

Risk characterisation - Statement on the guidance levels for the fortificants in the Bread and Flour Regulations

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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.