Background

In this guide

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1. In 2019, the Scientific Advisory Committee on Nutrition (SACN) agreed to conduct a risk assessment on nutrition and maternal health focusing on maternal outcomes during pregnancy, childbirth and up to 24 months after delivery; this would include the effects of chemical contaminants and excess nutrients in the diet.

2. SACN agreed that, where appropriate, other expert committees would be consulted and asked to complete relevant risk assessments e.g., in the area of food safety advice. This subject was initially discussed during the COT's horizon scanning item at their January 2020 meeting, with a scoping paper being presented to the COT in July 2020. This included background information on a provisional list of chemicals proposed by SACN.

3. Following discussion at the September 2020 meeting, the COT agreed that papers on a number of substances should be prioritised, including the use of dietary supplements during pregnancy.

4. A scoping paper (TOX/2020/51) was presented to the Committee in October 2020, in which the dietary supplements commonly used during pregnancy were reviewed. These were supplements that were not officially recommended by the relevant authorities, but which have been promoted by anecdotal evidence and unofficial sources as having various purported benefits. The review was confined to herbal dietary supplements that would be regulated under food law, and which would not be considered to be traditional herbal medicines, which are the responsibility of the Medicines and Healthcare Products Regulatory Agency (MHRA).

5. Paper TOX/2020/51 provided a detailed summary of ginger, chamomile, raspberry leaf, echinacea, peppermint oil and leaves, dandelion, and evening primrose oil, focusing where available, on studies relevant to pregnancy and maternal outcomes. The main areas of investigation were general toxicity to the mother, effects on the development of the fetus or embryo, and possible interactions with medicines. The COT agreed that ginger required further investigation, noting that both human and animal *in vitro* and *in vivo* data were available. The following paper provides the advice of the COT on whether exposure to ginger would pose a risk to maternal health.

6. In May 2021, the Committee considered the potential effects of ginger and ginger supplements during pregnancy and lactation. Paper TOX/2021/26 (Available on the COT website) reviewed the available data on toxicity to the mother, effects on the development of the fetus or embryo, and possible interactions with drugs, as well as data on potential exposure.

7. Overall, it was concluded that the data were limited. The human data presented were not strongly indicative of any toxicological concern but there were some indications of possible side effects in mothers and many uncertainties. Ginger did not appear to be systemically toxic but in studies in experimental animals there was some evidence for reprotoxic effects at high doses. The Committee suggested looking at the animal data in detail to try to identify a point of departure (POD) (No Observed Adverse Effect Level - NOAEL), followed by calculation of the potential exposure to ginger supplements to determine whether there was cause for concern.

8. Paper TOX/2021/51 provided further information with respect to animal studies, primarily centred on the effects of ginger on prostaglandin production, reproductive and developmental toxicity, the possible contaminants present in ginger, and exposure to ginger supplements.

9. Members noted that although the different ginger extracts were not comparable across animal studies, they did appear to exhibit some biological activity in the early stages of pregnancy at high doses.

10. The COT noted that intake of ginger in foodstuffs should also be considered because ginger was consumed not only as a supplement but also as part of the diet in foods such as ginger biscuits, tea and ginger beer. Therefore, aggregate exposures would need to be considered when addressing the safety of ginger supplement use during pregnancy.