scotland only consultation was also carried out from 19 August 2024 to 27 September 2024 on the implementation of the agreed amendments in order to seek additional information on costs and any potential issues specific to Scottish stakeholders. Although no Scottish specific issues were identified, some industry stakeholders raised a general concern about the implementation of the introduction of folic acid to flour. This concern centred on the implementation of the changes due to the volume of products affected by the policy proposals, and due to the fact both the composition and labelling for the products require to change simultaneously. In response, and to support implementation, a transitional period from December 2024 to December 2026 has been provided to enable businesses to act to phase in the changes and minimise cost as far as possible. The timescale also offers scope for businesses to coordinate changes as far as possible with their own labelling and packaging update cycles.

## **Impact Assessments**

An Impact Assessment was provided alongside the UK wide consultation when it was carried out. Subsequently a further Scottish specific Partial Business and Regulatory Impact Assessment was provided alongside the Scotland only consultation. Subsequent to that a full Business and Regulatory Impact Assessment (BRIA) has been carried out and accompanies this policy note.

The BRIA has been placed in the Scottish Parliament Information Centre.

A Child Rights and Wellbeing Impact Assessment (CRWIA) has been undertaken to consider the impact of the policy delivered by these Regulations on children's rights, summarising the potential for positive impact. The CRWIA for these Regulations concluded that the provisions of the Regulations would be compatible with the UNCRC requirements. A copy of the completed CRWIA accompanies this policy note.

A copy of the BRIA and the CRWIA may be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL and online at <https://www.legislation.gov.uk>.

## **Financial Effects**

The impact of this policy on business is anticipated to be mainly an associated financial cost for updating packaging and labelling due to the introduction of folic acid to the fortification requirements for flour. This includes potential packaging waste due to businesses having to discard any labelling/packaging which does not reflect the composition of the food product once folic acid is added. There will also be some familiarisation costs due to businesses and local authorities having to take time to properly understand the legislative requirements.

Food Standards Scotland  
12 December 2024

## **Annexe B: Correspondence from the Minister for Public Health and Women's Health**

20 December 2024

Dear Convener

The Bread and Flour Amendment (Scotland) Regulations 2024

(The Amendment of the Bread and Flour Regulations 1998 and the implementation of the mandatory fortification of flour with folic acid)

As you are aware, Scottish Ministers have long advocated for the mandatory fortification of flour with folic acid to help prevent foetal neural tube defects (NTDs), such as spina bifida. There is strong evidence that many NTDs can be prevented by women increasing their intake of folic acid, prior to conception and until the 12th week of pregnancy.

I am pleased to update that legislation has been laid today for the fortification of non-wholemeal wheat flour with folic acid. There are around 1,000 NTD affected pregnancies each year in the UK. The new requirements will help to prevent around 200 babies being born with life-changing brain and spinal conditions.

Flour is already fortified with calcium, thiamin, niacin and iron for public health reasons. The addition of folic acid is a significant step in our efforts to improve public health outcomes for women and their babies.

Existing advice is for women trying to conceive or newly pregnant to take a daily 400 microgram supplement of folic acid prior to and up until the 12th week of pregnancy. This advice will continue as fortification is intended to supplement, not replace that advice. It is there to help, particularly with unplanned pregnancies where a woman may not find out she is pregnant until well into the crucial window when the neural tube is forming.

Reducing the prevalence of unplanned pregnancy and increasing preparation for pregnancy, through preventative actions such as folic acid supplementation, is an area that the Scottish Government is separately focussing on as part of our collective efforts to improve [early child development](#). As part of that work, we have developed content and combined advice for individuals [planning a pregnancy](#) on NHS Inform, which launched in late 2023.

The development of the UK wide policy to fortify flour with folic acid has been a close collaboration with Food Standards Scotland, as well as the UK Government and devolved administrations in Wales and Northern Ireland. Legislation has been laid in England and Northern Ireland, and Wales also intend to lay similar legislation soon. There will be a transition period for industry to implement the changes, with the legislation due to come into effect across all four nations by end December 2026.

**HSCS/S6/25/3/1**

Food Standards Scotland and the Scottish Government will continue to engage with industry during the transition period to support them to make the required changes.

Yours sincerely,

Jenni Minto MSP