

## **Lay summary Statement on the guidance levels for the fortificants in the Bread and Flour Regulations**

### **Lay summary statement on the UK regulations for guidance levels for the fortificants in bread and flour**

1. In 2022, the Department for Environment, Food and Rural Affairs (Defra) held a consultation relating to the [Bread and Flour Regulations \(BFR\) 1998](#) and a proposed increase in the levels of fortification of non-wholemeal wheat flour with certain nutrients 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 (vitamin B3) required to be added to non-wholemeal wheat flour to 15% of the nutrient reference values (NRV). The NRV is the recommended daily amount of a nutrient an average individual needs for adequate health. The daily NRVs for calcium, iron, and niacin are 800, 14, and 16 milligrams, respectively. 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 the NRV, respectively. The minimum amount of thiamin (vitamin B1) required to be present in non-wholemeal wheat flour would remain unchanged at 19% of the NRV (which is 1.1 milligrams).

2. Following this proposal by Defra, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked by the Department of Health and Social Care (DHSC) to perform a risk assessment of dietary exposure to calcium, iron, niacin and thiamin at current and proposed fortification levels in non-wholemeal wheat flour.

#### **Toxicity of calcium, iron, niacin (vitamin B3) and thiamin (vitamin B1)**

3. Excessive intakes of calcium can result in elevated calcium levels in the blood, excess alkali in the body and impaired kidney function. These are associated with symptoms of high blood pressure, problems affecting the brain, effects on the gastrointestinal (GI) tract such as abdominal pain, and buildup of calcium in body tissue.

4. Excessive intakes of iron can result in nausea and gastrointestinal issues (such as irritation of the GI tract, constipation, vomiting and diarrhoea). Iron toxicity can also lead to inflammation and perforations of (holes in) the GI tract, as well as disruptions in the function of the central nervous system, liver and heart.

5. Symptoms of niacin (also known as vitamin B3) toxicity include reddening of the face, neck or upper chest, itchy skin, nausea, vomiting and GI issues (such as diarrhoea and constipation). Other symptoms include jaundice (yellowish appearance of the skin and eyes), high blood glucose levels and abdominal pain. Effects on the liver can also occur as indicated by elevated levels of bilirubin and, in a small number of cases, liver enzymes in the blood.

6. Thiamin (vitamin B1) is considered to be of very low toxicity, with symptoms of headache and nausea occurring only at very high doses (i.e. 7,000 milligrams of thiamine hydrochloride). However, a small number of cases have been reported of muscle tremors, rapid pulse and nerve hyperirritability at doses as low as 17 milligrams per day.

### **Health based guidance values**

7. The European Scientific Committee on Food (SCF) established a tolerable upper level (a level of nutrient intake that is unlikely to cause adverse health effects in the population) of 2,500 milligrams per day for calcium. There were insufficient data for either the SCF or the UK Expert Group on vitamins and minerals (EVM) to establish tolerable upper levels for iron, niacin or thiamin. However, the EVM concluded that, for guidance, levels of supplemental iron and niacin of 17 milligrams per person per day would not be expected to cause adverse health effects. For thiamin, the EVM concluded, for guidance, that a level of 100 milligrams per day as a supplement was not expected to cause adverse health effects.

### **Exposures and risk characterisation for the UK population**

## Calcium

8. Exposure to calcium from non-wholemeal wheat flour alone did not exceed the SCF tolerable upper level of 2,500 milligrams either at current actual levels or at the EU proposed fortification level. Exposures to calcium from the overall diet (which includes all food and drink sources of calcium but not supplements), were also well below this level. Therefore, any risk to health from dietary exposure is very unlikely.

9. Combined exposures to calcium from the diet (food and drink) and supplements revealed that only 97.5<sup>th</sup> percentile exposures in those aged 19 years and over exceeded the tolerable upper level of 2,500 milligrams per day and the exceedance was marginal. Also, these exceedances are below the levels at which toxic effects such as milk-alkali syndrome occur (i.e. 4,000 milligrams/day). Such exposures from calcium are unlikely to result in adverse health effects as the exceedance is so small and is based on a number of conservative assumptions.

## Iron

10. Exposures to iron from non-wholemeal wheat flour alone did not exceed the respective EVM guidance level of 17 milligrams per day at either the current actual levels or the proposed fortification level. Exposure to iron from the diet (which includes all food and drink sources of iron but not supplements) was marginally exceeded in those aged 19 years and over. These exceedances are marginal, and the guidance level is based on supplemental intake and not dietary intake. Also, these exceedances are below the levels at which adverse effects such as constipation, nausea and vomiting occur (i.e., 200-300 mg/kg bw), therefore a risk to health is unlikely.

11. Combined exposures to iron from diet (food and drink) and supplements revealed both mean and 97.5<sup>th</sup> percentile exposures led to exceedance of the guidance level of 17 milligrams of iron per day. These exposures are unlikely to be of risk to health in the general population as the analysis assumed that all individuals in this assessment consumed supplements at the maximum levels (while in reality many people will be supplementing at lower levels). However, it is important to note

that that the EVM guidance level for iron does not apply to individuals with genetic conditions that increase their susceptibility to iron overload. These individuals would normally be under medical supervision to ensure their exposure to iron was appropriate.

## **Niacin**

12. Exposures to niacin from non-wholemeal wheat flour did not exceed the EVM guidance level of 17 milligrams per day at either current actual levels of fortification or at the proposed fortification levels.

13. Exposures to niacin from the diet (which includes all food and drink sources of niacin but not supplements) exceeded the guidance level up to 4-fold. However, it is important to note that the EVM guidance level is based on supplemental intakes of bolus doses (doses taken in one go) and not dietary intake, therefore a risk to health is unlikely.

14. Combined exposures to niacin from the diet (food and drink) and supplements revealed that both mean and 97.5<sup>th</sup> percentile exposures exceeded the guidance level of 17 milligrams per day. However, much of this exceedance comes from the consumption of supplements containing high doses of niacin at 1,000 milligrams per day. It is considered that this is unlikely to be a health concern as the individuals in this assessment consumed supplements at the maximum levels over long periods of time (while in reality many people will be supplementing at lower levels). Furthermore, these exceedances are below the reported level to cause jaundice (yellowish appearance of the skin and eyes), high blood glucose levels and abdominal pain.

## **Thiamin**

15. Exposures to thiamin from non-wholemeal wheat flour did not exceed the EVM guidance level of 100 milligrams per day either at current actual levels or at the proposed fortification levels (for which no change is proposed).

16. Exposures to thiamin from the diet (which includes all food and drink sources of thiamin but not supplements) were also below the guidance level, which indicates that it is unlikely there would be any risk of adverse health effects.

17. Combined exposures to thiamin from the diet (food and drink) and supplements revealed that both mean and 97.5<sup>th</sup> percentile exposures exceed the guidance level of 100 milligrams per day in those aged over 19 years by up to 5-fold. However, the EVM guidance level is based on supplemental intake of bolus doses (doses taken in one go) and not overall dietary intake. Also, these exceedances are below the levels at which adverse effects of headache, nausea and irritability occur (i.e 7,000 milligrams/day), therefore these exposures are unlikely to be a risk to health.

18. The COT concluded that an increase in in fortification of non-wholemeal wheat flour to the proposed level of 15% of the NRV for calcium, iron and niacin would not result in any significant increase in risk when compared to the current actual fortification levels. However, it is important to note that the EVM guidance level for iron does not apply to individuals with genetic conditions that increase their susceptibility to iron overload. No change is proposed in the fortification level of thiamin.

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