Committee on Toxicity

TOX/2023/03

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

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 of non-wholemeal wheat flour with calcium as calcium carbonate, iron and niacin 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 these nutrients, added to 15% of their respective 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% of their NRVs, respectively. The minimum amount of thiamin required to be present in non-wholemeal wheat flour would remain unchanged, at 19% of its NRV. NRVs are established guidelines for recommended daily nutrient consumption.

2. Further to Defra's proposal, 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 a risk assessment of dietary exposure to calcium, iron, niacin (vitamin B3) and thiamin (vitamin B1), based on current and proposed fortification levels. The risk assessment provides a comparison of estimated dietary exposure to the UK Expert Group on Vitamins and Minerals (EVM) guidance levels for the four nutrients, and allows for a conclusion on whether there is a potential risk to

human health from the proposed increased fortification in non-wholemeal wheat flour.

Background

3. The BFR 1998 stipulates the levels of calcium as calcium carbonate, iron, thiamin (vitamin B1) and niacin that are required to be present in all wheat flour other than wholemeal (i.e., non-wholemeal wheat 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 in the form of either nicotinic acid or nicotinamide.

4. The existing BFR (1998) set a minimum fortification level for thiamin (vitamin B1) of 0.24 mg thiamin hydrochloride, which is equivalent to 0.21 mg of thiamin (supplied by 100 g of non-wholemeal wheat flour) or 19% of the NRV. The proposed minimum fortification levels of calcium, iron and niacin have been set at 15% of their respective NRVs, as stated in Annex XIII of regulation EC No. 1169/2011 (in point 1 of Part A). In practice, 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 hypertension, neurological problems, abdominal pain and tissue calcification (EVM, 2003).

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 GI 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, GI 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 GI tract and iron disrupts cellular metabolism in the central nervous system, liver and heart. 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 (vitamin B3)

10. Symptoms of acute toxicity from niacin include flushing, itchy skin, nausea, vomiting and GI 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, indicative of effects on the liver, 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 ≥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 daily doses as low as 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). In a 2018 report, a few patients with Parkinson's disease 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).

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 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 GI 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/person/day (0.22 mg/kg bw per day for a 78.6 kg adult) (based on the average body weight in the UK National Diet and Nutrition Survey (NDNS) data) (Bates *et al.*, 2014, 2016, 2020; Roberts *et al.*, 2018) 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 ULs of 40 mg/day/person for individuals aged 0 months to 13 years and 45 mg/day for individuals aged 14 years and over (Institute of Medicine, 2001). However, it has been reported that ingestion <20 mg/kg of elemental iron is non-toxic and moderate symptoms of iron toxicity can occur between 20 to 60 mg/kg (Yuen and Becker, 2022).

18. The EVM proposed that a guidance level of 17 mg/day for niacin 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 but 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 applicable only 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) who may not be representative of the population in general. 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 observed at high oral doses of ≥7,000 mg/day thiamin hydrochloride (EVM, 2003).

Exposure assessment

20. Exposures to calcium, iron, niacin and thiamin were estimated using consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) and the 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 wheat 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. Exposures to these nutrients were calculated in Crème Global, the software used by the FSA 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 exposures or intakes of these nutrients are presented. Chronic intake is estimated from the average amount of flour consumed per day over the survey days multiplied by the levels of nutrients. Chronic exposure or intake is calculated for each consumer. The mean and 97.5th percentile are then calculated.

Table 1**.** Concentration data used to estimate 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 wheat flour)**	**Level based on fortification at 15% (mg/100 g non-wholemeal wheat 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.

Methodology for estimating actual and proposed exposures from non-wholemeal wheat flour

21. Exposures based on actual and proposed levels of fortification were calculated from foods containing non-wholemeal wheat 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 wheat flour (n = 1835). A selection of food groups (foods with non-wholemeal wheat flour), each containing more than 20 foods, is shown in Table A1 in Annex A.

22. The fortification level for thiamin remains unchanged, therefore exposures at the proposed fortification levels were calculated only 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). Doses of calcium supplements ranged from 200 - 1200 mg/day for adults and 80 - 450 mg/day for children. Whereas doses of iron supplements ranged from 14 - 28 mg/day in adults and 2.8 - 7.5 mg/day in children. Doses of niacin supplements ranged from 50 – 1,000 mg/day in adults and 4.8 - 20 mg/day in children. Doses of thiamin supplements ranged from 100 - 500 mg/day for adults and 0.5 – 5.0 mg/day for children.

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

24. Exposures to the nutrients from the entire diet (including food groups containing non-wholemeal wheat flour at the actual and proposed levels of fortification) was estimated using all food groups from NDNS years 1 - 11, and are presented in Table A2 of Annex A. All food groups, including the foods containing non-wholemeal wheat flour. are detailed in Table A1 of Annex A. The levels of the nutrients for each of the foods included were derived from the nutrient databank from the NDNS.

25. It should be noted that the nutrient data from NDNS used in the assessment of the entire diet accounts for industry use of overage (the industry practice of increasing the level of fortificants added to food in order to account for degradation during manufacture and storage) only in foods such as flour but not in other foods such as breakfast cereals and is therefore a potential source of uncertainty. Estimates for flour at the actual and proposed fortification levels, also do not account for overage as they are based on nutrient levels that are stipulated by legislation, not the nutrient databank, and is also a source of uncertainty.

26. Estimated exposure to calcium, iron, niacin and thiamin from the entire diet and from non-wholemeal wheat flour fortification at actual and proposed levels are shown in Tables 2 - 5.

27. For calcium, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current actual 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 97.5th percentile levels, respectively (Table 3).

28. For iron, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current actual 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).

29. For niacin, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current actual 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).

30. For thiamin, across all age groups (4 months to 65+ years), the maximum mean and maximum 97.5th percentile exposures at the current actual level of fortification are 0.17 and 0.36 mg/person/day, respectively. No increase in the fortification level of thiamin is proposed. The maximum exposures 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).

Table 2. Estimated chronic exposures to calcium from the diet and from non-wholemeal wheat flour fortification at actual and proposed levels (15% of the nutrient reference value supplied by 100 g flour) levels.

Age group	**Category**	**Mean chronic exposure to calcium (mg/person/day)**	**97.5th percentile chronic exposure to calcium (mg/person/day)**
Infants (4-18 months)	**Entire diet**	**680**	**1,200**
Infants (4-18 months)	Actual levels in flour	15	48
Infants (4-18 months)	Proposed levels in flour	19	61
1.5-3 years	**Entire diet**	**740**	**1,300**
1.5-3 years	Actual levels in flour	34	78
1.5-3 years	Proposed levels in flour	43	99
4 - 10 years	**Entire diet**	**760**	**1,400**
4 - 10 years	Actual levels in flour	55	110
4 - 10 years	Proposed levels in flour	71	140
11 – 18 years	**Entire diet**	**770**	**1,500**

11 – 18 years	Actual levels in flour	68	140
11 – 18 years	Proposed levels in flour	87	180
19 – 64 years	**Entire diet**	**810**	**1,600**
19 – 64 years	Actual levels in flour	58	140
19 – 64 years	Proposed levels in flour	74	180
65 + years	**Entire diet**	**820**	**1,500**
65 + years	Actual levels in flour in flour	49	120
65 + years	Proposed levels	62	150

Table 3. Estimated chronic exposures to iron from the diet and non-wholemeal wheat from flour fortification at actual and proposed (15% of the nutrient reference value supplied by 100 g flour) levels.

Age group	**Category**	**Mean chronic exposure to iron (mg/person/day) ***	**97.5th percentile chronic exposure to iron (mg/person/day) ***
Infants (4-18 months)	**Entire diet**	**6.8**	**12**
Infants (4-18 months)	Actual levels in flour	0.27	0.84
Infants (4-18 months)	Proposed levels in flour	0.34	1.1
1.5-3years	**Entire diet**	**6**	**10**
1.5-3years	levels in flour	0.6	1.4
1.5-3years	Proposed levels in flour	0.76	1.7
4 - 10 years	**Entire diet**	**8.1**	**14**
4 - 10 years	Current levels in flour	0.97	1.9
4 - 10 years	Proposed levels in flour	1.2	2.4

11 – 18 years	**Entire diet**	**9.3**	**17**
11 – 18 years	Current levels in flour	1.2	2.5
11 – 18 years	Proposed levels in flour	1.5	3.2
19 - 64 years	**Entire diet**	**10**	**19**
19 - 64 years	Current levels in flour	1	2.4
19 - 64 years	Proposed levels in flour	1.3	3.1
65 + years	**Entire diet**	**9.7**	**17**
65 + years	Current levels in flour	0.85	2.1
65 + years	Proposed levels in flour	1.1	2.6

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

Age group	Category	Mean chronic exposures to niacin (mg/person/day) *	97.5th percentile chronic exposures to niacin (mg/person/day) *
Infants (4-18 months)	**Entire diet**	**14**	**25**
Infants (4-18 months)	Actual levels in flour	0.26	0.81
Infants (4-18 months)	Proposed levels in flour	0.39	1.2
1.5-3years	**Entire diet**	**18**	**28**
1.5-3years	Actual levels in flour	0.58	1.3
1.5-3years	Proposed levels in flour	0.87	2
4 - 10 years	**Entire diet**	**25**	**39**
4 - 10 years	Actual levels in flour	0.94	1.9
4 - 10 years	Proposed levels in flour	1.4	2.8

11 - 18years	**Entire diet**	**31**	**55**
11 - 18years	Actual levels in flour	1.2	2.4
11 - 18years	Proposed levels in flour	1.7	3.6
19 - 64 years	**Entire diet**	**36**	**68**
19 - 64 years	Actual levels in flour	0.98	2.4
19 - 64 years	Proposed levels in flour	1.5	3.6
65 + years	**Entire diet**	**31**	**52**
65 + years	Actual levels in flour	0.83	2
65 + years	Proposed levels in flour	1.2	3

Table 5: Estimated chronic exposures to thiamin in the diet and from non-wholemeal wheat flour fortification at actual (19% of the nutrient reference value supplied by 100g flour; there is no proposed increase to thiamin) levels.

Age group	Category	Mean chronic intake of thiamin (mg/person/day) *	97.5th percentile chronic intake of thiamin (mg/person/day) *
Infants (4-18 months)	**Entire diet**	**0.81**	**1.3**
Infants (4-18 months)	Actual levels in flour	0.039	0.12
1.5-3years	**Entire diet**	**1**	**1.8**
1.5-3years	Actual levels in flour	0.087	0.2
4 - 10 years	**Entire diet**	**1.3**	**2.3**
4 - 10 years	Actual levels in flour	0.14	0.28
11 - 18years	**Entire diet**	**1.4**	**2.8**
11 - 18years	Actual levels in flour	0.17	0.36
19 - 64 years	**Entire diet**	**1.5**	**2.8**
19 - 64 years	Actual levels in flour	0.15	0.36
65 + years	**Entire diet**	**1.5**	**2.7**
65 + years	Actual levels in flour	0.12	0.3

* **Rounded** to 2 significant figures.

Exposure from supplements

31. It should be noted that supplements data were derived from various online sources and are shown in Tables A7 – A10 in Annex A. The highest doses of calcium, iron, niacin and thiamin in supplements were used as the values for the upper exposures from supplements. The exact consumption by the population was unknown therefore exposures were calculated based on recommended dose sizes. The exposure data for supplements do not take into account industry use of overage in this assessment and is therefore a potential source of uncertainty.

32. Across all age groups (4 months to 65+ years) the upper exposures to 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 (2,000 mg/day) and 97.5th percentile (2,800 mg/day) calcium exposures from the entire diet (which includes all food groups including non-wholemeal wheat flour), respectively.

33. Across all age groups (4 months to 65+ years) the upper exposures to 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 (38 mg/day) and 97.5th percentile (47 mg/day) iron exposures from the entire diet, respectively.

34. Across all age groups (4 months to 65+ years) the upper exposures to 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 (1000 mg/day) and 97.5th (1000 mg/day) percentile niacin exposures from the entire diet, respectively.

35. Across all age groups (4 months to 65+ years) the upper exposures to 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 (500 mg/day) and 97.5th percentile (500 mg/day) thiamin exposures from the entire diet.

Risk characterisation

Exposures from food

36. Chronic exposure to calcium from non-wholemeal wheat flour at the current actual and proposed fortification levels (Table 2) did not exceed the guidance level of 1,500 mg/person/day (EVM, 2003) or 2,500 mg/day (EFSA, 2012), in any age group. Exposure from the entire diet was up to 1,600 mg/person day, which, although marginally exceeding the EVM guidance level, is below the SCF TUL of 2,500 mg/day.

37. Chronic exposures to iron from non-wholemeal wheat flour at the current actual and proposed fortification levels (Table 3) did not exceed the guidance levels of 17 mg/day (EVM, 2003) in any age group. Exposures from the entire diet were up to 19 mg/person/day, which would result in marginal exceedance of the EVM guidance level. However, it is important to note that the guidance level is based on supplemental intake and not dietary intake. The level did not exceed that reported to cause moderate symptoms of iron toxicity, i.e. 20 mg/kg bw per day (1572 mg per person/day for a 78.6 kg adult) (Madiwale and Liebelt, 2006). Hence, it is not anticipated that there would be a risk to health from exposure to iron in the entire diet in 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 genotype. Such individuals would normally be under medical supervision to ensure their exposure to iron was appropriate.

38. Chronic exposures to niacin equivalents from non-wholemeal wheat flour (Table 4) at the current actual and proposed fortification levels did not exceed the guidance level for niacin of 17 mg/day (EVM, 2003) in any age group. Exposures to niacin from the entire diet were up to 68 mg/person/day, which exceed 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 from the diet, although there is some uncertainty.

39. Chronic exposures to thiamin at the actual fortification level (Table 5) did not exceed the current guidance level of 100 mg/day (EVM, 2003) in any age group. 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 any adverse health effects from thiamin in the diet.

Exposure from supplements

40. 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 result in exceedance of 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).

Combined exposure from supplements and food

41. Mean calcium exposures from food (the entire diet and flour at the current and proposed fortification levels) and supplements (Table A3, Annex A) 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 of 18 years and over marginally exceeded the SCF TUL but it is unlikely that there would be a

risk of adverse health effects at these exposures, given the assumptions made in this assessment.

42. Mean and 97.5th percentile iron exposures from food and supplements were up to 25 mg/person/day (Table A4, Annex A) and included values which were either below or slightly exceeded 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, given the assumptions made in this assessment. 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 exceeded the guidance level by up to 2.2-fold and 2.8-fold, respectively. It is unlikely that there is a risk of adverse health effects in the majority of the population, as it was assumed that all individuals use supplements, at the maximum reported iron levels. It should be noted that 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.

43. Mean and 97.5th percentile niacin exposure from food (entire diet) and supplements (Table A5, Annex A) exceeded the guidance level of 17 mg/day (EVM, 2003) in all age groups. In those aged up to 18 years, exceedances 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 1.06-fold) for mean and 97.5th percentile consumers, respectively). In those aged over 18 years the exceedances were up to 59- and 65-fold for mean and 97.5th percentile consumers, respectively. Much of this exceedance comes from the consumption of supplements containing niacin at 1,000 mg. It is important to note that the guidance level of 17 mg/day is based on supplemental intake.

44. As noted previously, the EVM guidance level is for supplementation only, as adverse effects from niacin seem to be related to acute, bolus intakes. Hence, 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 levels over a prolonged period of time.

45. Exposures to thiamin from food and supplements (Table A6, Annex A) 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 guidance level for thiamin only in the 19-64 years and 65+ years age groups. 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 dietary exposures would cause adverse health effects, as the EVM guidance level is based on supplemental intake.

Conclusion

46. Chronic exposures to calcium (as calcium carbonate), iron and niacin from non-wholemeal wheat flour at the current actual and proposed fortification levels, and to thiamin (for which no change was proposed) at the current actual fortification level 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 form 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 the risk of adverse health effects, particularly when considering the entire diet and consumption of supplements.

47. 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. The TUL used in the risk characterisation for calcium is based on supplemental intake, making the assessment conservative for exposures from an increase in calcium in non-wholemeal wheat flour and the entire diet. There is unlikely to be a risk of adverse health effects.

48. 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. It is unlikely that there is a risk of adverse health effects in the majority of the population, as not all individuals use supplements, and those that do, do not all use those with the maximum reported iron levels. However, the NHS advises that you should be able to get all the iron you need from your daily diet (NHS, 2020). For individuals not consuming iron supplements in addition to their daily diet, there is unlikely to be any risk of adverse health effects. 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.

49. In those aged less than18 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 of non-wholemeal wheat flour. 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.

50. No change in the fortification level of thiamin was proposed. Actual 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 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 for the reasons explained above.

51. Although not materially impacted by the level of fortification of non-wholemeal wheat flour (actual current or proposed), it was noted that intakes of calcium from supplements alone did not exceed the guidance level for this mineral whereas consumption of higher dosage iron, niacin and thiamin supplements may result in exceedances of the respective guidance levels.

52. As discussed in paragraph 23 it should be noted that the estimates for non-wholemeal wheat flour at the actual and proposed fortification levels do not account for overage as they are based on nutrient levels stipulated by legislation and not nutrient levels in the databank, creating a source of uncertainty in this review.

53. Overall, the COT 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 actual current fortification levels.

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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Secretariat

March 2023

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 A7. 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.
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.
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)	No data.
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 : Amazon.co.uk: Health & Personal Care	children aged 3+ advised to take 2 gummies.
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.
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 A8. 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.
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	No data.
Tasty Chews, A Chewable Multivitamin and Mineral for Children 4-14 years.	2.8	Children's Chewable Multivitamins | Nature's Best (naturesbest.co.uk)	No data.
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 A9. 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.
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.
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 suitbale for 4+ years.
Children's Chewable Multivitamins | Nature's Best (naturesbest.co.uk).	9	Children's Chewable Multivitamins | Nature's Best (naturesbest.co.uk)	No data.
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 day children 6+ years 2 per day.

Table A10. 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 in UK by Futurevits 6 Month Supply, Premium Grade only.	100	Vitamin B1 100mg (Thiamin) 180 Tablets Suitable for Vegans and Vegetarians Made in UK by Futurevits 6 Month Supply, Premium Grade only. : Amazon.co.uk: Health & Personal Care	1 tablet per day.
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	100	Lindens Vitamin B1 Thiamine Tablets - 100 Pack - for Heart, Immune and Psychological Function &	1 tablet per day.

Function & Energy Release - UK Manufacturer, Letterbox Friendly.		Energy Release - UK Manufacturer, Letterbox Friendly : Amazon.co.uk: Health & Personal Care	
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 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	No data.
[New] Creekside Naturals Mighty Eyes, Eye Vitamin and Mineral Supplement for Children with Lutein, Zeaxanthin, Thiamine,	5	[New] Creekside Naturals Mighty Eyes, Eye Vitamin and Mineral Supplement for Children with Lutein, Zeaxanthin, Thiamine, and Zinc, Vegan,	1 tablet per day.

and Zinc, Vegan, Zero Sugar, 30 Soft Chewables.		Zero Sugar, 30 Soft Chewables : Amazon.co.uk: Health & Personal Care	
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 per day children 6+ years 2 per day.

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

Table A3: Calcium exposure from foods and supplements.

Age group	Category	Mean chronic exposure of calcium from food (mg/person/day)	97.5th percentile 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 (97.5th percentile) (mg/person/day)
Infants (4 - 18 months)	**Entire diet**	**680**	**1200**	**450**	**1100**	**1700**
Infants (4 - 18 months)	Current levels in flour	15	48	450	470	500
Infants (4 - 18 months)	Proposed levels in flour	19	61	450	470	500
1.5 - 3 years	**Entire diet**	**740**	**1300**	**450**	**1200**	**1800**
1.5 - 3 years	Current levels in flour	34	78	450	490	530
1.5 - 3 years	Proposed levels in flour	43	99	450	490	550
4 - 10 years	**Entire diet**	**760**	**1400**	**450**	**1200**	**1900**
4 - 10 years	Current levels in flour	55	110	450	510	560
4 - 10 years	Proposed levels in flour	71	140	450	520	590

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

Table A4: Iron exposure from food and supplements.

Age group	Category	Mean chronic exposure to iron (mg/person/day)*	97.5th percentile 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 (97.5th percentile) (mg/person/day)
Infants (4 - 18 months)	**Entire diet**	**6.8**	**12**	**7.5**	**14.0**	**20**
Infants (4 - 18 months)	Current levels in flour	0.27	0.84	7.5	7.8	8.3
Infants (4 - 18 months)	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**
1.5 - 3 years	Current levels in flour	0.6	1.4	7.5	8.1	8.9
1.5 - 3 years	Proposed levels	0.76	1.7	7.5	8.3	9.2
4 - 10 years	**Entire diet**	**8.1**	**14**	**7.5**	**16**	**22**
4 - 10 years	Current levels in flour	0.97	1.9	7.5	8.5	9.4

4 - 10 years	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**
11 - 18 years	Current levels in flour	1.2	2.5	7.5	8.7	10
11 - 18 years	Proposed levels in flour	1.5	3.2	7.5	9	11
19 - 64 years	**Entire diet**	**10**	**19**	**28**	**38**	**47**
19 - 64 years	Current levels in flour	1	2.4	28	29	30
19 - 64 years	Proposed levels in flour	1.3	3.1	28	29	31
65 + years	**Entire diet**	**9.7**	**17**	**28**	**38**	**45**
65 + years	Current levels in flour	0.85	2.1	28	29	30
65 + years	Proposed levels in flour	1.1	2.6	28	29	31

Table A5: Exposure to niacin from food and supplements.

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

4 - 10 years	Current levels in flour	0.94	1.9	20	21	22
4 - 10 years	Proposed levels in flour	1.4	2.8	20	21	23
11 - 18 years	**Entire diet**	**31**	**55**	**20**	**51**	**75**
11 - 18 years	Current levels in flour	1.2	2.4	20	21	22
11 - 18 years	Proposed levels in flour	1.7	3.6	20	22	24
19 - 64 years	**Entire diet**	**36**	**68**	**1000**	**1000**	**1100**
19 - 64 years	Current levels in flour	0.98	2.4	1000	1000	1000
19 - 64 years	Proposed levels in flour	1.5	3.6	1000	1000	1000
65 + years	**Entire diet**	**31**	**52**	**1000**	**1000**	**1100**
65 + years	Current levels in flour	0.83	2	1000	1000	1000

65 + years	Proposed levels in flour	1.2	3	1000	1000	1000

Table A6: Exposure to thiamin from food and supplements.

Age group	Category	Mean chronic exposure to thiamin (mg/person/day) *	97.5th percentile 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 (97.5th percentile) (mg/person/day)
Infants (4 - 18 months)	**Entire diet**	**0.81**	**1.3**	**5**	**5.9**	**6.3**
Infants (4 - 18 months)	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**
1.5 -3 years	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**
4 - 10 years	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**

11 - 18 years	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**
19 - 64 years	Current levels in flour	0.15	0.36	500	500	500
65 + years	Entire diet	1.5	2.7	500	500	500
65 + years	Current levels in flour	0.12	0.3	500	500	500