

## COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

## FOLIC ACID – STATEMENT ON THE TOLERABLE UPPER LEVEL (TUL) – Lay Summary

Introduction.

1. Supplementation with folic acid has been shown to reduce the risk of having a neural tube defect (NTD) affected pregnancy. This is where the brain, spine or spinal cord do not form properly in an unborn baby and results in life-long health problems or can even be fatal. UK Government advice is that women should take a 400µg supplement of folic acid daily before getting pregnant and up to the third month of pregnancy; women who have already had a NTD affected pregnancy are advised to take a 5 mg supplement.

2. However, as many women do not take supplements and many pregnancies are unplanned, the rate of affected pregnancies has not significantly changed since this advice was issued. Consequently, advisors to the government have recommended that wheat flour should be fortified with folic acid to ensure that all population groups receive adequate amounts of this vitamin. This recommendation was accompanied by advice that folic acid levels in supplements and foods that are currently fortified such as breakfast cereals should be adjusted so that there is no increase in the number of people who were currently consuming more folic acid than is necessary.

3. Safe levels (sometimes called Safe Upper Levels or Guidance Levels (or equivalent)) for folic acid have been established by a number of risk assessment bodies. All of these bodies set a maximum recommended intake of 1 mg/day folic acid based on the observations of nerve damage in patients with pernicious anaemia.

4. Pernicious anaemia is an auto-immune disease (where the immune system of the patient destroys healthy cells of the body). In the case of pernicious anaemia, the immune system destroys cells that line the stomach. These cells secrete a substance that allows the body to absorb vitamin B<sub>12</sub>, therefore these patients become deficient in vitamin B<sub>12</sub> regardless of the amount of vitamin B<sub>12</sub> present in the diet. Vitamin B<sub>12</sub> is an essential vitamin which is necessary for producing haemoglobin – the oxygen carrying molecule in blood; and for producing the myelin sheath that surrounds and protects the nerves of the body. If the myelin sheath become damaged and is not repaired by new myelin, then the messages carried from the brain to the extremities of the body, can be disrupted resulting in numbness

and/or muscle weakness. The damage caused to the nerves in pernicious anaemia can be permanent.

5. Often the first symptom of pernicious anaemia to be identified is extreme tiredness resulting from anaemia (low blood haemoglobin) which can be identified through a simple blood test. There are many causes of anaemia, one of which can also be low dietary folate (the natural form of folic acid found in the diet). Should a patient with pernicious anaemia dramatically increase their intake of folic acid or folate, then their anaemia and associated symptoms may improve but the damage to the nerves would continue unchecked. This has been called "masking vitamin B<sub>12</sub> deficiency".

6. The COT reviewed the safe level for folic acid and the studies on which it was based. Although the studies were limited, the COT agreed that, from the information available, it was appropriate to base a safe level on the masking of vitamin B<sub>12</sub> deficiency. They also agreed that 1mg/day of folic acid in the form of supplements (not including dietary folates) was still the most appropriate level to use but noted that the data on which this was based were poor.

7. The COT also noted that currently reliable diagnostic tests for pernicious anaemia were not routinely or consistently applied across the UK. Should this situation change, with diagnosis becoming more reliable, then there were would be no need to stipulate an upper level for folic acid.

The full COT statement can be found here:

https://cot.food.gov.uk/sites/default/files/cotfolicacidstatement.pdf

Lay Summary to COT statement 2019/03