First Draft Statement on the Potential Health Effects of Raspberry Leaf Tea in the Maternal Diet

Introduction - the Potential Health Effects of Raspberry Leaf Tea in the Maternal Diet

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This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

Introduction

1. As part of the COT's current programme of work assessing risks from the maternal diet, to feed into the Scientific Advisory Committee on Nutrition's

(SACN) review of nutrition and maternal health, focusing on maternal outcomes during pregnancy, childbirth and up to 24 months after delivery, in 2020 the COT considered a scoping paper which reviewed commonly used herbal supplements during pregnancy. These were promoted by anecdotal evidence and unofficial sources as having various purported benefits.

2. The review was confined to herbal dietary supplements which would be regulated as foods and which would not be considered to be traditional herbal medicines within the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). Among those investigated was raspberry leaf, which is most commonly taken during pregnancy to stimulate and facilitate labour and to shorten its duration.

3. The COT agreed that raspberry leaf required further consideration, noting that human, animal and *in vitro* data were available. The main areas of concern included general toxicity to the mother, effects on the development of the fetus or embryo and possible interactions with drugs. Others included potential effects on offspring and on uterine contractility. A more extensive literature search was undertaken to evaluate the safety of raspberry leaf use during pregnancy, and a scoping paper produced, which was considered by the COT at its September 2022 meeting.

4. Members considered that the risk associated with raspberry leaf consumption during pregnancy was low, but with a high level of uncertainty. This conclusion was based primarily on the results of two human studies identified in the literature search, a retrospective cohort study and a double-blind, placebo-controlled, randomised trial. Neither study reported adverse effects to mother or child associated with raspberry leaf consumption during pregnancy. However, Members did note that the dose of raspberry leaf tea tested in the trial was several times lower than an exposure estimate based on data provided by the FSA’s exposure assessment team.

5. In addition, a limited number of reports of raspberry leaf exposure during pregnancy had been received by the UK Teratology Information Service (UKTIS) since its inception in 1983 to the present date, with no evidence of adverse effects at normal consumption levels.

6. COT Members considered that it was not possible to identify any point of departure for use in risk assessment for various reasons. These included the lack of data available on the active components of raspberry leaf; the potential for the sampling and the preparation method to affect the activity of the

supplement; the large variation in the literature as to raspberry leaf's critical effects (smooth muscle relaxation vs. contraction), which appeared to depend on a number of factors, such as the species, preparation and whether it was tested *in vitro* or *in vivo*; and uncertainty regarding the most appropriate animal model for studying raspberry leaf's effects in humans. Limited data were available on the pharmacokinetics of raspberry leaf, although there were indications in the literature that it was less toxic when administered orally rather than parenterally. Limited reproductive toxicity data were available, and only one study, in mice, appeared to have evaluated it for sub-acute toxicity. Finally, the potential for contaminants such as cadmium, and pesticide residues, was noted.

7. Members commented that one of the reasons why raspberry leaf appeared to be of low concern to human health, based on the safety data available, was low bioavailability. However, concern was expressed that if raspberry leaf extracts were reformulated, such as by micronisation or microencapsulation, as has been done for some other supplements such as cannabidiol (CBD) and turmeric, this might increase bioavailability. The safety of any such products may need to be evaluated separately.

8. The scoping paper (TOX/2022/50) and minutes of the meeting are available online at COT Meeting: 6th September 2022 | Committee on Toxicity (food.gov.uk).

9. A draft Statement has been prepared, incorporating Members' comment, which is included at Annex A.

Questions for the Committee

The Committee are asked to consider the following questions:

a) Does the Committee have any comments on the structure or content of the draft Statement?

b) Does the Committee consider that any further information should be included in the risk characterisation and/or conclusions sections on the results of animal studies?

c) Does the Committee have any other comments?

Secretariat

June 2024