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TOX/2023/17

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Second draft statement on the guidance levels for the fortificants in the Bread and Flour Regulations

Introduction

1. In 2022, the Department for Environment, Food and Rural Affairs (Defra) held a consultation on the Bread and Flour Regulations (BFR) 1998 to increase the fortification level to allow harmonisation with EU retained [Regulation \(EU\) No 1169/2011](#). Defra asked whether the consultees agreed with the proposal to raise the minimum levels of calcium carbonate, iron and niacin added to non-wholemeal flour to 15% of the nutrient reference values (NRV). The minimum amount of thiamin required to be present in non-wholemeal wheat flour would remain the same at 19% of the NRV. NRVs are established guidelines for the recommended daily energy and nutrient consumption.

2. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) have been asked by the Department of Health and Social Care (DHSC) to provide an assessment on the dietary exposure of calcium carbonate, iron, niacin and thiamin (Vitamin B1) at current and proposed fortification levels. The exposure assessment should provide a comparison to the UK Expert Group on Vitamins and Minerals (EVM) safe levels and upper levels (UL) and assess whether there is a potential risk to human health from the proposed increased fortification in non-wholemeal wheat flour.

3. A first draft statement (TOX/2023/03) was presented to the Committee in February 2023 and DHSC have requested that a statement be published with the conclusions of the Committee.

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4. The Committee requested clearer wording in the discussion of the nutrient reference values of calcium and calcium carbonate. It was also asked that the dose of iron discussed in the toxicity section is noted to be in its elemental form and clarified that reports of iron poisoning in adults are related to free iron.

5. It was further requested that statement address more recent case reports on thiamin toxicity and reflect that the homozygous haemochromatosis genotype is predominantly a concern for the Caucasian population.

6. Finally, the Committee requested the conclusions to be revised to better address the risk of the proposed fortification levels for individuals with the homozygous genotype. As well as a clear statement on the influence on supplement usage on the overall risk from the proposed fortification levels of calcium, iron, thiamine and niacin.

7. The Committee are asked to consider the second draft statement (attached in Annex A) which includes further information on the above which has been highlighted in yellow.

Questions on which the views of the Committee are sought

Members are invited to consider the following questions:

i). Do the Members have any comments on the amendments of the second draft statement?

ii). Do Members have any further comments?

Secretariat
March 2023

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TOX/2023/17 Annex A

Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment.

Second draft statement on the guidance levels for fortificants in the Bread and Flour Regulations (BFR)

Background

1. In 2022, the Department for Environment, Food and Rural Affairs (Defra) held a consultation on the Bread and Flour Regulations (BFRs) 1998 to increase the fortification level to allow harmonisation with EU retained [Regulation \(EU\) No 1169/2011](#). Defra asked whether the consultees agreed with the proposal to raise the minimum levels of calcium as calcium carbonate, iron and niacin added to non-wholemeal flour to 15% of the nutrient reference values (NRV). The current minimum amounts of calcium, iron and niacin required to be present in non-wholemeal wheat flour are 11.75%, 12% and 10% respectively. However, the minimum amount of thiamin required to be present in non-wholemeal wheat flour would remain the same at 19% of the NRV. NRVs are established guidelines for the recommended daily energy and nutrient consumption.

2. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) have been asked by the Department of Health and Social Care (DHSC) to provide an assessment on the dietary exposure of calcium, iron, niacin (nicotinic acid) and thiamin (Vitamin B1) at current and proposed fortification levels. The exposure assessment provides a comparison to the UK Expert Group on Vitamins and Minerals (EVM) guidance levels and assess whether there is a potential risk to human health from the proposed increased fortification in non-wholemeal wheat flour.

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Introduction

3. The [BFR 1998](#) stipulates the levels of calcium as calcium carbonate, iron, thiamin (vitamin B1) and niacin (nicotinic acid) that are required to be present in all wheat flour other than wholemeal (i.e. non-wholemeal flour). Calcium is added in the form of calcium carbonate. Natural calcium found in food would not be present in the form of calcium carbonate. Therefore, exposure to calcium from fortified food can be distinguished from natural or supplementary sources when analysed. Niacin is added to flour using either nicotinic acid or nicotinamide.

4. The existing BFRs (1998) set a minimum fortification level for thiamin (vitamin B1) of 0.24 mg for thiamin hydrochloride, which is equivalent to 0.21 mg of thiamin or 19% of the NRV. The proposed minimum fortification levels of calcium, iron and niacin have been set at 15% of the nutrient reference value (NRV) as stated in [Annex XIII of regulation EC No. 1169/2011](#) (in point 1 of Part A). In practise, foods are not currently fortified at these respective levels, but industry are looking to increase fortification to the set minimum levels. The daily NRVs for calcium, iron, niacin and thiamin (Vitamin B1) are 800 (or 2,000 as calcium carbonate), 14, 16 and 1.1 mg, respectively.

Toxicity

Calcium

5. High intakes of calcium carbonate of around 4,000 mg/day (equivalent to 1,600 mg calcium) can result in a condition called milk-alkali syndrome in people with underlying medical conditions such as peptic ulcers (EFSA, 2006). This condition is characterised by hypercalcaemia, alkalosis and renal impairment, which is associated with symptoms of hypertension, neurological problems, abdominal pain and tissue calcification (EVM, 2003).

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6. Calcium supplements have been administered to people with colonic polyps or people who are at risk of colonic polyps. Gastrointestinal (GI) effects were reported in a small number of patients receiving 1,600 or 2,000 mg/day of calcium (EVM, 2003).

7. High calcium diets can affect the bioavailability of other minerals such as iron, zinc, magnesium and phosphorous by inhibiting the absorption of iron salts, haem-iron and zinc, reducing magnesium absorption and excretion, and the binding of calcium acetate and calcium carbonate to phosphate in the intestinal lumen (EFSA, 2006).

Iron

8. Iron toxicity is particularly hazardous in children and most poisoning cases are reported in children consuming iron supplements intended for adults. Symptoms in infants include gastrointestinal irritation at acute doses of around 20 mg/kg bw and systemic effects which occur at doses <60 mg/kg bw. The lethal dose in children is between 200-300 mg/kg bw (EVM, 2003).

9. In adults, gastrointestinal effects such as constipation, nausea, vomiting and diarrhoea have been reported at therapeutic doses of 50-220 mg/person/day (EFSA, 2006). Iron toxicity can lead to inflammation and perforation of the gastrointestinal tract and iron disrupts the cellular metabolism in the central nervous system, liver and heart. The free iron in the serum enters and concentrates in the mitochondria where it forms free radicals, which can impair energy metabolism and can eventually lead to cell death (Baranwal and Singhi, 2003; Yuen and Becker, 2022). However, iron poisoning (where iron is in its free form) in adults is rare, individual case reports suggest a lethal dose of 1,400 mg/kg bw (EVM, 2003)

Niacin (nicotinic acid/vitamin B3)

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10. Symptoms of acute toxicity from niacin include flushing, itchy skin, nausea, vomiting and gastrointestinal issues (such as diarrhoea and constipation). Long term intakes of 3,000 mg/day of niacin have been reported to cause jaundice, hyperglycaemia and abdominal pain. In addition to elevated serum bilirubin, increased alkaline phosphatase and aminotransferase levels have been reported in a small number of cases. Anorexia, ophthalmological effects, skin hyperpigmentation and precipitation of incipient psychosis have also been reported as side effects of niacin therapy (EVM, 2003).

11. Patients with hypercholesterolaemia that have been treated with niacin at 3-9 g/day over a period of months to years showed symptoms of severe liver dysfunction which has the potential to be life threatening and may require liver transplantation (EFSA, 2006).

Thiamin (Vitamin B1)

12. Thiamin is considered to be of very low toxicity with symptoms such as headache, nausea, irritability, insomnia, rapid pulse and weakness being seen at high oral doses of $\geq 7,000$ mg thiamin hydrochloride (EVM, 2003).

13. However, a small number of case reports have shown association with adverse effects such as muscle tremors, rapid pulse and nerve hyperirritability at low daily doses of 17 mg/day of thiamin hydrochloride. In one case, a patient consuming thiamin at 100 mg/day for a period of 15 days, 2 months prior to consumption of a single oral dose of thiamin of 100 mg, experienced an anaphylactic reaction followed by death. In another case, a patient experienced exacerbated eczema after receiving an oral dose of 200 mg of thiamin in an experimental provocation (EVM, 2003). A 2018 case report where patients with Parkinson's disease were treated with 2-3 intramuscular doses of 100 mg of thiamin/week experienced adverse effects of discomfort, unrest and an overall worsening of symptoms of Parkinson's disease, and a medium intensity migraine (Costantini and Fancellu 2018).

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14. The COT noted that alcohol consumption may be a confounding factor in some of the case reports. Most cases of thiamin deficiency were associated with chronic alcoholism where absorption and utilisation of thiamin are impaired (EVM, 2003).

Health based guidance values

15. No tolerable upper levels (TUL) or safe upper levels (UL) have been established for calcium, iron, niacin (nicotinic acid) and thiamin by the EVM due to the lack of sufficient animal and human data (EVM, 2003).

16. However, the EVM stated that “1,500 mg/day of supplemental calcium would not be expected to result in any adverse effect, but that higher doses could result in adverse gastrointestinal symptoms in a few people” (EVM, 2003). The Scientific Committee on Food (SCF) established a TUL of 2,500 mg/day for calcium in 2003 (SCF, 2003). This TUL was based on long duration intervention studies of different time periods in which total daily calcium intakes of 2,500 mg from both diet and supplements were tolerated without adverse effects and was endorsed by EFSA in 2012 (EFSA, 2012).

17. The EVM proposed that a supplemental intake of 17 mg/day for iron would not be expected to produce adverse effects in the majority of individuals. However, this guidance value does not apply to individuals who have an increased susceptibility to iron overload, a condition which is associated with a homozygous haemochromatosis genotype (with an estimated prevalence of up to 0.4% in the Caucasian population). An UL for iron has not been established by EFSA. The National Institutes of Health Office of Dietary Supplements in the United States have advised safe ULs of 40 mg/day for individuals aged 0 months to 13 years and 45 mg/day for individuals aged 14 years and over (Institute of Medicine, 2001). However, moderate symptoms of iron toxicity have been reported from (20 mg/kg

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bw/day (Madiwale and Liebelt, 2006) or 1,572 mg/person/day for a 78.6kg adult (based on the average body weight in NDNS data) (Bates *et al.*, 2014, 2016, 2020; Roberts *et al.*, 2018)). However, Madiwale and Liebelt (2006) reported that ingestion <20 mg/kg is non-toxic and moderate symptoms of iron toxicity can occur between 20 to 60 mg/kg.

18. The EVM proposed that a guidance level of 17 mg/day for niacin (nicotinic acid) would not be expected to result in any adverse effects. However, it was noted by the EVM that this guidance level is for supplementation only, as adverse effects from niacin seem to be related to acute, bolus intakes. Adverse effects from long term exposure of niacin in food would be less likely as free niacin levels in food are low. Additionally, the EVM noted that the guidance level is based on intakes of conventional formulations of niacin. This would not be applicable to sustained release preparations and niacin contained in dietary supplements is not in the sustained release form (EVM, 2003). In 2002, the SCF set an UL of 10 mg/day for niacin based on flushing of skin (EFSA, 2014).

19. The EVM proposed a guidance level for supplemental thiamin of 100 mg/day which would not be expected to result in adverse effects. The EVM noted however that this guidance level was only applicable to the water-soluble forms of thiamin. Furthermore, the study by Gokhale *et al.* (1999), used to derive the guidance level, was conducted in young women (EVM, 2003). An UL for thiamin was not established by the SCF as there were only limited data on adverse effects in humans and lack of dose-response studies (EFSA, 2016). Whilst there is a lack of evidence of toxicity from a high intake of thiamin from food or supplements (Martel *et al.*, 2021), symptoms such as headache, nausea, irritability, insomnia, rapid pulse and weakness have been seen at high oral doses of $\geq 7,000$ mg/day thiamin hydrochloride (EVM, 2003).

Exposure assessment

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20. Exposures to calcium, iron, niacin and thiamin were determined using consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) and the National Diet and Nutrition Survey (NDNS). Levels of these nutrients in the entire diet were obtained from the nutrient databank (Bates *et al.*, 2014, 2016, 2020; Roberts *et al.*, 2018). Levels of nutrients in non-wholemeal flour used in the exposure assessment were those currently in use by industry. Exposure to the nutrients based on the proposed increases were also determined, except for thiamin, where no increases have been proposed. Table 2 provides information about current and proposed fortification levels for each nutrient where applicable. Exposure to these nutrients were calculated in Crème Global, the software that the FSA uses to interrogate dietary data and calculate exposure. Exposure estimates were derived by multiplying food consumption amounts by the levels of the nutrients in the foods. Chronic exposure or intake of these nutrients are presented. Chronic intake is derived from the average amount of flour consumed over the survey days multiplied by the levels of nutrients. Chronic exposure or intake is calculated for each consumer. The mean and P97.5 are then computed.

Table 1. Concentration data used to derive exposure to calcium, iron, niacin and thiamin

Nutrient	Nutrient reference value (mg/person/day)	Guidance level (mg/person/day)	Current minimum levels (mg/100 g non-wholemeal flour)	Level based on fortification at 15% (mg/100 g non-wholemeal flour)
Calcium	800	2,500	94	120
Iron	14	17 (supplemental)**	1.65	2.1
Niacin	16	17 (supplemental)**	1.6	2.4
Thiamin	1.1	100 (supplemental)**	0.24	NA*

* A change in fortification level has not been proposed.

**Guidance level is for supplementation only.

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Methodology for estimating current and proposed exposures from non-wholemeal flour

21. Exposures based on current and proposed levels were calculated from foods containing non-wholemeal flour. This by definition is wheat flour without whole grain wheat. The recipe database associated with the NDNS food groupings identified foods containing non-wholemeal flour (n=1835). A selection of food groups (foods with non-wholemeal flour), each containing more than 20 foods are shown in Table A1 in Annex A.

22. The fortification level for thiamin remains unchanged, therefore exposures at the proposed fortification levels were only calculated for calcium, iron, and niacin.

23. Exposures to these nutrients from supplements were also considered. Data for supplements were obtained from market sources (e.g., websites of major retailers). Concentrations of calcium supplements ranged from 200-1200 mg for adults and 80-450 mg for children. Whereas concentrations of iron supplements ranged from 14-28 mg in adults and 2.8-7.5 mg in children. Concentrations of niacin supplements ranged from 50-1000 mg in adults and 4.8-20 mg in children. Concentrations of thiamin supplements ranged from 100-500 mg for adults and 0.7-5 mg for children.

Exposures from the entire diet and from flour at the current and proposed fortification levels

24. Exposure to the nutrients from the entire diet was estimated using all food groups from NDNS years 1-11, which are presented in Table A2 of Annex B. All food groups including the foods containing non-wholemeal flour are detailed in paragraph 21. The levels of the nutrient for each of the foods included were derived from the nutrient databank from the NDNS.

25. Exposure to calcium, iron, niacin and thiamin from the entire diet and from flour fortification at current and proposed levels are shown in Table 2-5.

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26. For calcium, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current level of fortification were 68 and 140 mg/person/day, respectively. The maximum mean and 97.5th percentile exposures at the proposed level of fortification are 87 and 180 mg/person/day, respectively. The maximum exposures to calcium from the entire diet are 820 and 1,600 mg/person/day at mean and 97.5 the percentile levels respectively (Table 3).

27. For iron, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current level of fortification are 1.2 and 2.5 mg/person/day respectively. The maximum mean and 97.5th percentile exposures at the proposed level of fortification are 1.5 and 3.2 mg/person/day respectively. The maximum exposures to iron from the entire diet are 10 and 19 mg/person/day at mean and 97.5th percentile levels respectively (Table 4).

28. For nicacin, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current level of fortification are 1.2 and 2.4 mg/person/day respectively. The maximum mean and 97.5th percentile exposures at the proposed level of fortification are 1.7 and 3.6 mg/person/day respectively. The maximum exposure to niacin from the entire diet are 36 and 68 at the mean and 97.5th percentile, respectively (Table 5).

29. For thiamin, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current level of fortification are 0.17 and 0.36 mg/person/day. The maximum exposure to thiamin from the entire diet are 1.5 and 2.8 mg/person/day at the mean and 97.5th percentile, respectively (Table 6).

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Table 2. Chronic exposures to calcium from the diet and from flour fortification at current and proposed levels (15% of the nutrient reference value supplied by 100 g flour) levels

Age group	Category	Chronic exposure to calcium (mg/person/day)	
		Mean	97.5th Percentile
Infants (4-18 months)	Entire diet	680	1200
	Current levels in flour	15	48
	Proposed levels in flour	19	61
1.5-3 years	Entire diet	740	1300
	Current levels in flour	34	78
	Proposed levels in flour	43	99
4 - 10 years	Entire diet	760	1400
	Current levels in flour	55	110
	Proposed levels in flour	71	140
11 – 18 years	Entire diet	770	1500
	Current levels in flour	68	140
	Proposed levels in flour	87	180
19 – 64 years	Entire diet	810	1600
	Current levels in flour	58	140
	Proposed levels in flour	74	180
65 + years	Entire diet	820	1500
	Current levels in flour in flour	49	120
	Proposed levels	62	150

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Table 3. Chronic exposures to iron from the diet and from flour fortification at current and proposed (15% of the nutrient reference value supplied by 100 g flour) levels

Age group	Category	Chronic exposure to iron (mg/person/day)*	
		Mean	97.5th Percentile
Infants (4-18 months)	Entire diet	6.8	12
	Current levels in flour	0.27	0.84
	Proposed levels in flour	0.34	1.1
1.5-3 years	Entire diet	6	10
	Current levels in flour	0.6	1.4
	Proposed levels in flour	0.76	1.7
4 - 10 years	Entire diet	8.1	14
	Current levels in flour	0.97	1.9
	Proposed levels in flour	1.2	2.4
11 – 18 years	Entire diet	9.3	17
	Current levels in flour	1.2	2.5
	Proposed levels in flour	1.5	3.2
19 - 64 years	Entire diet	10	19
	Current levels in flour	1	2.4
	Proposed levels in flour	1.3	3.1
65 + years	Entire diet	9.7	17
	Current levels in flour	0.85	2.1
	Proposed levels in flour	1.1	2.6

Table 4. Chronic exposures to niacin equivalents from the diet and from flour fortification at current and proposed (15% of the nutrient reference value supplied by 100 g flour) levels

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	Category	Chronic exposures to niacin (mg/person/day)*	
		Mean	97.5th Percentile
Infants (4-18 months)	Entire diet	14	25
	Current levels in flour	0.26	0.81
	Proposed levels in flour	0.39	1.2
1.5-3years	Entire diet	18	28
	Current levels in flour	0.58	1.3
	Proposed levels in flour	0.87	2
4 - 10 years	Entire diet	25	39
	Current levels in flour	0.94	1.9
	Proposed levels in flour	1.4	2.8
11 - 18years	Entire diet	31	55
	Current levels in flour	1.2	2.4
	Proposed levels in flour	1.7	3.6
19 - 64 years	Entire diet	36	68
	Current levels in flour	0.98	2.4
	Proposed levels in flour	1.5	3.6
65 + years	Entire diet	31	52
	Current levels in flour	0.83	2
	Proposed levels in flour	1.2	3

Table 5: Chronic exposures to thiamin in the diet and from flour fortification at current (19% of the nutrient reference value supplied by 100g flour; there is no proposed increase to thiamin) levels

		Chronic intake of thiamin (mg/person/day)*	

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Age group	Category	Mean	97.5th Percentile
Infants (4-18 months)	Entire diet	0.81	1.3
	Current levels in flour	0.039	0.12
1.5-3years	Entire diet	1	1.8
	Current levels in flour	0.087	0.2
4 - 10 years	Entire diet	1.3	2.3
	Current levels in flour	0.14	0.28
11 - 18years	Entire diet	1.4	2.8
	Current levels in flour	0.17	0.36
19 - 64 years	Entire diet	1.5	2.8
	Current levels in flour	0.15	0.36
65 + years	Entire diet	1.5	2.7
	Current levels in flour	0.12	0.3

* Rounded to 2.s.f

Exposure from supplements

30. It should be noted that supplements data were derived from various online sources in Tables A5-A8 in Annex A. The exact consumption by the population was unknown therefore exposures were calculated based on recommended serving sizes.

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31. Across all age groups (4 months to 65+ years) the upper exposures of supplemental calcium were up to 1,200 mg/day. In adults aged over 18 years, this exposure is equivalent to 1.48- and 0.75-fold the mean and 97.5th percentile calcium exposures from the entire diet (which includes all food groups including non-wholemeal flour), respectively.

32. Across all age groups (4 months to 65+ years) the upper exposures of supplemental iron were up to 28 mg/day. In adults aged over 18 years, this exposure is equivalent to 3- and 1.6-fold the mean and 97.5th percentile calcium exposures from the entire diet, respectively.

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33. Across all age groups (4 months to 65+ years) the upper exposures of supplemental niacin were up to 1,000 mg/day. In adults aged over 18 years this exposure is equivalent of up to 32- and 19-fold of the mean and 97.5th percentile niacin exposures from the entire diet, respectively.

34. Across all age groups (4 months to 65+ years) the upper exposures of supplemental thiamin were up to 500 mg/day. In adults aged over 18 years, this exposure is equivalent to 330- and 185-fold the mean and 97.5th percentile thamin exposures from the entire diet.

Risk characterisation

Exposures from food

35. Chronic exposure of calcium from non-wholemeal wheat flour at the current and proposed fortification levels (Table 2) did not exceed the guidance levels of 1,500 mg/person/day (EVM, 2003) and 2,500 mg/day (EFSA, 2012) across all age groups. Exposures from the entire diet were up to 1,600 mg/person day which although it exceeds the EVM guidance level, marginally, is below the SCF TUL of 2,500 mg/day

36. Chronic exposures to iron from non-wholemeal wheat flour at the current and proposed fortification levels (Table 3) did not exceed the guidance levels of 17 mg/day (EVM, 2003) across all ages. However, it is important to note that the guidance level is based on supplemental intake. Exposures from the entire diet were up to 19 mg/person/day, which would result in marginal exceedance of the EVM guidance level but not the level reported to cause moderate symptoms of iron toxicity of 20 mg/kg bw per day (1572 mg per person/day for a 78.6 kg adult) (Madiwale and Liebelt, 2006). It is not anticipated that there would be a risk to health from iron exposures in the entire diet to most of the population. However, the EVM guidance value does not apply to individuals who have an increased susceptibility to iron overload, a condition which is associated with a homozygous haemochromatosis

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genotype. Such individuals would normally be under medical supervision to ensure their exposure to iron was appropriate.

37. Chronic exposures to niacin equivalents from non-wholemeal wheat flour (Table 4) at the current and proposed fortification levels did not exceed the guidance level for niacin of 17 mg/day (EVM, 2003) across all age groups. Exposures to niacin from the entire diet were up to 68 mg/person/day, which exceeds the EVM guidance level up to 4-fold. However, the EVM guidance level is for supplementation only, as adverse effects from niacin seem to be related to acute, bolus intakes. It is unlikely that there would be a risk of adverse health effects at these exposures although there is some uncertainty because of the data used to establish the EVM guidance level: that it is intended for supplements and is based on a bolus intake.

38. Chronic exposures to thiamin at the current fortification level (Table 5) did not exceed the current guidance level of 100 mg/day (EVM, 2003). Exposures to thiamin from the entire diet were up to 2.8 mg/person/day which were also well below the EVM guidance level and it is unlikely that there would be a risk of adverse health effects.

Exposure from supplements

39. Daily exposure to calcium supplements did not exceed the EVM guidance level of 1,500 mg/day (EVM, 2003) or the SCF guidance level of 2,500 mg/day in adults and children (SCF, 2003). Exposure to higher dosage iron supplements (i.e., 28 mg/day) can exceed the guidance level of 17 mg/day (EVM, 2003) by up to 1.6-fold in adults. Daily exposure to niacin supplements could result in exceedances of the guidance level of 17 mg/day (EVM, 2003), by between 3- and 60-fold. For thiamin supplements, daily exposure could lead to up to a 5-fold exceedance of the guidance level of 100 mg/day (EVM, 2003).

Exposure from supplements and food

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40. Mean calcium exposures from food (the entire diet and flour at the current and proposed fortification levels) and supplements (Table A3) were up to 2,000 mg/person/day, respectively and below either the EVM guidance level and/or the SCF TUL, with the exception of 65+ years, in whom there was a 30% exceedance of the guidance level. Exposures associated with 97.5th percentile consumption were between 1,700 and 2,800 mg/person/day. For population groups below 19 years of age, the exposures are below the SCF TUL and it is unlikely that there would be a risk of adverse health effects. Population groups for 18 years and over marginally exceeded the SCF TUL and it is unlikely that there would be a risk of adverse health effects in humans at these exposures.

41. Mean and 97.5th percentile iron exposures from food and supplements were up to 25 mg/person/day which were either below or a minor exceedance of the guidance level of 17 mg/day (EVM, 2003) in those aged up to 18 years. There is unlikely to be a risk of adverse health effects in these populations due to exposures from iron. However, in the 19-64 and 65+ years age groups, mean and 97.5th percentile iron exposures were up to 38 and 47 mg/person/day which were exceedances of up to 2.2-fold and 2.8-fold, respectively. It is unlikely that there is a risk of adverse health effects. The EVM guidance value does not apply to individuals who have an increased susceptibility to iron overload, a condition which is associated with a homozygous haemochromatosis genotype, and who should be advised appropriately by a medical practitioner.

42. Mean and 97.5th percentile niacin exposure from food (entire diet) and supplements exceeded the guidance level of 17 mg/day (EVM, 2003) across all age groups. In those aged up to 18 years exceedances of the 17 mg/day guidance level were up to 3- and 4.4-fold for mean and 97.5th percentile consumption, respectively. In individuals aged up to 3 years the exceedances were approximately half of these (up to 2.2- and .8-fold for mean and 97.5th percentile consumers, respectively). In those aged over 18 years the exceedances of the 17 mg/day guidance level were up to 59- and 65-fold for

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mean and 97.5th percentile consumers, respectively. Most of this exceedance comes from the consumption of supplements containing niacin at 1,000 mg.

43. As noted previously, the EVM guidance level is for supplementation only, as adverse effects from niacin seem to be related to acute, bolus intakes. Adverse effects from long term exposure to niacin in food would be less likely. Exposures from consumption of supplements containing high levels of niacin e.g., 1,000 mg could result in increased risk of adverse health effects, especially when consumed consistently at these high doses over a prolonged period of time.

44. Exposures to thiamin for all age groups below 18 years of age are below the guidance level of 100 mg/day (EVM, 2003). Mean and 97.5th percentile intakes from food and supplements only exceeded the guidance level for thiamin of 100 mg/day (EVM, 2003) in the 19-64 years and 65+ years age groups. In these age groups both exceeded the guidance level by 5-fold. This was predominantly from consumption of supplements which may contain up to 500 mg. It is unlikely that these exposures would cause adverse health effects.

Conclusion

45. Chronic exposures of calcium (as calcium carbonate), iron, niacin and thiamin (for which no change was proposed) from non-wholemeal wheat flour at the current and proposed fortification levels did not exceed their respective guidance levels. For each of the nutrients, the difference in exposure between current and proposed levels of fortification is at most 4%, when compared to exposures from the entire diet and even less when compared with combined exposure from the diet and supplements. Therefore, the 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.

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46. Independent of the proposed increase in the level of fortification, calcium exposure from food and supplements exceeded the EFSA TUL of 2,500 mg/day, however the exceedance was marginal and only in high (97.5th percentile) consumers in those aged over 18 years. There is unlikely to be a risk of adverse health effects based on these exposures.

47. Iron exposures from food and supplements exceeded the guidance levels of 17 mg/day in some age groups, up to a maximum of 2.8-fold, independent of the proposed increase in the level of fortification. There is unlikely to be a risk of adverse health effects based on these exposures. However, the EVM guidance value does not apply to individuals who have an increased susceptibility to iron overload, a condition which is associated with a homozygous haemochromatosis genotype. For these individuals medical advice would be necessary on the appropriate level of iron intake.

48. In those aged <18 years niacin exposure from food and supplements exceeded the guidance level of 17 mg/day (EVM, 2003), up to 3- and 4.4-fold for mean and 97.5th percentile consumption, respectively. In those aged over 18 years the exceedances of the 17 mg/day guidance level were up to 59- and 65-fold for mean and 97.5th percentile consumers, respectively. These exceedances were independent of the proposed increase in the level of fortification. Most of the exceedances are due to consumption of supplements containing niacin at 1,000 mg. Adverse effects from long term exposure to niacin in food would be less likely. However, there is some uncertainty because of the data used to establish the EVM guidance level. It is intended for supplements and is more relevant for a bolus intake. Exposures from consumption of supplements containing high levels of niacin e.g., 1,000 mg could lead to increased risk of adverse health effects, especially when consumed consistently over a prolonged period of time.

49. No change in the fortification level of thiamin was proposed. Current exposures to thiamin from food and supplements for all age groups below 18 years of age are below the guidance level of 100 mg/day (EVM, 2003). Mean and 97.5th percentile intakes from food and supplements exceeded the

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guidance level for thiamin only in consumers aged over 18, by a maximum of up to 5-fold. This was predominantly from consumption of supplements which may contain up to 500 mg. It is unlikely that these exposures would cause adverse health effects.

50. Although not impacted by the level of fortification of non-wholemeal wheat, it was noted that intakes of calcium from supplements alone did not exceed the guidance level for this mineral. However, consumption of higher dosage iron, niacin and thiamin supplements may result in exceedances of the respective guidance levels.

51. The COT, overall concluded, that an increase in the minimum fortification level of calcium (as calcium carbonate), iron and niacin to 15% of the NRV would not result in any material increase in risk when compared to current fortification levels.

Secretariat

March 2023

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List of Abbreviations and Technical terms

BFR	Bread and Flour Regulations
COT	Committee on Toxicity Chemicals in Food, Consumer Products and the Environment.
DHSC	Department of Health and Social Care
SCF	Scientific Committee on Food
TUL	Tolerable Upper Level
NRV	Nutrient reference Value

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TOX/2022/XX ANNEX B

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Review of the guidance levels for fortificants in the bread and flour regulations (BFR)

Table A1: A selection of food groups containing foods with non-wholemeal flour

Food group	Number of foods assessed in the group
Biscuits (manufactured/retail)	105
Brown, granary and wheatgerm bread	25
Buns cakes and pastries (homemade)	118
Buns cakes and pastries (manufactured)	103
Burgers and kebabs purchased	24
Fruit pies (homemade)	20
Manufactured coated chicken/turkey products	34
Meat pies and pastries (homemade)	39
Meat pies and pastries (manufactured)	38
Other breakfast cereals (not high fibre)	24
Other cereal-based puddings (homemade)	40
Other cereals	41
Other manufactured vegetable products (including ready meals)	21
Other sausages (including homemade dishes)	30

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Pasta (manufactured products and ready meals)	26
Savoury sauces pickles gravies & condiments	31
White bread (not high fibre, not multiseed bread)	56
White fish coated or fried	112

Table A2: All food groups from the NDNS used to estimate the intake of nutrients from the entire diet

Food group	Number of foods assessed in the group
1% Milk (60R)	5
Alcoholic soft drinks (Alcopops) (49E)	4
Apples and pears not canned (40A)	27
Artificial sweeteners (55R)	11
Baked beans (37C)	8
Bananas (40C)	5
Beans and pulses (including ready meal & homemade dishes) (37I)	72
Beers and lagers (49A)	29
Beverages dry weight (50A)	44
Biscuits (homemade) (7B)	15
Biscuits (manufactured/retail) (7A)	153
Block margarine (20A)	2
Bottled water still or carbonated (51D)	11
Brown, granary and wheatgerm bread (59R)	42
Buns cakes and pastries (homemade) (8E)	132
Buns cakes and pastries (manufactured) (8D)	113

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Burgers and kebabs purchased (29R)	31
Butter (17R)	6
Calcium only or with vitamin D (54F)	17
Canned fruit in juice (40D)	24
Canned fruit in syrup (40E)	41
Carrots (raw) (36A)	4
Carrots not raw (37E)	11
Cereal based milk puddings (homemade) (9D)	26
Cereal based milk puddings (manufactured) (9C)	40
Cheddar cheese (14B)	9
Chips purchased including takeaway (38A)	42
Chocolate confectionery (44R)	53
Cider and perry (49C)	7
Citrus fruit not canned (40B)	12
Cod liver oil and other fish oils (54A)	1
Cod liver oil and other fish oils (including with vitamins A,D,E) (54N)	47
Coffee (made up weight) (51A)	25
Commercial toddlers drinks (52A)	9
Commercial toddlers foods (52R)	131
Cottage cheese (14A)	5
Cream (including imitation cream) (13B)	41
Crisps and savoury snacks (42R)	43
Dairy desserts (homemade) (15D)	11
Evening primrose oil and other plant oils (54B)	18
Folic acid (54D)	2
Fortified wine (48B)	10

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Fromage frais and other dairy desserts (manufactured) (15C)	51
Fruit juice (45R)	45
Fruit pies (homemade) (8C)	24
Fruit pies (manufactured) (8B)	7
Green beans not raw (37B)	8
Herbal tea (made up) (51C)	3
High fibre breakfast cereals (5R)	128
Ice cream (53R)	40
Infant formula (13A)	82
Iron only or with vitamin C (54E)	11
Leafy green vegetables not raw (37D)	28
Liqueurs (47A)	9
Liver and dishes (28R)	36
Low alcohol & alcohol-free beer & lager (49B)	9
Low alcohol & alcohol-free cider & perry (49D)	3
Low alcohol and alcohol-free wine (48C)	4
Low fat spread not polyunsaturated (19R)	7
Manufactured beef products (including ready meals) (23A)	49
Manufactured canned tuna products (including ready meals) (34G)	8
Manufactured chicken products (including ready meals) (27A) - 79 foods.	79
Manufactured coated chicken/turkey products (26A)	34

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Manufactured egg products including ready meals (16C)	18
Manufactured lamb products (including ready meals) (24A)	11
Manufactured oily fish products (including ready meals) (35A)	45
Manufactured pork products (including ready meals) (25A)	9
Manufactured shellfish products (including ready meals) (34E)	17
Manufactured white fish products (including ready meals) (34C)	8
Meat alternatives (including ready meals and homemade dishes) (37K)	41
Meat pies and pastries (homemade) (31B)	39
Meat pies and pastries (manufactured) (31A)	38
Minerals (two or more including multiminerals) no vitamins (54H)	4
Multivitamins and/or minerals with omega (54P)	30
Non-nutrient supplements (including herbal) (54J)	46
Nutrition powders and drinks (50E)	62
Nuts and seeds (56R)	53
Other bacon and ham (including homemade dishes) (22B)	66
Other beef & veal (including homemade recipe dishes) (23B)	135
Other bread (4R)	17

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Other breakfast cereals (not high fibre) (6R)	70
Other canned tuna (including homemade dishes) (34H)	7
Other cereal-based puddings (homemade) (9H)	58
Other cereal-based puddings (manufactured) (9G)	23
Other cereals (1R)	106
Other cheese (14R)	80
Other chicken/turkey (including homemade recipe dishes) (27B)	146
Other cooking fats and oils not polyunsaturated (20C)	28
Other eggs and egg dishes including homemade (16D) -	98
Other fried/roast potatoes (including homemade dishes) (38D) -	55
Other fruit not canned (40R)	193
Other lamb (including homemade recipe dishes) (24B)	80
Other manufactured potato products fried/baked (38C)	20
Other manufactured vegetable products (including ready meals) (37L)	49
Other meat (including homemade recipe dishes) (32B)	66
Other meat products (manufactured including ready meals) (32A)	34
Other milk (13R)	72
Other nutrient supplements (54K)	55

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Other oily fish (including homemade dishes) (35B) - 71 foods.	71
Other pork (including homemade recipe dishes) (25B)	69
Other potato products and dishes (manufactured) (39A)	20
Other potatoes (including homemade dishes) (39B)	50
Other sausages (including homemade dishes) (30B)	46
Other shellfish (including homemade dishes) (34F)	45
Other vegetables (including homemade dishes) (37M)	217
Other white fish (including homemade dishes) (34D)	83
Pasta (manufactured products and ready meals) (1D)	39
Pasta (other, including homemade dishes) (1E)	36
Peas not raw (37A)	20
Pizza (1C)	12
Polyunsaturated low fat spread (19A)	10
Polyunsaturated margarine (18A)	1
Polyunsaturated oils (18B)	7
Preserves (41B)	22
Ready meals based on sausages (30A)	2
Ready meals/meal centres based on bacon and ham (22A)	3
Reduced fat spread (not polyunsaturated) (21B)	16

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Reduced fat spread (polyunsaturated) (21A)	9
Rice (manufactured products and ready meals) (1F)	9
Ice (other, including homemade dishes) (1G)	53
Salad and other raw vegetables (36B)	93
Savoury sauces pickles gravies & condiments (50R)	203
Semi-skimmed milk (11R)	9
Single vitamins/minerals not Folic acid, iron, calcium or vitamin C (54M)	61
Skimmed milk (12R)	11
Smoothies (61R)	10
Soft drinks low calorie carbonated (58B)	24
Soft drinks low calorie concentrated (58A)	13
Soft drinks low calorie, ready to drink, still (58C)	26
Soft drinks not low calorie carbonated (57B)	39
Soft drinks not low calorie concentrated (57A)	23
Soft drinks not low calorie, ready to drink, still (57C)	43
Soft margarine not polyunsaturated (20B)	3
Soup (homemade) (50D)	39
Soup (manufactured/retail) (50C)	48
Spirits (47B)	1
Sponge puddings (homemade) (9F)	10

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Sponge puddings (manufactured) (9E)	9
Sugar (41A)	15
Sugar confectionery (43R)	54
Sweet spreads fillings and icing (41R)	23
Tap water only (51R) -	2
Tea (made up) (51B) -	9
Tomatoes not raw (37F)	14
Tomatoes raw (36C)	3
White bread (not high fibre, not multiseed bread) (2R)	58
White fish coated or fried (33R)	139
Whole milk (10R)	11
Wholemeal bread (3R)	31
Wine (48A)	16
Yogurt (15B)	82

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Table A3: Calcium exposure from foods and supplements

Age group	Category	Chronic exposure of calcium from food (mg/person/day)*		Calcium exposure from supplements, upper range (mg/person/day)	Calcium exposure from supplements and diet (mean) (mg/person/day)	Calcium exposure from supplements and diet (97.5 th percentile) (mg/person/day)
		Mean	97.5th Percentile			
Infants (4 - 18 months)	Entire diet	680	1200	450	1100	1700
	Current levels in flour	15	48	450	470	500
	Proposed levels in flour	19	61	450	470	500
1.5 - 3 years	Entire diet	740	1300	450	1200	1800
	Current levels in flour	34	78	450	490	530
	Proposed levels in flour	43	99	450	490	550
4 - 10 years	Entire diet	760	1400	450	1200	1900
	Current levels in flour	55	110	450	510	560

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	Proposed levels in flour	71	140	450	520	590
11 - 18 years	Entire diet	770	1500	450	1200	2000
	Current levels in flour	68	140	450	520	590
	Proposed levels in flour	87	180	450	540	630
19 - 64 years	Entire diet	810	1600	1200	2000	2800
	Current levels in flour	58	140	1200	1300	1300
	Proposed levels in flour	74	180	1200	1300	1400
65 + years	Entire diet	820	1500	1200	2000	2700
	Current levels in flour	49	120	1200	1200	1300
	Proposed levels in flour	62	150	1200	1300	1400

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Table A4: Iron exposure from food and supplements

Age group	Category	Chronic exposure to iron (mg/person/day)*		Iron exposure from supplements, upper range (mg/person/day)	Iron exposure from supplements and diet (mean) (mg/person/day)	Iron exposure from supplements and diet (97.5 th percentile) (mg/person/day)
		Mean	97.5th Percentile			
Infants (4 - 18 months)	Entire diet	6.8	12	7.5	14.0	20
	Current levels in flour	0.27	0.84	7.5	7.8	8.3
	Proposed levels in flour	0.34	1.1	7.5	7.8	8.6
1.5 - 3 years	Entire diet	6	10	7.5	14	18
	Current levels in flour	0.6	1.4	7.5	8.1	8.9
	Proposed levels	0.76	1.7	7.5	8.3	9.2
4 - 10 years	Entire diet	8.1	14	7.5	16	22

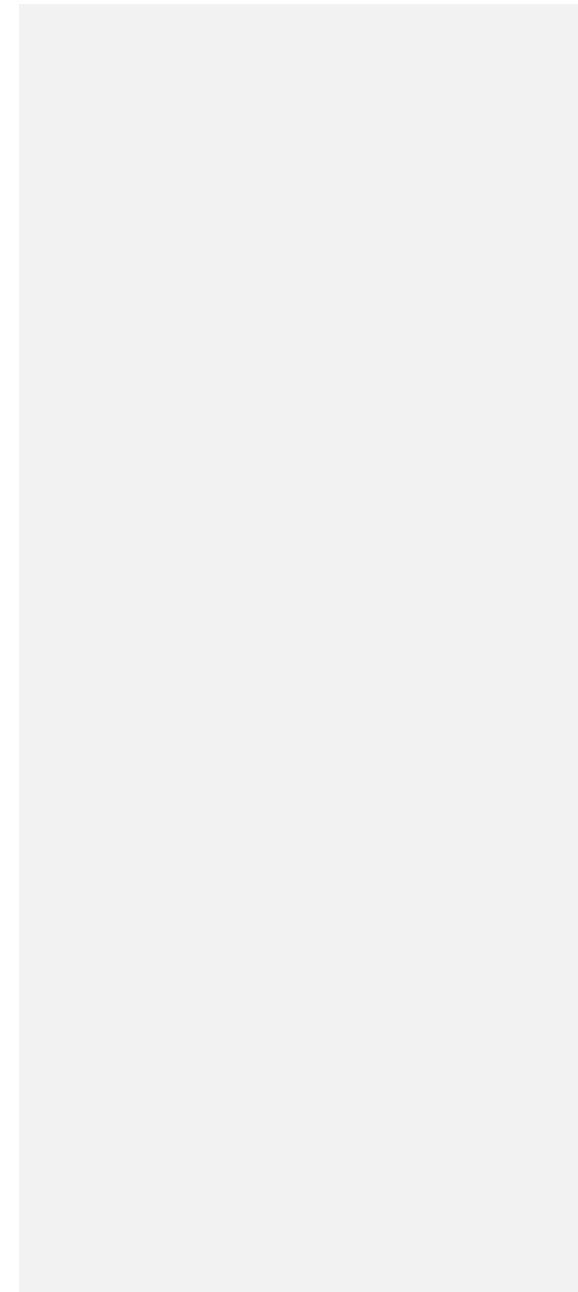
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	Current levels in flour	0.97	1.9	7.5	8.5	9.4
	Proposed levels in flour	1.2	2.4	7.5	8.7	9.9
11 - 18 years	Entire diet	9.3	17	7.5	17	25
	Current levels in flour	1.2	2.5	7.5	8.7	10
	Proposed levels in flour	1.5	3.2	7.5	9	11
19 - 64 years	Entire diet	10	19	28	38	47
	Current levels in flour	1	2.4	28	29	30
	Proposed levels in flour	1.3	3.1	28	29	31
65 + years	Entire diet	9.7	17	28	38	45
	Current levels in flour	0.85	2.1	28	29	30

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	Proposed levels in flour	1.1	2.6	28	29	31
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Table A5: Exposure to niacin from food and supplements

	Category	Chronic exposure to niacin (mg/person/day)*		Niacin exposure from supplements, upper range (mg/person/dy)	Niacin exposure from supplements and diet (mean) (mg/person/day)	Nacin exposure from supplements and diet (97.5 th percentile) (mg/person/day)
		Mean	97.5th Percentile			
Infants (4 - 18 months)	Entire diet	14	25	20	34	45
	Current levels in flour	0.26	0.81	20	20	21
	Proposed levels in flour	0.39	1.2	20	20	21
1.5 - 3 years	Entire diet	18	28	20	38	48
	Current levels in flour	0.58	1.3	20	21	21
	Proposed levels in flour	0.87	2	20	21	22
4 - 10 years	Entire diet	25	39	20	45	59

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	Current levels in flour	0.94	1.9	20	21	22
	Proposed levels in flour	1.4	2.8	20	21	23
11 - 18 years	Entire diet	31	55	20	51	75
	Current levels in flour	1.2	2.4	20	21	22
	Proposed levels in flour	1.7	3.6	20	22	24
19 - 64 years	Entire diet	36	68	1000	1000	1100
	Current levels in flour	0.98	2.4	1000	1000	1000
	Proposed levels in flour	1.5	3.6	1000	1000	1000
65 + years	Entire diet	31	52	1000	1000	1100
	Current levels in flour	0.83	2	1000	1000	1000

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	Proposed levels in flour	1.2	3	1000	1000	1000
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Table A6: Exposure to thiamin from food and supplements

Age group	Category	Chronic exposure to thiamin (mg/person/day)*		Exposure of thiamin from supplements, upper range (mg/person/day)	Thiamin exposure from supplements and diet (mean) (mg/person/day)	Thiamin exposure from supplements and diet (97.5 th percentile) (mg/person/day)
		Mean	97.5th Percentile			
Infants (4 - 18 months)	Entire diet	0.81	1.3	5	5.9	6.3
	Current levels in flour	0.039	0.12	5	5.0	5.1
1.5 -3 years	Entire diet	1	1.8	5	6	6.8
	Current levels in flour	0.087	0.2	5	5.1	5.2
4 - 10 years	Entire diet	1.3	2.3	5	6.3	7.3
	Current levels in flour	0.14	0.28	5	5.1	5.3
11 - 18 years	Entire diet	1.4	2.8	5	6.4	7.8
	Current levels in flour	0.17	0.36	5	5.2	5.4
19 - 64 years	Entire diet	1.5	2.8	500	500	500

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	Current levels in flour	0.15	0.36	500	500	500
65 + years	Entire diet	1.5	2.7	500	500	500
	Current levels in flour	0.12	0.3	500	500	500

Table A5. Online sources for iron supplement data

Supplement	Iron dosage per day (mg)	Link	Notes
Sainsbury's Health Multivitamins & Iron Tablets 1 a Day x60	14	Sainsbury's Health Multivitamins & Iron Tablets 1 a Day x60 Sainsbury's (sainsburys.co.uk)	1 tablet per day
Feroglobin Capsules	17	Feroglobin® Capsules Iron Supplement Vitabiotics	Iron (as fumerate) 1 tablet per day
Ultra Iron	14	Ultra Iron Iron Tablets Vitabiotics	1 tablet per day
Holland & Barrett Gentle Iron 20mg 90 Capsules	20	Holland & Barrett Gentle Iron 20mg 90 Capsules : Amazon.co.uk: Health & Personal Care	1 tablet per day
Iron Complex 90 Capsules	14	Iron Complex 90 Capsules BioCare	1 tablet per day
Iron & Folic Acid Tablets	14	Iron & Folic Acid Tablets MYPROTEIN™	1 tablet per day

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Nature's Bounty Gentle Iron Complex with Vitamins B12 and C Capsules x100	17	Nature's Bounty Gentle Iron Complex with Vitamins B12 and C Capsules x100 Sainsbury's (sainsburys.co.uk)	Iron (as Ferrous Bisglycinate) 1 tablet per day
Solgar® Gentle Iron (Iron Bisglycinate) 20 mg Vegetable Capsules - Pack of 90	20	Solgar® Gentle Iron (Iron Bisglycinate) 20 mg Vegetable Capsules - Pack of 90 : Amazon.co.uk: Health & Personal Care	1 tablet per day
Iron 14 mg	28	Iron Tablets 14mg Simply Supplements	1-2 tablet per day
Iron (Ferrous Bisglycinate) Capsules (K-Pure®) 20 mg	20	Iron Capsules (K-Pure) Ferrous Bisglycinate Bulk™	1 tablet per day
Nature's Bounty, Gentle Iron, 28 mg, 90 Capsules	28	Nature's Bounty, Gentle Iron, 28 mg, 90 Capsules (iherb.com)	1 tablet per day
Range	14-28		
Supplement	Iron dosage per day (mg)	Link	Notes
Holland and Barrett Kids Multivits & Iron Tablets Holland & Barrett	7.5	Holland and Barrett Kids Multivits & Iron Tablets Holland & Barrett	
Tasty Chews, A Chewable Multivitamin and Mineral For Children 4-14 years	2.8	Children's Chewable Multivitamins Nature's Best (naturesbest.co.uk)	

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Wellkid Smart Chewable	7	Wellkid® Smart Chewable By Vitabiotics Vitamins For Kids	1 tablet per day children aged 4-12 years
Solgar Kangavites Tropical Vitamins for Children - 120 Chewables	5	Solgar Kangavites Tropical Vitamins for Children - 120 Chewables bodykind	Children 3-5 years 1 tablet per day children 6+ years 2 per day

Table A6. Online sources for calcium supplement data

Supplement	Calcium dosage per day (mg)	Link	Notes
Calcium & Magnesium Tablets MYPROTEIN™	800	Calcium & Magnesium Tablets MYPROTEIN™	3 tablets per day
Osteocare Original	800	Osteocare® Original Bone Health Tablets Vitabiotics	2 tablets per day The UK's No.1 calcium formula for women and men of all ages.

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Numark Chewable Calcium & Vitamin D - 30 x 400mg Tablets	800	Numark Chewable Calcium & Vitamin D - 30 x 400mg Tablets Chemist 4 U (chemist-4-u.com)	1 tablet per day Numark Vitamin D and Calcium Tablets are not suitable for children under the age of 12.
OsteoGuard®, High Strength Calcium and Magnesium Formula	1000	Osteoguard® Calcium & Magnesium Tablets Nature's Best (naturesbest.co.uk)	1-2 tablets per day This product is suitable for all adults.
Natures Aid Chewable Calcium with Vitamin D - 60 Tablets	800	Natures Aid Chewable Calcium with Vitamin D - 60 Tablets bodykind	1-2 tablets per day
Calcium + Vitamin D3 + Vitamin K1 Capsules 1000 mg	200	Calcium + Vitamin D3 + Vitamin K1 Supplement Bulk™	1 tablet per day
Super Calcium	780	Super Calcium Higher Nature	1-3 tablets per day
Nature's Bounty, Calcium Plus Vitamin D3, 600 mg, 220 Rapid Release Softgels	1200	Nature's Bounty, Calcium Plus Vitamin D3, 600 mg, 220 Rapid Release Softgels (iherb.com)	2 per day For adults, take two (2) softgels daily, preferably with meals.

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Alive! Calcium Gummies with Vitamin D3 60 Chewable Gummies Specially Formulated for Adults and Children From 3 Years.	500	Alive! Calcium Gummies with Vitamin D3 60 Chewable Gummies Specially Formulated for Adults and Children From 3 Years. : Amazon.co.uk: Health & Personal Care	2 soft gels per day 13+ years
Range	200-1200		
Supplement	Calcium dosage per day (mg)	Link	Notes
Children's Chewable Multivitamins Nature's Best (naturesbest.co.uk)	80	Children's Chewable Multivitamins Nature's Best (naturesbest.co.uk)	
CALCI-YUMMIES	150	Calci-YUMMies 1st Phorm	Children 2+ years take 1 gummy per day
Lil Critters Calcium Gummy Bears with Vitamin D-200 Bears	200	Lil Critters Calcium Gummy Bears with Vitamin D-200 Bears :	children aged 3+ advised to take 2 gummies

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		Amazon.co.uk: Health & Personal Care	
NaturesPlus Animal Parade Source of Life Calcium Children's Chewable - Natural Vanilla Sundae Flavour - 90 Chewable Animal Shaped Tablets - Gluten Free - 90 Servings : Amazon.co.uk: Health & Personal Care	250	NaturesPlus Animal Parade Source of Life Calcium Children's Chewable - Natural Vanilla Sundae Flavour - 90 Chewable Animal Shaped Tablets - Gluten Free - 90 Servings : Amazon.co.uk: Health & Personal Care	2+ years 2 gummies per day
Wellkid Calcium Liquid	300-450	Wellkid® Calcium Liquid By Vitabiotics Vitamins For Kids	10ml (300mg) children aged 4-6 years and 15 ml (450 mg) for children aged 7-12 years
Calcium and Vitamin D softies 30	280	Haliborange Kids Calcium and Vitamin D softies 30 : Amazon.co.uk: Health & Personal Care	1-2 softies per day Recommended for children

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Alive! Calcium Gummies with Vitamin D3 60 Chewable Gummies Specially Formulated for Adults and Children From 3 Years.	250	Alive! Calcium Gummies with Vitamin D3 60 Chewable Gummies Specially Formulated for Adults and Children From 3 Years. : Amazon.co.uk: Health & Personal Care	1 soft gel per day for children aged 3-12 years
Solgar Kangavites Tropical Vitamins for Children - 120 Chewables	128	Solgar Kangavites Tropical Vitamins for Children - 120 Chewables bodykind	Children 3-5 years 1 tablet per day children 6+ years 2 per day

Table A7. Online sources for Niacin supplement data

Supplement	Niacin dosage per day (mg)	Link	Notes
Vitamin B3 Niacin/Nicotinic Acid (Flush Effect) 50mg, Magnesium Stearate Free & No Nasty Additives, Made in Wales ... (180 Capsules)	50	Vitamin B3 Niacin/Nicotinic Acid (Flush Effect) 50mg, Magnesium Stearate Free & No Nasty Additives, Made in Wales ... (180 Capsules) : Amazon.co.uk: Health & Personal Care	1 tablet per day

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NOW Foods, Niacin, 500 mg, 250 Tablets	500	NOW Foods, Niacin, 500 mg, 250 Tablets (iherb.com)	1 tablet per day
Solgar Niacin (Vitamin B3) 500 Mg Vegetable Capsules - Pack Of 100	500	Solgar Niacin (Vitamin B3) 500 mg Vegetable Capsules - Pack of 100 – Your Health Store (healthstoreexpress.co.uk)	1 tablet per day
Solgar Niacin 100mg Tablets 100	100	Solgar Niacin 100mg Tablets 100 Landys Chemist	1 tablet per day
Swanson Niacin, 100mg - 250 tablets	100	Swanson Niacin, 100mg - 250 tablets (lifestylehealthstore.co.uk)	1 tablet per day
Niacin, 100 mg, 300 Tablet	100	Niacin, 100 mg, 300 Tablets PipingRock Health Products	1 tablet per day
Niacin, 1000 mg, 100 Quick Release Capsules, 2 Bottles	1000	Niacin 1000 mg 2 x 100 Capsules Niacin 1000 Tablets PipingRock Health Products	1 tablet per day
Vitamin B3 250mg (Niacin), Contributes to the Normal Function Of The Nervous System	250	Vitamin B3 & Niacin Tablets Nature's Best (naturesbest.co.uk)	1 tablet per day
Source Naturals, Niacin, 100 mg, 250 Tablets	100	Source Naturals, Niacin, 100 mg, 250 Tablets (iherb.com)	1 tablet per day

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Nature's Way, Niacin, Vitamin B3, 100 mg, 100 Capsules	100	Nature's Way, Niacin, Vitamin B3, 100 mg, 100 Capsules (iherb.com)	1 tablet per day
Range	50-1000		
Supplement	Niacin dosage per day (mg)	Link	Notes
Holland and Barrett Kids Multivits & Iron Tablets Holland & Barrett	13.5	Holland and Barrett Kids Multivits & Iron Tablets Holland & Barrett	1 tablet per day suitable for 4+ years
Children's Chewable Multivitamins Nature's Best (naturesbest.co.uk)	9	Children's Chewable Multivitamins Nature's Best (naturesbest.co.uk)	
Wellkid Peppa Pig Multi-vits	4.8	Wellkid® Peppa Pig Multi Vitamins By Vitabiotics	2 jellies per day children 3+ NE
Wellkid Smart Chewable	9	Wellkid® Smart Chewable By Vitabiotics Vitamins For Kids	1 tablet per day children aged 4-12 years
Kids Multivitamin Gummies	8.2	Kids Multivitamin Gummies MYPROTEIN™	1 gummy per day
Solgar Kangavites Tropical Vitamins for Children - 120 Chewables	20	Solgar Kangavites Tropical Vitamins for Children - 120 Chewables bodykind	Children 3-5 years 1 tablet per

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			day children 6+ years 2 per day
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Table A8. Online sources for thiamin supplement data

Supplement	Thiamin dosage per day (mg)	Link	Notes
Solgar Vitamin B1 (Thiamin) 500 mg Tablets - Pack of 100 - Supports Energy Metabolism and Nervous System - Vegan	500	Solgar Vitamin B1 (Thiamin) 500 mg Tablets - Pack of 100 - Supports Energy Metabolism and Nervous System - Vegan : Amazon.co.uk: Health & Personal Care	1 tablet per day
Natures Aid Vitamin B1 Thiamin - 90 x 100 mg Tablets	100	Natures Aid Vitamin B1 Thiamin - 90 x 100mg Tablets bodykind	1 tablet per day
Vitamed Thiamine 100 mg 100 Tablets	107	Vitamed Thiamine 100mg 100 Tablets : Amazon.co.uk: Health & Personal Care	1 tablet per day
Vitamin B1 100 mg (Thiamin) 180 Tablets Suitable for Vegans and Vegetarians Made	100	Vitamin B1 100mg (Thiamin) 180 Tablets Suitable for Vegans and Vegetarians Made in UK by	1 tablet per day

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in UK by Futurevits 6 Month Supply, Premium Grade only.		Futurevits 6 Month Supply, Premium Grade only. : Amazon.co.uk: Health & Personal Care	
B-1 (Thiamin), 100 mg, 250 Tablets PipingRock Health Products	100	B-1 (Thiamin), 100 mg, 250 Tablets PipingRock Health Products	1 tablet per day
HealthAid Vitamin B1 (Thiamin) 100mg - Prolong Release - 90 Tablets	100	HealthAid Vitamin B1 (Thiamin) 100mg - Prolong Release - 90 Tablets : Amazon.co.uk: Health & Personal Care	1 tablet per day
Source Naturals, B-1, Thiamin, 100 mg, 100 Tablets	100	Source Naturals, B-1, Thiamin, 100 mg, 100 Tablets (iherb.com)	1 tablet per day
Holland & Barrett Vitamin B1 + Thiamine 100 mg 120 Tablets	100	Holland & Barrett Vitamin B1 + Thiamine 100mg 120 Tablets Holland & Barrett (hollandandbarrett.com)	1 tablet per day
Lindens Vitamin B1 Thiamine Tablets - 100 Pack - for Heart, Immune and Psychological Function & Energy Release - UK Manufacturer, Letterbox Friendly	100	Lindens Vitamin B1 Thiamine Tablets - 100 Pack - for Heart, Immune and Psychological Function & Energy Release - UK Manufacturer, Letterbox Friendly : Amazon.co.uk: Health & Personal Care	1 tablet per day
Vitamin B1 (Thiamin) 100 mg 180 Vegan Tablets	100	Vitamin B1 (Thiamin) 100mg 180 Vegan Tablets : Amazon.co.uk: Health & Personal Care	1 tablet per day
Range	100-500		

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Supplement	Thiamin dosage per day (mg)	Link	Notes
Wellkid Peppa Pig Multi-vits	0.7	Wellkid® Peppa Pig Multi Vitamins By Vitabiotics	2 jellies per day children 3+
Wellkid Smart Chewable	0.9	Wellkid® Smart Chewable By Vitabiotics Vitamins For Kids	1 tablet per day children aged 4-12 years
Centrum Kids Multivitamins & Minerals, 30 Tablets	0.5	Centrum Kids Multivitamins & Minerals, 30 Tablets : Amazon.co.uk: Health & Personal Care	
[New] Creekside Naturals Mighty Eyes, Eye Vitamin and Mineral Supplement for Children with Lutein, Zeaxanthin, Thiamine, and Zinc, Vegan, Zero Sugar, 30 Soft Chewables	5	[New] Creekside Naturals Mighty Eyes, Eye Vitamin and Mineral Supplement for Children with Lutein, Zeaxanthin, Thiamine, and Zinc, Vegan, Zero Sugar, 30 Soft Chewables : Amazon.co.uk: Health & Personal Care	1 tablet per day
Solgar Kangavites Tropical Vitamins for Children - 120 Chewables	1.5	Solgar Kangavites Tropical Vitamins for Children - 120 Chewables bodykind	Children 3-5 years 1 tablet

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			per day children 6+ years 2 per day
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