COT Assurance - 2023

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Assessment of the risk of allergic reaction from fortification of non-wholemeal wheat flour with folic acid

1.41 The FSA and Food Standards Scotland undertook a risk assessment to consider the risk in terms of hypersensitivity to UK consumers if folic acid were used to fortify non-wholewheat wheat flour at a level of 250 µg per 100 g without its presence being labelled on the packaging or not conveyed by other means during a 3-month derogation period. The Committee were asked to review and assure the draft risk assessment.

1.42 The UK prevalence of hypersensitivity to folic acid is not known. Leading UK allergy specialists and the UK wide charity operating for people at risk from severe allergic reactions and anaphylaxis were contacted to inform the risk assessment and were not aware of evidence of hypersensitivity to folic acid in the UK. A small number of cases have been reported in the literature although these were linked to the use of food supplements rather than the consumption of food.

1.43 An allergen reference dose for folic acid has not been established and so the usual approach for assessing hypersensitivity risk could not be followed. Instead, the 75^{th} and 97.5^{th} percentile amount of folic acid that would be consumed if non-wholemeal flour is fortified at the proposed level was estimated and found to be lower than the amount reported to have caused adverse reactions from supplements described in the published literature, with the exception of two cases.

1.44 This suggests that while it may be possible for the proposed amount of folic acid in fortified non-wholemeal wheat flour to trigger reactions, this is only likely to occur very rarely in highly sensitive individuals and is not significant on a population basis.

1.45 Symptoms of the reported adverse reactions to folic acid supplements range from mild to severe (including anaphylaxis) although no deaths have been

reported in the literature. There are currently no reports of hypersensitivity to folic acid in food.

1.46 Overall, if non-wholemeal wheat flour is fortified with folic acid at 250 µg per 100 g without its presence being labelled on the packaging of the final food or, in the case of food sold loose, not conveyed by other means during a 3-month derogation period, then the risk of hypersensitivity to folic acid in UK consumers is estimated to be as follows:

- The **frequency of adverse reactions to folic acid in food** to be **very low** (i.e., very rare but cannot be excluded).
- The **severity of illness in relation to adverse reactions to folic acid in food** to be **medium** (i.e., moderate illness: not usually life-threatening, sequelae rare, moderate duration).
- The **level of uncertainty** to be **medium** (i.e., there are some but not complete data available; evidence is provided in small number of references).

1.47 This risk assessment was published in 2023: Assessment of the risk of allergic reaction from fortification of non-wholemeal wheat flour with folic acid.