Annex A - Conclusions

In this guide

55. Overall, the COT concluded that the risk associated with raspberry leaf use during pregnancy was low but with high uncertainty. This was based on the results of the two Australian human safety studies, including a retrospective cohort study and a double-blind, placebo-controlled, randomised trial. Neither reported adverse effects in mother or child following raspberry leaf consumption during pregnancy at doses of 1-8 cups of tea/tablets per day or a single dose of tincture, or 2.4 g extract daily, respectively. However, Members noted that the estimated combined consumption of raspberry leaf from tea (up to 10 g/person/day) or from tea, tinctures and capsules combined (up to 12.421 g/person/day), based on data collected from online sources by the FSA's exposure assessment team, was up to four or more times higher than the raspberry leaf dose tested in the randomised controlled trial.

56. The COT's conclusion was also based on the limited number of reports of adverse effects in pregnant women taking raspberry leaf or their children

received by the UKTIS since its inception in 1983 to the present date. Members considered that the low bioavailability of raspberry leaf was probably also why it appeared to be of low concern to human health. However, it was recognised that micronised raspberry leaf products might exhibit increased bioavailability and may require a separate safety evaluation.

57. Members identified various uncertainties in the risk assessment of raspberry leaf. These underpinned the high level of uncertainty in their conclusion on its safety for use during pregnancy and prevented the Committee from establishing a point of departure for raspberry leaf. The main sources of uncertainty identified included: the lack of data available on the active components of raspberry leaf; the potential for the preparation method to affect the activity of the supplement and the sampling effect; the large variation in the literature as to raspberry leaf's critical effects (smooth muscle relaxation vs. contraction), which appeared to depend on numerous factors, such as the species, preparation and whether extracts were tested *in vitro* or *in vivo*; and the lack of clarity in the literature as to the most appropriate choice of animal model for studying raspberry leaf's effects in humans. Other sources of uncertainty included the limited data available on the pharmacokinetics and toxicity (including reproductive toxicity) of raspberry leaf, and on levels of contaminants and residues.

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