



IPH response to consultation on Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998

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Key Points

1. We support mandatory fortification with folic acid and would recommend this is implemented as soon as possible

For more than thirty years, scientific evidence has been unequivocal that folic acid supplementation prior to conception reduces the risk of neural tube defects (NTDs), such as spina bifida, anencephaly or encephalocele, by up to 70%.^{1,2} NTDs are major malformations that occur in early pregnancy, and lead to serious, long-term conditions associated with substantial harms for individuals and their families, as well as wider societal costs as these conditions require a high level of complex service response.

Mandatory fortification of flour with folic acid has been introduced in approximately 80 countries worldwide, with considerable population health benefits achieved. For example, in Europe (where mandatory fortification of flour has not been introduced) research has shown that prevalence of NTDs between 1991 and 2011 remained static (~0.91 per 1000 births)³. In comparison, prevalence rates in Canada, where mandatory fortification of flour has been introduced, have reduced substantially from 1.58 per 1,000 births before fortification to 0.86 per 1,000 births after fortification⁴.

There is convincing evidence that this measure will reduce the incidence of neural tube defects in the UK⁵ and so, we recommend this is implemented on a mandatory basis as soon as possible but no later than the 24-month period outlined in the consultation document.

Research has been undertaken to identify key facilitators in the implementation of folic acid fortification in countries across the world. The following facilitators and barriers have been identified:

Facilitators:

- strong advocacy by fortification champions
- research capacity
- partnership working between public and private agencies, academia and civil society.

Barriers:

- lack of political will
- poor monitoring and quality control
- low compliance from the food industry⁶.

¹ Czeizel A, Dudas I. Prevention of the first occurrence of neural tube defects by periconceptional vitamin saupplementation, *N Engl J Med*, 1992, vol. 327 (pg. 1832-5)

² MRC Vitamin Study Research Group. Prevention of neural tube defects: results of the Medical Research Council vitamin study. *Lancet*. (1991) 338:131-7. doi: 10.1016/0140-6736(91)90133-A

³ Khoshnood B, Loane M, de Walle H, Arriola L, Addor MC, Barisic I, et al. Long term trends in prevalence of neural tube defects in Europe: population based study. *BMJ*. (2015) 351:h5949. doi: 10.1136/bmj.h5949

⁴ De Wals P, Tairou F, Van Allen MI, Uh SH, Lowry RB, Sibbald B, et al. Reduction in neural-tube defects after folic acid fortification in Canada. *N Engl J Med*. (2007) 357:135-42. doi: 10.1056/NEJMoa067103

⁵ Morris JK, Rankin J, Draper ES, Kurinczuk JJ, Springett A, Tucker D, Wellesley D, Wreyford B, Wald NJ. Prevention of neural tube defects in the UK: a missed opportunity. *Arch Dis Child*.

⁶ Kancherla et al. A global update on the status of prevention of folic acid preventable spina bifida and anencephaly in year 2020: 30-Year anniversary of gaining knowledge about folic acid's prevention potential for neural tube defects. *Birth Defects Research*. 2022;1-12.

2. Investment in monitoring and evaluation is needed from the outset, with the establishment of a national register for congenital anomalies in each jurisdiction, including Northern Ireland

We welcome the commitment to develop a programme for monitoring and evaluation. Investment in evaluation from the start will provide essential data needed to monitor the impact of fortification on health outcomes across the population and in vulnerable groups. Monitoring at defined, regular intervals will help to ensure that all health benefits and potential adverse effects are being captured in the UK and by each devolved administration to inform decision making.

We would welcome further detail on how folic acid fortification will be monitored. Whilst there is mention of *'ongoing costs associated with monitoring folic acid intake and blood folate levels'*⁷, no further information is provided. At present, the impact assessment only highlights the National Diet and Nutrition Survey (NDNS) as a source of information to monitor health impacts, and this does not include monitoring of folic acid intake.

We recommend the development of a UK-wide monitoring framework with oversight from the four UK CMOs to inform decision-making, as well as the establishment of a national register for congenital anomalies in each jurisdiction, including Northern Ireland. This should include and feed into health inequalities monitoring, and so, where possible, data should be collected on age, socioeconomic status and ethnicity. This data will indicate which population sub-groups may or may not be reached by the measure.

We recommend mandatory monitoring of the following outcomes:

✓ *Fortification levels within the end-product*

Levels of folic acid present within the end-product need to be measured. It will be prudent to be certain of the folic acid dose present in the end-product to ensure that evaluation findings are accurate and that producers are complying with the folic acid levels stated by the regulations. Compliance data from Chile found that, in flour samples tested for folic acid, levels ranged from undetectable to a level that was 28 times higher than the recommended maximum. Continuous monitoring, therefore, will be needed to ensure that all products contain sufficient levels of folic acid, and are safe to consume. This is essential from a safety and quality perspective, to prevent under or over-dosing of the product, and to improve the accuracy of evaluation findings⁹.

✓ *Serum folate and red cell folate across the population and in women of childbearing age*

This data will be essential to inform the evaluation of fortification on health; for example, as to whether greater health benefits could be derived at a higher dose, or if the policy is having any adverse effects.

⁷ Fortification of flour with folic acid: impact assessment (publishing.service.gov.uk)

⁸ Peake, JN, Knowles, RL, Shawe, J, Rankin, J, Copp, AJ. Maternal ethnicity and the prevalence of British pregnancies affected by neural tube defects. Birth Defects Research. 2021; 113: 968– 980. <https://doi.org/10.1002/bdr2.1893>

⁹ Kancherla et al. A global update on the status of prevention of folic acid preventable spina bifida and anencephaly in year 2020: 30-Year anniversary of gaining knowledge about folic acid's prevention potential for neural tube defects. Birth Defects Research. 2022;1-12.

We recommend that the following biochemical measurements are taken to support the evaluation of this policy:

- Measurement of population serum folate and red cell folate at regular intervals among women of reproductive age (at least every 5 years)
- Measurement of red cell folate and serum folate in women of a childbearing age at routine antenatal appointments

When collecting this data, it would be useful to include additional data such as age, ethnicity and socioeconomic status to evaluate the impact of fortification in different sub-groups of the population.

✓ *Uptake of folic acid supplements in women of childbearing age*

Dietary modification alone is not considered sufficient for risk reduction, which is why a comprehensive approach including folic acid supplements and fortified foods is necessary. Whilst folic acid supplements during pre-conception and the first trimester are recommended, the proportion of women who take this supplement is relatively low, with estimates ranging from 10.4-35%. This may be due to a lack of awareness, financial barriers or other reasons, but it reinforces the importance of fortification.

Prevention of NTDs requires a comprehensive approach, and fortification of food is only one of a suite of measures required. At present there is a need for access to information on uptake of folate supplements, and so we recommend that the following information is collected across devolved administrations:

1. Uptake of folic acid supplements in women of childbearing age
2. Duration of supplementation prior to conception, and during the first trimester
3. Barriers to supplementation

The re-establishment of the annual Infant Feeding Survey could be a useful mechanism to collect this data. GP prescribing data and pharmacy dispensing data would also be useful to monitor, particularly for women who are at higher risk for NTDs.

✓ *Incidence and prevalence of NTDs in the UK and Ireland*

In order to evaluate the effectiveness of fortification, accurate and timely surveillance data on incidence (new cases) and prevalence (existing cases) of NTDs, across the UK and in each devolved administration, is needed. This should include all affected pregnancies, such as those resulting in still birth or elective termination after prenatal diagnosis. Current information systems do not support this, which provides challenges in quantifying the true burden of NTDs on population health and may hinder any evaluation of these regulations.

Within the UK and Ireland, several regional registries for congenital anomalies exist, however there is no national registry. A summary of existing registries is displayed in Table 1:

	Registry	Prevalence rates per year (per 10,000 births) between 2000-2019
England	National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)	12.16 ¹²
Scotland	Scottish Linked Routine Data Congenital Anomaly Register/Congenital Conditions and Rare Diseases Registration & Information Service for Scotland (CARDRISS)	10.3 ¹³
Wales	Congenital Anomaly Register and Information Service (CARIS)	13.89 ¹⁴
Northern Ireland	None	NA
Europe	European network of Congenital Anomaly Registries (EUROCAT)	9.83 ¹⁵
Ireland	Cork & Kerry South East Ireland	8.52 ¹⁶

Caution should be taken when comparing prevalence rates, as the population included in each registry differs between jurisdictions. For example, the registry in Ireland only includes a selection of regions and may not be representative of the national prevalence rate.

We recommend that the government invests in the establishment of a UK-wide national register on congenital anomalies which should contribute to EUROCAT. This should supplement existing regional registries, including a dedicated national registry for Northern Ireland.

¹² [Prevalence charts and tables | EU RD Platform \(europa.eu\)](#) NTD Prevalence per 10,000 births. 2000 to 2019 - East Midlands & South Yorkshire (United Kingdom), Northern England (United Kingdom), South West England (United Kingdom), Thames Valley (United Kingdom), Wessex (United Kingdom), West Midlands (United Kingdom), Yorkshire and Humber (United Kingdom) - Excluding genetic anomalies

¹³ [Congenital anomalies in Scotland - 2000 to 2019 - Congenital anomalies in Scotland - Publications - Public Health Scotland](#) pregnancies ending in years 2000-19 including live birth (any gestation), spontaneous still birth (>=24 weeks), spontaneous late fetal loss (20-23 weeks) and termination of pregnancy (any gestation)

¹⁴ [Prevalence charts and tables | EU RD Platform \(europa.eu\)](#) NTD Prevalence per 10,000 births. 2000 to 2019 - Wales (United Kingdom) - Excluding genetic anomalies

¹⁵ [Prevalence charts and tables | EU RD Platform \(europa.eu\)](#) NTD Prevalence per 10,000 births. 2000 to 2019 - All full registries - Excluding genetic anomalies

¹⁶ [Prevalence charts and tables | EU RD Platform \(europa.eu\)](#) NTD Prevalence per 10,000 births. 2000 to 2019 - Cork and Kerry (Ireland), Dublin (Ireland), SE Ireland (Ireland) - Excluding genetic anomalies

There is no formal estimate of NTD incidence or prevalence in Northern Ireland due to the absence of validated registry data. However, in 2019, data on NTDs was shared with IPH by the Department of Health NI Hospital Information Branch (Information & Analysis Directorate). This data captured the number of individual birth admissions where there was a diagnosis of a NTD between 2009 and 2018 in Northern Ireland, and is displayed in Table 2. Please see notes of interpretation for further detail.

Table 2: Number of Individuals Admitted ^(1,2) to HSCT Hospitals in Northern Ireland where there was a diagnosis of Neural Tube Defects ^(3,4,5) 2009 – 2018^P

Number of birth admissions with Neural Tube Defects	Live Birth	Still Birth
2018^P	48	6
2017	49	<5
2016	39	<5
2015	35	<5
2014	38	<5
2013	28	-
2012	24	<5
2011	24	<5
2010	29	<5
2009	22	<5

Source: Hospital Inpatient System, Hospital Information Branch, Information & Analysis Directorate, Department of Health, NI

Notes of interpretation

- ^P Due to a lag in clinical coding, 2018 data is provisional.
- ¹ Admissions are approximated through deaths and discharges. Figures will not include admissions to mental health facilities.
- ² In this dataset only an individual's birth admission has been counted, where age of infant is less than 1 day. As such, diagnosis of NTD must have occurred on or before, day of birth.
- ³ Individuals may have more than one neural tube defect.
- ⁴ Cell counts of 1-4 have been replaced by '<5' to protect patient confidentiality.
- ⁵ The below table details the ICD-10 Codes used to identify individuals with neural tube defects in any of the recorded diagnosis fields.

ICD-10 Description	ICD-10 Coding
Anencephaly	Q00
Encephalocele	Q01
Microcephaly	Q02
Congenital Hydrocephalus	Q03
Other Congenital Malformations of Brain	Q04
Spina Bifida	Q05
Other Congenital Malformations of Spinal Cord	Q06
Other Congenital Malformations of Nervous System	Q07

Using the hospital admission data provided as a proxy indicator for NTD incidence, we concluded that:

- Recorded cases of neural tube defects in Northern Ireland are increasing over time
- Recorded cases are likely to represent a minority of the total cases
- Increases in recorded cases occurred at a time when the birth rate was decreasing

We are not aware of any significant changes in case detection practices over this period. Taken as a whole, the pattern is suggestive of either static or rising incidence in Northern Ireland. We have not presented a comprehensive analysis and recommend further epidemiological investigation on this matter. However, the pattern suggests that prevention measures applied over the past decade have failed to drive reductions in incidence over time, a conclusion also reached by a recent analysis of UK data¹⁷. It is estimated that had mandatory fortification been introduced in 1998 (the year of introduction of the Northern Ireland Bread and Flour Regulations) at the level used in the United States of America, there would have been 64 fewer babies born with NTDs in Northern Ireland by the year 2012¹⁸.

This data is likely an underrepresentation of the true incidence of NTDs, due to the lack of a registry, but also the absence of abortion services and data on the termination of pregnancy for fetal anomaly over this time period. European studies suggest that termination of pregnancy for congenital anomaly may be three times more frequent than infant deaths and stillbirths associated with congenital anomaly combined¹⁹.

¹⁷ Morris JK, Rankin J, Draper ES, Kurinczuk JJ, Springett A, Tucker D, Wellesley D, Wreyford B, Wald NJ. Prevention of neural tube defects in the UK: a missed opportunity. *Arch Dis Child*. 2016 Jul;101(7):604-7. doi: 10.1136/archdischild-2015-309226. Epub 2015 Dec 17. PMID: 26681697; PMCID: PMC4941168.

¹⁸ Morris JK, Rankin J, Draper ES, Kurinczuk JJ, Springett A, Tucker D, Wellesley D, Wreyford B, Wald NJ. Prevention of neural tube defects in the UK: a missed opportunity. *Arch Dis Child*. 2016 Jul;101(7):604-7. doi: 10.1136/archdischild-2015-309226. Epub 2015 Dec 17. PMID: 26681697; PMCID: PMC4941168.

¹⁹ Boyle B, Addor M, Arriola L, et al (2018) Estimating Global Burden of Disease due to congenital anomaly: an analysis of European data. *Archives of Disease in Childhood - Fetal and Neonatal Edition* 2018;103:F22-F28

Wider societal impacts of NTD-affected pregnancies

Prevention of NTD-affected pregnancies could hold substantial cost savings for the Northern Ireland health and social care service. NTD-affected pregnancies incur high costs, from direct expenditure on healthcare for women and affected individuals as well as costs to wider society through lost human capital²⁰. The impact assessment supporting the 2019 consultation estimated a direct health gain benefit of just under £3m per fatal NTD avoided²¹. It would be of benefit to have estimates of costs saved through folic acid fortification within each nation, particularly given the cost-of-living crisis. Trends on monetary and non-monetary costs, such as the harms experienced by families, employers and wider society, should also be examined including:

a) parental mental health and wellbeing and ability to remain in employment, as research has demonstrated parents living with children diagnosed with a NTD can experience psychological stress impacting on their everyday life²².

(b) estimates of costs associated with disability, educational and healthcare needs for children living with an NTD.

3. We remain concerned that exemptions to fortification may attenuate the impact on health and could widen health inequalities. If exemptions are put in place, measures must be taken to adequately support women who may not derive the benefit of fortification

Our position during the 2019 consultation on folic acid fortification was that mandatory fortification with folic acid should apply to all flour in the UK including other non-wheat products such as 'gluten free'. The Institute remains concerned regarding exemptions to fortification and suggests that all women of childbearing age should have the opportunity to benefit from the full preventative potential of mandatory fortification.

Population demographics have changed substantially since commencement of the Bread and Flour Regulations in 1998. Food consumption is highly dynamic, which is reflected in the demand for choice and wide range of flour available to consumers. This shift in demand may be due to increased awareness of the health benefits of wholemeal food products, cultural differences or medical requirements, for example for those with gluten intolerances. Not all women consume non-wholemeal flour as part of their diet, and so the potential exists for subgroups of women to be disadvantaged by the proposed exemptions. This may be amplified by increasing globalisation and immigration, with global pressures such as international conflict (for example, the war in Ukraine) and climate change leading to migration, predominantly of women and children, to countries including the UK and Ireland.

The Department for Environment, Food and Rural Affairs (DEFRA) may wish to undertake a Health Impact Assessment (HIA) to assess the potential impact of the proposed exemptions on population health. HIA is used to determine the impact of proposed policies, laws, programmes or plans on the health of communities to ensure they are more inclusive, more equitable, and more sustainable for everyone. The Institute recently launched

²⁰ Yi, Y., M. Lindemann, A. Colligs, et al. 2011. Economic burden of neural tube defects and impact of prevention with folic acid: a literature review. *Eur. J. Pediatr.* 170: 1391–1400.

²¹ Fortification of flour with folic acid: impact assessment (publishing.service.gov.uk)

²² Abichandani, D & Shah, R 2015, 'Psychological Problems in Parents of Children with Spina Bifida', *International Journal of Science and Research*, vol. 4, no. 9, pp. 1183-1188.

guidance on HIA which can be accessed on the [IPH website](#). If the decision is taken to proceed with the exemptions listed, steps need to be taken to inform women who may not benefit from the measure. A public communications campaign to highlight the benefits of folic acid in the prevention of NTDs and to launch the revised regulations could explicitly outline the scope of the policy- for example, that it will only impact non-wholemeal flour- to inform consumer decision-making.

4. Implementation bodies in Northern Ireland may require additional support and resource due to challenges posed by the NI protocol.

Northern Ireland has a lot to gain from mandatory folic acid fortification. There are several factors which may contribute to higher risk of NTD-affected pregnancies including:

- higher levels of social deprivation in Northern Ireland compared to many other regions of the United Kingdom – a factor increasing population risk²³
- evidence of a less nutritious diet among women of childbearing age in Northern Ireland compared to most other regions of the UK²⁴
- evidence of lower serum folate levels among women of childbearing age, indicating a lower level of protection²⁵

However, Northern Ireland also faces substantial challenges due to uncertainty surrounding the NI protocol and Windsor Framework. The consultation indicates that, due to mutual recognition arrangements with the EU single market, millers in Northern Ireland could act as key suppliers of unfortified flour for exempt products for the wider UK. There is the potential for cross-border trade of fortified products to benefit the population in Ireland, where mandatory fortification legislation is not in place. It is imperative that millers in Northern Ireland are encouraged to implement fortification rather than provide a market for unfortified products because of the unique trade arrangements in place.

It is likely that additional resource and support will be required to support the implementation process, and to ensure that external constraints do not hinder the impact of fortification on the local population.

5. A strategic, comprehensive approach is needed to prevent NTD-affected pregnancies. This should sit within a wider cross-departmental governance framework, with annual reporting to the Department of Health in each jurisdiction and bolstered by North South East West collaboration

The amendment of these regulations provides a window of opportunity for governments to adopt a more strategic and comprehensive approach to the prevention of NTD-affected pregnancies. Ideally, fortification with folic acid should act as one public health measure

²³ Abel GA, Barclay ME, Payne RA (2016) Adjusted indices of multiple deprivation to enable comparisons within and between constituent countries of the UK including an illustration using mortality rates. *BMJ Open*, 6 (11), [e012750]. <https://doi.org/10.1136/bmjopen-2016-012750>

²⁴ https://webarchive.nationalarchives.gov.uk/ukgwa/20200803152403/https://www.food.gov.uk/sites/default/files/media/document/national-diet-and-nutrition-survey-northern-ireland-y5-9-executive-summary_0.pdf

²⁵ Public Health England (2017) National Diet and Nutrition Survey Rolling Programme (NDNS RP) Supplementary report: blood folate results for the UK as a whole, Scotland, Northern Ireland (Years 1 to 4 combined) and Wales (Years 2 to 5 combined) A survey carried out on behalf of Public Health England, Food Standards Scotland, the Food Standards Agency in Northern Ireland and the Food Standards Agency in Wales Revised November 2017. Prepared by: Beverley Bates, Polly Page, Lorna Cox, Sonja Nicholson, Caireen Roberts, David Collins, Nida Ziauddeen, Toni Steer, Chris Bates, Prentice, A. Swan, G Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/661932/National_Diet_and_Nutrition_Survey_Rolling_Programme__NDNS_RP_.pdf

within a wider cross-departmental strategy and action plan on preventing congenital birth defects. Within any new strategy, there is a need to ensure that all women, individuals and families have access to comprehensive, multidisciplinary healthcare and support; from diagnosis, in the event of a pregnancy loss or bereavement and postnatally.

Any new strategy should be governed by an interdepartmental fortification oversight group in each jurisdiction. In Northern Ireland, this should include the Department of Health and Department for Agriculture, Environment and Rural Affairs. This strategy should also harmonise with related policies, such as those relating to maternal health. A new strategy for maternity care in Northern Ireland is due, with the current strategy running until 2018²⁶. There may be economies of scale in coinciding the development of a new maternity strategy with the introduction of mandatory fortification in Northern Ireland and a potential new strategy on preventing congenital birth defects, as both will likely benefit from similar actions such as improved information infrastructure and data collection.

Data collected from the evaluation of this policy should be presented to the Minister for Health and CMO in all four jurisdictions at regular intervals (at least annually) to inform decision-making, and should include at a minimum:

- Serum folate and red cell folate levels across the population and in women of childbearing age
- Uptake of folic acid supplements in women of a childbearing age
- National data on incidence and prevalence of NTDs
- Impact on health inequalities

A North South approach to prevention of NTDs on the island of Ireland would provide economy of scale, and whilst fortification laws differ in the two jurisdictions, an all-island memorandum of understanding (MOU) could be put in place to encourage cooperation on this shared public health challenge.



²⁶ [A Strategy for Maternity Care in Northern Ireland 2012 - 2018 \(health-ni.gov.uk\)](https://www.health-ni.gov.uk/publications/a-strategy-for-maternity-care-in-northern-ireland-2012-2018)

Collaboration with public health and academic experts on folic acid will be key to support implementation; for example, to inform revised product labelling to accurately reflect health benefits. The consultation document currently outlines that it is industry stakeholders who will shape the design of evaluation processes, with an emphasis on the clarity and consistency of the amended regulations for those working in the industry. From a population health perspective, the evaluation of this policy would be optimised if it was extended to include consultation with expert stakeholders from a public health background, as well as health care professionals and academics with specialist expertise.







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