Meeting

# First Draft Statement on the potential health effects of Echinacea in the maternal diet

**This is a paper for discussion. This does not represent the views of the Committee and should not be cited.**

## Introduction

1. In 2020 the COT considered a scoping paper (TOX/2020/51) that reviewed commonly used herbal supplements during pregnancy. This was part of COT's ongoing programme to assess the potential risks from the maternal diet, intended to support 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.

2. The scoping paper (TOX/2020/51) 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 *Echinacea*, which is commonly used for immune support, prevention of colds and treatment of cold and flu-like symptoms.

3. In December 2024, a discussion paper on the effects of *Echinacea* on maternal health was presented to the Committee (TOX/2024/43). This paper reviewed the available data from *in vitro*, *in vivo* and human studies covering the mechanisms of action of *Echinacea*, drug-herb interactions, presence of contaminants, toxicity including genotoxicity, reproductive and developmental toxicity and the adverse effects of *Echinacea* reported in human studies. The limited information available on human exposures to *Echinacea* during pregnancy was also discussed.

4. The Committee considered the risk to maternal health from Echinacea exposure during pregnancy likely to be low but highlighted that there was insufficient information to enable a robust risk assessment. Members agreed that the point of departure was difficult to derive due to complexity in terms of preparations, extracts, doses and lack of sufficient, high-quality data to determine clear safety risks. It was also acknowledged that individuals with atopic disease or autoimmune disorders will be at higher risk from exposure to Echinacea products than the general population and this should be taken into account for the risk assessment.

5. Members noted that many of the food supplements suggest a short-term use of *Echinacea* and that this should be more clearly emphasised within the exposure section. The transient exposure makes it difficult to accurately estimate the percentage of women using *Echinacea* at different stages of pregnancy and assess the implications of extrapolating findings from diverse study designs.

6. The COT Members commented that the paper would benefit from a clearer segmentation of the reproductive and developmental data to highlight any data gaps in the reproductive and developmental window covered when considering the safety of Echinacea in the maternal diet. It was suggested that this could be done in the form of a table or schematic summary of the reproductive and developmental end points covered by the animal and human studies available.

7. Members also requested a clarification on the scope of the maternal health project, particularly regarding the stages of the reproductive and developmental cycle assessed. This has been incorporated in a separate Annex entitled Scope of the Nutrition and maternal health project (please see Annex A to TOX/2025/44).

8. The COT Members agreed there was lack of high-quality available data on the reproductive end points from both animal and human studies. A potential data gap identified by Members was the absence of studies looking at the at the placenta and the maintenance of pregnancy. It was highlighted that identifying these data gaps is particularly important given the recommended short-term use of *Echinacea* leading to a transient exposure window during the different parts of the reproductive and developmental cycle.

9. Members discussed the *in vivo* mice study by Chow *et al*. (2006) and the epidemiological study by Gallo *et al.* (2000) in more detail. They considered that the conclusion reached by Chow *et al*. (2006) that *Echinacea* could lead to miscarriages in early pregnancy was not convincing as the authors used a mouse

strain (DBA) with small litter size and they did not provide any range/standard deviation with their results on foetal loss. Members commented that the sample size (n=206) in the study by Gallo *et al.* (2000) would not give sufficient statistical power to detect the birth defects and malformations studied.

10. Members also commented that the limited human studies on the use of *Echinacea* during pregnancy focus on observations that can be detected at birth and did not consider any longer-term effects such as epigenetic changes. It was suggested that that this should be added as a caveat in the risk characterisation section.

11. COT Members also emphasised the need for clearer structuring of data, including tables and summaries for complex and conflicting findings. This was particularly relevant for the section on the immunomodulatory effects of *Echinacea*, which contained information on variety of effects exerted by *Echinacea* on different immune system cell types and subsequent cytokine production. The Members also suggested that the anti-inflammatory and immunomodulatory effects of *Echinacea* should be considered in the same section rather than as separate items.

12. A section on the pharmacokinetics of *Echinacea* constituents has been added to this draft statement.

13. A draft Statement has been prepared, incorporating Members' comment, which is included at Annex A. It was suggested that the statement should make a clear distinction between the conclusions reached by the individual studies and the COT conclusions.

# 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 agree with the risk characterisation and conclusions sections?

c) Does the Committee have any other comments on the draft Statement?

**Secretariat**

**December 2025**