

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

COT statement on the potential risks from high levels of vitamin A in the infant diet: lay summary

1. The Committee on Toxicity (COT) were asked by the Scientific Advisory Committee on Nutrition (SACN) to review the risks of toxicity from chemicals in the infant diet. SACN will use the COT advice in determining whether the Government's dietary recommendations for infants and young children should be revised. This statement focuses on possible risks from high levels of vitamin A in the infant diet. It does not deal with risks associated with insufficient intakes of vitamin A.
2. It is currently recommended that if solid foods are introduced before age 6 months then liver should be avoided. Children over the age of 6 months (and also adults) are recommended not to eat more than one portion of liver per week, because the vitamin A content in the liver can be harmful in large amounts
3. There are two dietary sources of vitamin A – preformed vitamin A in foods of animal origin, and provitamin A carotenoids in fruit and vegetables. The food with the highest concentration of vitamin A is liver. Preformed vitamin A is more active biologically than provitamin A carotenoids.
4. Vitamin A toxicity arises from high intakes of preformed vitamin A, and does not result from high intakes of provitamin A carotenoids. Depending on the level of intake, possible adverse effects in infants include bulging fontanelles¹, loss of appetite, dry skin and damage to the liver.
5. The COT concluded that the adverse effect of vitamin A which occurs most readily in infants (i.e. at the lowest doses) is bulging of fontanelles, and that a Tolerable Upper Level (TUL) of exposure should be established below which this effect would not be expected to occur. There have been a number of reports of infants developing bulging fontanelles following vitamin A supplementation at doses of about 800 µg RE/kg bw/day², but not (except in children with certain rare diseases) at lower intakes. This value was divided by a factor of 4 to allow for uncertainties because the number of case studies that were available was small and they related to exposures of only limited duration. Thus, a TUL of 200 µg RE/kg bw/day was determined.

¹ Fontanelles are the soft spots on babies' heads where the bones of the skull have not yet fully formed.

² Micrograms of retinol equivalent per kilogram bodyweight per day. Retinol equivalents are a measure of dose that take into account the varying biological activity of different forms of vitamin A.

6. Where mothers are not taking vitamin A supplements, the estimated exposure of exclusively breastfed infants is below the TUL, and not a health concern. Maternal use of dietary supplements could increase the vitamin A content of breast milk by a small amount. However, with the supplements available on the UK market, any resultant exceedance of the TUL would only be minor. Moreover, it would be for only a short period of time.

7. Estimated exposures based on reported concentrations of vitamin A in infant formula are below the TUL and not a health concern. However if vitamin A were present in formula at the maximum legally permitted level (180 µg RE/100 mL), resulting exposures could exceed the TUL by up to about 80 %.

8. Data on total exposures to vitamin A from breast milk, infant formula and complementary foods in UK infants indicate that the TUL could be exceeded by up to about 25% at high levels of intake. However, this exceedance is small, and at most is likely to occur only rarely. Thus, while the possibility of adverse effects cannot be excluded, they would not be expected to occur in other than a very small proportion of infants, if at all.

9. There is evidence that a very small proportion of infants eat foods containing liver. Frequently consuming liver at the levels reported could lead to the TUL being exceeded. Therefore the current Government recommendation that infants over the age of 6 months should not have more than one portion of liver per week is appropriate.

10. Dietary multivitamin supplements marketed for infants in the UK were also evaluated. The brand with the highest recommended dosage could produce an estimated exposure of more than half the TUL. This could result in total intake above the TUL for exclusively breastfed infants, and increase the potential for exceedance of the TUL for formula-fed infants, and infants consuming large amounts of complementary foods rich in vitamin A. The recommended dosage provided under the Healthy Start scheme would give a lower exposure, and any resultant exceedances of the TUL are likely to be minor.

11. Overall the COT concluded that there is potential for some infants to exceed the TUL under the following circumstances:

- if exclusively breastfed by mothers taking dietary supplements containing high levels of vitamin A,
- if fed with infant formula at the upper limit of the retinol content allowed by regulation,
- if given high dose vitamin A supplements
- if consuming liver more than once per week

The possibility of adverse effects from such exceedances cannot be excluded, but if they do occur, it is likely to be in only a very small proportion of infants.

The full COT statement can be found at: <http://cot.food.gov.uk/pdfs/cotstavita.pdf>

Lay Summary to COT Statement 2013/03