Annex A - Second Draft Statement on the Safety of Ginger Supplement Use in Pregnancy

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Background

1. As part of the current programme of work on the maternal diet, the Committee considered the use of dietary supplements during pregnancy. A scoping paper (TOX/2020/51) was presented, reviewing the commonly used dietary supplements during pregnancy. These were supplements that were not officially recommended by the relevant authorities, but which were promoted by anecdotal evidence and unofficial sources as having various purported benefits. The review was confined to herbal dietary supplements which 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). Following this review, the COT agreed ginger required further investigation, noting that human, animal and in vitro data were available.

2. Paper TOX/2020/51 provided a detailed summary of the supplements most recommended during pregnancy (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. Members suggested that ginger required further investigation, noting that both human and animal *in vitro* and *in vivo* data were available.

3. 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.

4. Overall, it was concluded that there were limited data. The human data presented were not strongly indicative of any toxicological concern but there were some indications of possible adverse effects and a lot of uncertainties. Ginger did not appear to be systemically toxic but did appear to have reprotoxic effects at high supplemental doses. The Committee suggested looking at the animal data in closer detail to determine the point of departure (No Observed Adverse Effect Level - NOAEL), followed by calculating the potential exposure to supplements to determine whether there was cause for concern.

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

6. The members noted that although the different ginger extracts were not comparable, from animal studies they did appear to exhibit some biological activity in the early stages of pregnancy. It was reiterated that there was no indication of general systemic toxicity from the use of ginger.

7. Initially, the COT noted that intake of ginger in foodstuffs should also be considered as ginger was noted to be 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.