Risk Characterisation - Statement on the effects of excess Vitamin A on maternal health

Risk Characterisation

As noted in paragraph 13, EFSA (2006) derived an UL for vitamin A of 3,000 mg of RE per day for women of childbearing age. This was based upon a study by Rothman et al. (1995). In Paragraph 55 Azaïs-Braesco and Pascal (2000) noted that the findings of the Rothman et al. (1995) study were inconsistent with previous retrospective studies and had been widely criticised on the grounds of possible misclassification of deformities but could not be ruled out in the consideration of the teratogenic effects of the vitamin. Conversely, the EVM (2003) was unable to reach a firm conclusion on an upper intake limit but considered that an intake greater that 1,500 µg/day was "inappropriate". It was noted that this was on the basis of the risk of hip fracture and not on the risk of fetal effects.

118 Based upon the EFSA UL and taking women of childbearing age as a whole, the intake of retinol equivalents from food at the 97.5th percentile of consumption is close to, but still below, the UL and therefore would not be a concern for their health nor for the development of a fetus borne by these women. However, the small group in the food surveys who consume liver at the mean level have an estimated intake that marginally exceeds the UL (117 %) and those who are in the highest consumer group have an estimated intake of 250 % of the UL. If the latter level of consumption were continued into a pregnancy, then this may lead to an increased risk of the fetus suffering a neural tube defect or other developmental lesion that may lead to deformity. Despite the caveat that the data on liver consumption are recorded only in a small number of women of childbearing age and thus bear a greater level of uncertainty, this explains the rationale behind the UK Government's advice for pregnant women to abstain from consuming liver and products containing liver during pregnancy. 119 Likewise, vitamin A-fortified food products if eaten to excess, may contribute to an exceedance of the UL, although this would only be marginal.

120 Moreover, although the consumption of vitamin A rich food supplements on their own does not provide sufficient RE to exceed the UL, the nature of their consumption, in addition to a normal diet, especially in the case of cod liver oil, could push RE intake over the UL. This is consistent with the current UK Government advice that supplements containing vitamin A are not recommended for pregnant women.

121 Conversely, taking the EVM maximum "appropriate" consumption level of 1,500 mg RE per day, although the mean dietary consumption is within the acceptable range, the 97.5th percentile dietary consumption exceeds this value. Even the mean consumption of liver would result in exceedance of the suggested "appropriate" intake. On this basis, current Government advice for pregnant women to limit their consumption of liver and other foodstuffs containing high concentrations of preformed vitamin A is still appropriate.