Statement on the potential health effects of raspberry leaf tea in the maternal diet: Lay summary

The Scientific Advisory Committee on Nutrition (SACN) is reviewing the scientific evidence that bears on the Government's dietary recommendations for women of childbearing age. To help SACN in this, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked to review the risks of toxicity from certain chemicals and products in the maternal diet. This statement focuses on the possible risks from taking raspberry leaf tea, or extracts of raspberry leaf, in tablets or tinctures, during pregnancy.

Raspberry leaf, as tea, tablet or tincture, is most commonly taken during pregnancy as a dietary supplement in the belief that it stimulates and facilitates labour and shortens its duration. A recent study in Australia reported use by 38% of pregnant women, while a UK study in 2007-2008 reported use by approximately 24% of pregnant women. In addition to such preparations, several raspberry leaf products are registered as traditional herbal medicines in the UK. However, these are directed at non-pregnant women for the symptomatic relief of menstrual cramps. Some clinics offer enemas containing raspberry leaf, though it is not clear whether any are aimed at pregnant women.

A number of studies, starting in the 1940s, have investigated the effects of extracts of raspberry leaf on the uterus (womb) or other smooth muscle, either in intact animals or isolated from animals. The results of these studies were highly variable, with some showing smooth muscle contraction and others relaxation. This variability was likely due to factors such as differences in the components in the extracts and doses of the extracts tested, the type of smooth muscle tissue tested, pregnancy status of the animal, and whether the study was in an intact animal or on isolated uterus or other smooth muscle. The mechanism by which raspberry leaf could have the claimed effects on labour is also poorly understood, and it is unclear what the active components might be. A number of mechanisms have been suggested, but the evidence for these is limited and contradictory.

Limited data were available on the reproductive toxicity of raspberry leaf in laboratory animals, and only one study was identified that had evaluated it for short-term repeat-dose toxicity, conducted in mice. Another source of uncertainty was a lack of specific information on the absorption, distribution, metabolism and excretion of the constituents of raspberry leaf by the body following their consumption. However, some evidence indicated that raspberry leaf extracts are less toxic when given to mice orally than when injected intravenously. This suggests that they have poor oral bioavailability; that is, that only small amounts of the toxic constituents reach the systemic circulation following ingestion.

Limited data were found on levels of contaminants, such as heavy metals, in raspberry leaf, and on levels of pesticide residues. However, the data available did not indicate any safety concerns.

The COT also took into account the available human data. These included two studies conducted in Australia. The first identified women who had given birth in hospital and who had taken raspberry leaf tea, tablets and/or tinctures during pregnancy, and compared them to matched women who had not taken raspberry leaf during pregnancy. No adverse effects were identified in the mothers or infants, or on the delivery, from consuming raspberry leaf. The second study, by the same group, was a double-blind, placebo-controlled trial, in which women were randomly assigned to receive raspberry leaf tablets or placebo tablets during pregnancy. No adverse effects were identified, with the possible exception of constipation, which was reported exclusively by 4 of the 96 women receiving raspberry leaf. However, the COT noted that estimates of UK consumption of raspberry leaf tea, or of raspberry leaf from tea, tinctures and capsules combined, which were based on data collected from online sources, were up to four or more times higher than the raspberry leaf dose tested in this trial.

In addition, the COT took into account data collected by the UK Teratology Information Service (UKTIS), a national service that collects pregnancy outcome data from women exposed to medicines and chemicals in pregnancy. There have been very few 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, despite the reported high prevalence of use of raspberry leaf.

Overall, the COT concluded that the risk associated with raspberry leaf use during pregnancy was low but with high uncertainty due to the data limitations.

The COT considered that poor oral bioavailability of the toxic constituents of raspberry leaf (based on indirect information) might also contribute to why it

appears to have little adverse effect on human health. However, if raspberry leaf products that are modified to increase their bioavailability become available in the future, these may require a separate safety evaluation.

The full COT Statement can be found at: <u>Statement on the potential health effects</u> of raspberry leaf tea in the maternal diet.

Lay summary of COT Statement 2024/06