

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

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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 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 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 than 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 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.

COT

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