Exposure assessment - Statement on the guidance levels for the fortificants in the Bread and Flour Regulations

In this guide

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*

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.