From: [redacted S.38(1)(b)]
Sent: 02 October 2024 15:58
To: Minister for Public Health and Women's Health [redacted S.38(1)(b)]
Cc: [redacted S.38(1)(b)] David Hutchison [redacted S.38(1)(b)]; Kate Higgins [redacted S.38(1)(b)]; Richard Foggo [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; George Burgess [redacted S.38(1)(b)]; Alice Biggins [redacted S.38(1)(b)]; Ashley Cooke [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; Heather Kelman [redacted S.38(1)(b)]; Geoff Ogle [redacted S.38(1)(b)]; Ian McWatt [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; FSS Communications Mailbox [redacted S.38(1)(b[redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; Communications Health and Social Care [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; [redacted S.38(1)(b)]; Communications Net Zero, Energy and Rural Affairs [redacted S.38(1)(b)]; Cabinet Secretary for Transport, Net Zero & Just Transition [redacted S.38(1)(b)]; [redacted S.38(1)(b)]

Subject: OFFICIAL: SENSITIVE FSS - Regulated Products - Information Note on the Publication of Risk Assessment for Titanium Dioxide

P/S Minister for Public Health and Women's Health

Timing – Routine, for information only – no action or decision required

Issue
Food Standards Scotland (FSS) are writing to inform the Minister that further to [redacted S.38(1)(b)] submission on the 20th of August 2024, regarding the UK's Independent Scientific Committees risk assessment on the food additive titanium dioxide (E 171), the full Risk Assessment has now been published.

Titanium Dioxide Science Summary for Ministerial Submission
In 2021 the European Food Safety Authority reviewed the safety of Titanium dioxide (E171, TiO_2) as a food additive. Their review found that it could no longer be considered safe, which led to a decision by the EU to implement a forthcoming ban on its use in food.

In response to this, and as part of the UK risk analysis process, FSS and the FSA worked with the independent Scientific Advisory Committees, the Committee on Toxicology (COM) and the Committee on Mutagenicity (COM) to review the safety of this additive. The conclusion of the risk assessment is that it is unlikely that there would be a risk to health from current UK dietary exposures of food-grade E171 TiO_2.

The conclusion of the UK risk assessment is in line with other international regulators and organisations, including Health Canada, Food Standards Australia New Zealand

and JECFA (Joint FAO/WHO Expert Committee on Food Additives). The conclusions are different from those found by EFSA, which considered evidence from studies that contained **non food-grade TiO_2,** including material containing a greater fraction of nanoparticles (which are thought to present a health risk). The UK assessment focused on studies assessing food-grade TiO_2.

FSS will update the Minister further with risk management advice in due course.

Kind Regards

[redacted S.38(1)(b)]
Policy Advisor– Regulated Products
Food Standards Scotland
Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL
[redacted S.38(1)(b)]
[redacted S.38(1)(b)]
www.foodstandards.gov.scot

UK Health Security Agency

EPHPB 24-36a

Environmental Public Health Programme Board

Title of meeting	Environmental Public Health Programme Board
Date	10 October 2024
Presenter	N/A – prepared by [Redacted - Section 38(1)(b)]
Title of paper	COC, COM and COT Report for EPHPB: covering July to October 2024

1. Purpose of the paper

1.1 This paper and Annex (EPHPB 24-41b) are provided for information to update the Environmental Public Health Programme Board of the activities of the Committees on Carcinogenicity, Mutagenicity and Toxicity of Chemicals in Food, Consumer Products and the Environment (COC, COM and COT).

2. Recommendation

2.1 This paper is for information. Feedback from members of the Board is requested:

2.1.1 comments on any of the items

3. Recent relevant COC, COM or COT publications

3.1 **COM statement on Titanium Dioxide** (publication due week commencing 7th October 2024): The COM has reviewed the available literature of in vivo and in vitro genotoxicity studies, and concluded there is little evidence that titanium dioxide is genotoxic. There is however a dearth of high-quality data and OECD compliant studies, making assessment difficult. The conclusion that there is limited evidence of genotoxicity in the in vitro and in vivo studies is a departure from evaluations by the European Food Safety Authority (EFSA) – that is significant for wider chemical regulation interest.

3.2 **COT statement on Titanium Dioxide**: The COT has considered food grade titanium dioxide and the evidence for a number of endpoints of concern. It has noted that while there are uncertainties in the toxicity of nano-sized titanium dioxide, food grade titanium dioxide is larger to achieve its function as an opacifier and white pigment. Overall, the COT has concluded that it is unlikely there would be a risk to health from currently UK dietary exposures to food grade titanium dioxide (food additive E171).

3.3 [Redacted - Ouit of Scope] [redacted].

4. Background

4.1 COC, COM and COT are independent advisory committee sponsored by DHSC and FSA, UKHSA provide the scientific secretariat jointly with FSA. These reports provide a short summary of the key agenda items and issues discussed by the Committees.

4.2 The Committees' roles are to provide advice to Government Departments and Agencies, and assess and advise on the carcinogenic, mutagenic and toxic risks of substances in food, consumer products or present in the environment, and to advise on general principles and scientific developments within their respective fields.

[Redacted - Section 38(1)(b)] **, General Toxicology and Biomonitoring Programme**

COC, COM and COT Report for EPHPB: covering July to October 2024

[Redacted - Out of Scope]

[Redacted - Out of Scope]

[Redacted - Out of Scope]

COM publication

Statement on Titanium dioxide

This statement is due to be published in the week commencing 7th October 2024.

The COM has reviewed the available literature of in vivo and in vitro genotoxicity studies, and concluded there is little evidence that titanium dioxide is genotoxic. There is however a dearth of high-quality data and OECD compliant studies, making assessment difficult.

The conclusion that there is limited evidence of genotoxicity in the in vitro and in vivo studies is a departure from evaluations by the European Food Safety Authority – that is significant for wider chemical regulation interest.

[Redacted - Out of Scope]

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[redacted]

COT publications

Statement on Titanium dioxide

The COT has reviewed the available literature for food grade titanium dioxide on the absorption, distribution, metabolism and excretion, and toxicity endpoints of concern relating to aberrant crypt foci as a marker of carcinogenicity, inflammation and immunotoxicity, reproductive and developmental effects and neurotoxicity.

The COT noted that the function of food grade titanium dioxide is as an opacifier and white pigment and to achieve this function it is important for it to exist as an aggregate of primary particles of approximated 200-300nm. Engineered nano-titanium dioxide where particles are less than 100nm will not achieve the required function. While there are uncertainties over the toxicological effects of titanium dioxide nanoparticles, the COT review focussed on food grade titanium dioxide.

The COT was informed of the COM review outlined above, and factored this in to its conclusion.

Overall, the COT has concluded that it is unlikely there would be a risk to health from currently UK dietary exposures to food grade titanium dioxide (food additive E171).

The executive summary of the statement is available:
https://cot.food.gov.uk/COT%20Statement%20on%20the%20Safety%20of%20Titanium%20dioxide%20(E171)%20as%20a%20Food%20Additive%20-%20Executive%20Summary

The statement is available:
https://cot.food.gov.uk/Statement%20on%20the%20safety%20of%20Titanium%20Dioxide%20(E171)%20as%20a%20Food%20Additive

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[redacted]

[redacted]

[redacted]

[redacted]

[Redacted - Sect on 38 (1)(b)]
COC and COT Assessor
COM Scientific Secretary
04 October 2024

[Redacted - Sect on 38 (1)(b)]
COC and COT Scientific Secretary

Annex A

Information requested

Titanium dioxide	
1a	Regulated Products - Information Note on the Publication of Risk Assessment for Titanium Dioxide – 02/10/2024 (Attached separately)
1b	Statement on the safety of Titanium Dioxide (E171) as a Food Additive | Committee on Toxicity https://cot.food.gov.uk/Statement%20on%20the%20safety%20of%20Titanium%20Dioxide%20%28E171%29%20as%20a%20Food%20Additive.
2	Environmental Public Health Programme Board – Update paper – October 2024 (Attached separately)
3	COC, COM and COT Report for EPHPB: covering July to October 2024 (Attached separately)
4	Statement on the COM assessment of in vitro and in vivo genotoxicity of titanium dioxide –Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment October 2024 https://www.gov.uk/government/publications/statement-on-the-com-assessment-of-in-vitro-and-in-vivo-genotoxicity-of-titanium-dioxide/statement-on-the-com-assessment-of-in-vitro-and-in-vivo-genotoxicity-of-titanium-dioxide
Folic acid	
5	Stochastic modelling to estimate the potential impact of fortification of flour with folic acid in the UK - Food Standards Scotland https://www.foodstandards.gov.scot/downloads/STOCHASTIC_MODELLING_TO_ESTIMATE_THE_POTENTIAL_IMPACT_OF_FORTIFICATION_OF_FLOUR_WITH_FOLIC_ACID_IN_THE_UK_-_FINAL_REPORT_-_July_31_2017.pdf
6	Folic acid fortification for the reduction of neural tube defects - Food Standards Scotland Board paper – August 2017 https://www.foodstandards.gov.scot/about-us/how-we-work/governance/fss-board-meeting-16-august-2017
7	UK-wide consultation - Folic Acid Impact Assessment Final Draft https://www.legislation.gov.uk/uksi/2024/1162/pdfs/uksiod_20241162_en_001.pdf
8	Bread and Flour Regulations Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 – Final consultation paper https://consult.defra.gov.uk/food-compositional-standards/bread-and-flour-consultation-2022/
9	Bread and Flour Regulations Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 – Consultation feedback and joint response 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#:~:text=The%20consultation%20covering%20the%20wider,calcium%20carbonate%20added%20to%20flour
10	Folic acid - Mandatory fortification of flour with folic acid -Submission - Routine - Options for implementation - 2 December 2021 (Attached separately)
11	The Bread and Flour Amendment (Scotland) Regulations 2024: Business and Regulatory Impact Assessment (BRIA) – Food Standards Scotland https://www.legislation.gov.uk/ssi/2024/387/pdfs/ssifia_20240387_en_001.pdf
12	Child Rights and Wellbeing Impact Assessment (CRWIA) for the Bread and Flour Amendment (Scotland) Regulations 2024 – Food Standards Scotland https://www.legislation.gov.uk/ssi/2024/387/pdfs/ssiod_20240387_en_001.pdf
13	Folic Acid and the Prevention of Disease - Report of the Committee on Medical - 2000
14.	Folate and Disease Prevention - SACN - 2006
15	SACN Report to CMO on folic acid and colorectal cancer risk
16	Update on folic acid - SACN - 2017
17	Folic Acid – Statement on the Tolerable Upper Level (TUL) - Committee on Toxicity - 2019
18	Lay summary Folic Acid – Statement on the Tolerable Upper Level (TUL) - Committee on Toxicity - 2019
19	Folic Acid Risk Assessment | Committee on Toxicity - 2023
20.	NDNS blood folate supplementary report
21	2019 - UK wide public consultation on the proposal for mandatory fortification of flour with folic acid.
22	2021 - Publication of the UK wide consultation response and announcement to proceed with legislation as part of wider Bread and Flour Regulations review to implement mandatory fortification with folic acid.

From: [redacted S.38(1)(b)]
Diet and Healthy Weight Team
02 December 2021

Minister for Public Health, Women's Health and Sport

MANDATORY FORTIFICATION OF FLOUR WITH FOLIC ACID - OPTIONS FOR FORTIFICATION

Purpose

[redacted – out of scope]

Priority

1. [redacted – out of scope]

Background

2. [redacted – out of scope]

3. [redacted – out of scope]

4. [redacted – out of scope].

[redacted – out of scope]

[redacted – out of scope]

5. [redacted – out of scope].

6. [redacted – out of scope].

Balancing the 'tolerable upper limit' (TUL) of folic acid against a meaningful reduction of NTDs

7. Food Standards Scotland (FSS) previously modelled the potential impact of the fortification of flour at different levels, both **with** capping and **without** capping restrictions of other dietary sources, including supplements, spreads and breakfast cereals. Further data from the FSS modelling, which was used to inform development of the options, is at **Annex A.**

8. Officials in the Office for Health Improvement and Disparities (which succeeded Public Health England) worked closely with FSS, Food Standards Agency (FSA) for NI and for Wales, to consider the required amount of folic acid per 100g of flour to achieve a meaningful decrease in the rate of NTDs. A key consideration was avoiding an unacceptable converse increase in the number of the general population exceeding the 1mg/day Tolerable Upper Level (TUL) advised by the Committee on Toxicity of Chemicals

in Food, Consumer Products and the Environment (COT). By exceeding the TUL, vitamin B12[1] deficiency in people over 65 may be masked by high folic acid levels.

Options

9. There are two ways in which we could proceed:

1) Mandating the fortification of non-wholemeal wheat flour **without placing a simultaneous restriction** (capping) on the voluntary fortification of other food and drink products (our recommended option)
2) Mandating the fortification of non-wholemeal wheat flour **alongside simultaneously restricting** voluntary fortification of supplements, breakfast cereals and spreads.

10. Both options would enable us to achieve our policy intention to help reduce the risk of NTDs. Pursuing option 1 would enable the policy to be implemented more quickly but would increase the risk of people exceeding the TUL. Close monitoring would be required to monitor folate and B12 levels and there would still be the opportunity after implementation to restrict voluntary fortification of supplements, breakfast cereals and spreads if required. The second option would reduce the risk of potential breaches of the TUL but would take significantly longer to implement. Our analysis of both options is set out in **Annex B**.

Position of Chief Medical Officers and Scientific Advisory Committee on Nutrition

11. On 15 October 2021, officials sought views from the four UK Chief Medical Officers (CMOs) on proposed options for implementation of mandatory fortification of flour with folic acid. The four UK CMOs confirmed that they were content to support non-restriction of voluntary fortification as set out in option 1. This was considered a pragmatic approach to ensure smooth and timely delivery of the policy.

12. The Scientific Advisory Committee on Nutrition (SACN), advisor to the four UK nations, has recommended in their reports on folic acid (most recently in 2017) that mandatory fortification of flour should be introduced to reduce NTDs alongside close monitoring of folic acid intakes and blood folate concentrations of the population. They also recommend that voluntary fortification should also be restricted.

13. On 10 November 2021, a paper with our recommended option for fortification was presented to SACN. The paper also contained a request seeking advice around monitoring pre and post-implementation. Overall, members were positive and pragmatic about the proposal. The majority also acknowledged that not restricting voluntary fortification would help ensure timely delivery of the policy and that this could be revisited in the future. However, some members raised concerns about the recommended option in respect to SACN's previous advice and in relation to how risk would be managed. Monitoring of voluntary fortification levels was agreed to be highly important. Officials will now consider the further advice provided by SACN on additional measures needed to ensure effective monitoring of the policy as it develops.

[1] Vitamin B12 is needed to make red blood cells and keep the body's nervous system healthy.

Monitoring

14. Both options would be accompanied by measures for monitoring folic acid intakes, blood folate and vitamin B12 concentrations of the population. This is to ensure there is not an unacceptable converse increase in the number of people in the general population exceeding the 1mg/day TUL (see **Annex A**), and preventing potential masking of vitamin B12 deficiency in older people. In addition to assessing the efficacy of the policy, through close monitoring and surveillance, there would be the option to later consider changing levels of fortificant and/or restricting voluntary fortification accordingly. We will return to Ministers in due course with further advice on how best to monitor these outcomes.

[redacted – out of scope]

15. [redacted – out of scope]

[redacted – out of scope]

16. [redacted – out of scope].

[redacted – out of scope]

17. [redacted – out of scope]

18. [redacted – out of scope]

19. [redacted – out of scope]

[redacted – out of scope]

20. **[redacted – out of scope]**

[redacted S.38(1)(b)]
Diet and Healthy Weight
2 December 2021

Copy List:	For Action	For Comments	For Information		
			Portfolio Interest	Constit Interest	General Awareness
Cabinet Secretary for Health and Social Care			X		
Cabinet Secretary for the Rural Affairs and Islands					X
Minister for Mental Wellbeing and Social Care					X
Minister for Business, Trade, Tourism and Enterprise					X

Chief Medical Officer
Director General Health and Social Care
Director of Population Health
Lord Advocate, Dorothy Bain QC
Solicitor General, Ruth Charteris QC
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[redacted S.38(1)(b)]
Geoff Ogle, Food Standards Scotland
[redacted S.38(1)(b)],
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[redacted S.38(1)(b)]
[redacted S.38(1)(b)]
David Hutchison, Special Advisor

ANNEX A

FOOD STANDARDS SCOTLAND (FSS) MODELLING

FSS Modelling for Option 1 – fortification of non-wholemeal wheat flour with no capping of voluntary fortification

Level of fortification per 100g of flour	People exceeding the TUL*	Reductions in NTD risk	Increased population daily intake
0 µg (micrograms)	0.417%	N/A	N/A
100 µg	0.476%	8-11%	39 µg
200 µg	0.545%	13-19%	78µg
250 µg	0.635%	15-22%	97 µg
300 µg	0.831%	17-25%	117 µg
350 µg	1.114%	19-28%	136 µg
450 µg	1.802%	23-32%	175 µg

*TUL – Tolerable Upper Limit

FSS Modelling for Option 2 – fortification of non-wholemeal wheat flour with folic acid with capping voluntary fortification of breakfast cereals, spreads, and supplements[2]

Level of fortification per 100g of flour	People exceeding the UL	Reductions in NTD risk	Increased population daily intake
0 µg	0.020%	N.A	-51µg
100 µg	0.034%	2-3%	-12µg
200 µg	0.059%	8-12%	27µg
250 µg	0.071%	11-16%	46µg
300 µg	0.102%	13-20%	66µg
350 µg	0.195%	16-22%	85µg
450 µg	0.539%	19-28%	124µg

FSS Modelling on the proportion of 14-49-year-old women beneath the Reference Nutrient Intake (RNI) of folic acid

Level of fortification per 100g of flour	No capping of voluntary fortification	Capping of voluntary fortification of breakfast cereals, spreads, supplements
0 µg	45.27%	60.75%
100 µg	28.70%	41.40%
200 µg	16.30%	24.51%
250 µg	12.59%	18.88%
300 µg	10.37%	15.72%
350 µg	9.50%	13.29%
450 µg	6.46%	9.13%

[2] The FSS modelling capped breakfast cereals at 15% of adult RNI per 100g (30µg/100g); capped spreads at 15% of adult RNI per 100g (30µg/100g); and capped supplements at 200µg/day (600µg/day for women aged 14-49 years)

FSS Modelling on the proportion of people aged 65 or more exceeding the Tolerable Upper Limit (TUL)

Level of fortification per 100g of flour	People exceeding the TUL aged 65 or older (no capping of voluntary fortification)	People exceeding the TUL aged 65 or older (capping of supplements only)[3]
0 µg	0.5%	0.5%
100 µg	0.7%	0.0%
200 µg	0.7%	0.0%
250 µg	0.7%	0.0%
300 µg	0.7%	0.0%
350 µg	0.7%	0.0%
450 µg	0.8%	0.1%

[3] The 2017 FSS modelling provided data on the proportion of over 65s exceeding the TUL according to no restriction on voluntary fortification and capping of supplements. Specific figures were not given for further restriction of cereals and spreads as well.

ANNEX B

OPTIONS ANALYSIS

Background

21. The mandatory fortification of flour with folic acid is an effective method for contributing to a reduction in the risk and number of Neural Tube Defect (NTD) affected pregnancies in the UK. Mandatory fortification would reach those with pregnancies that are unplanned and those women that do not take folic acid supplements before and during the first 12 weeks of pregnancy. The use of flour fortified with folic acid has been adopted in more than 60 countries world-wide, which have seen falls in the rates of NTDs.

22. The recent Public Health England and Food Standards Agency (FSA) National Diet and Nutrition Survey (NDNS) published in September, which covers the UK, found that mean intakes of folate have decreased compared to previous years, for all age groups except children under 11 years.[4] In particular, mean folate intake was 23 micrograms (µg) per day lower in women of childbearing age, increasing the risk of NTD-affected pregnancies. Modelling by Food Standards Scotland (FSS) in 2017 found that 45% of women aged 14-49 years were consuming less than the reference nutrient intake (RNI) for folic acid.[5] NDNS rolling data from 2016 to 2019 also found that in 2019, the number of women of childbearing age with a red blood cell folate concentration less than 748nmol/L (the level below which there is an increased risk of NTDs) was 89%, an increase of 20% since 2008.

OPTION 1 (recommended option): Enacting the requirements for the mandatory fortification of (non-wholemeal wheat flour) without placing a simultaneous restriction (capping) on the voluntary fortification of other food and drink products

23. We recommend a folic acid fortificant level of 250µg/100g of flour. This is based on FSS modelling (see **Annex A**) which shows:

a. This is the lowest amount of folic acid/100g that would support the four nations' policy in reducing NTDs by around 20% a year (15-22%) as announced. It is important to note that the FSS modelling had an uncertainty of +/- 20%, and so this reduction cannot be guaranteed.
b. The number of people exceeding the TUL would increase by around 0.2% (from 0.4% to 0.6%), while still increasing daily consumption of folic acid by around 97µg.

Timeline

24. We expect it will take around 18 months before we can commence the lead-in time (the period between the regulations being laid and coming into effect) with industry. This is due to continuing engagement with industry, clearance for the impact assessment, consultation on draft legislation, and a nine-month notification period for the EU

[4] The NDNS covers the UK as a whole.
[5] The Reference Nutrient Intake (RNI) for folic acid for adults is 200 µg/day. RNI is the amount of a nutrient (in this case folic acid) that is required for 97.5% of the population to be healthy.

Commission in respect of Northern Ireland and also the World Trade Organisation (WTO) in respect of Great Britain regarding technical barriers to trade.

Discussion of Option 1

25. This option can be seen as a **first step** to mandate the fortification of non-wholemeal wheat flour with folic acid. By not restricting voluntary fortification at the same time as mandating flour fortification, as is the case for Option 2 below, we would avoid opposition from businesses who would be affected by the cap. Option 1 should therefore require less time to implement than Option 2. There would still be opportunity thereafter to extend towards Option 2 after Option 1 has been implemented and monitored. In line with standard UK Government practice, following close monitoring of the policy, and regular engagement with industry, we will review and evaluate the policy in five years, with the option to change the fortificant levels or introduce restrictions on voluntary fortification, if levels of B12 deficiency increase or the rate of NTDs does not decrease.

26. Internationally, Australia has used a similar folic acid fortification range and has found no significant adverse effects. Since October 2009, all wheat flour used for bread making in Australia must contain between 200-300µg folic acid per 100g flour, with most bread sold in Australia (except organic bread) fortified with folic acid.

27. In 2016, Australia published the outcomes of the policy. This showed the rate of NTDs decreased following mandatory folic acid fortification by 14.4%, with a minimal change of less than 1% of adults exceeding the TUL.[6] A higher proportion of children aged 2–16 exceeded the TUL but that was not considered a health risk, as the TUL incorporates a fivefold safety margin and is based on an end point for high intakes in older adults.

28. Fortifying non-wholemeal wheat flour with a set level of folic acid rather than a range will support more straightforward data collection for monitoring the impacts of the policy as levels will be standardised across all (non-wholemeal wheat) flour.

OPTION 2: Mandating the fortification of non-wholemeal wheat flour alongside simultaneously restricting voluntary fortification of supplements, breakfast cereals and spreads

29. We recommend a fortificant level of 350µg folic acid/100g of flour. This is based on FSS modelling (see **Annex A**) which shows:

a. 350µg is the highest amount of folic acid/100g that would help reduce NTDs without increasing the number of people exceeding the TUL (would decrease from 0.4% to 0.2%).
b. The risk of NTDs would reduce by 16-22%, increasing the daily consumption of folic acid by around 85µg. Please note that the FSS modelling had an uncertainty of +/-20%, and so this reduction cannot be guaranteed.
c. The fortificant level could be raised to 450µg/100g of flour to maximise the decrease in NTDs (19-28%), however this would also increase the number of people exceeding the TUL by 0.1%.

[6] The estimates for the proportion of adults exceeding the TUL were based on previous nutrition surveys that did not include the use of supplements.

Timeline

30. We expect this option to take around 24-30 months before we can commence the lead-in stage with industry. This is because we will need to engage with industry and hold further consultation on the impact of restricting voluntary fortification, as well as consulting on the draft legislation, developing the draft Impact Assessment, and notifying relevant bodies in relation to technical barriers to trade (WTO for Great Britain and the EU Commission for Northern Ireland).

Discussion of Option 2

31. A wide range of products are already voluntarily fortified with folic acid (e.g. breakfast cereals and spreads), as well as newer additions including certain bakery products (e.g. 'vitamin boost' bread). To reverse this position and restrict voluntary fortification, significant discussion and consultation with industry would be required, which would in turn also **elongate the timeline for mandatory fortification** being implemented. Similarly, we know that the UK supplements industry has historically opposed action to mandate upper levels for vitamins and minerals, and we have no reason to expect this position has changed.

32. Both proposed options satisfy SACN's recommendations to introduce mandatory fortification to reduce NTDs and closely monitor implementation (see also paragraph 15). Option 2 also fulfils SACN's recommendation to restrict voluntary fortification. Further detail on SACN's recommendations is set out at paragraphs 13-14.

33. As with option 1, fortifying non-wholemeal wheat flour with a set level of folic acid rather than a range will support more straightforward data collection for monitoring the impacts of the policy as levels will be standardised across all flour.