

Item 5: Joint SACN/COT draft report on plant-based drinks- response to consultation (Reserved) (TOX/2024/37)

The item was previously being treated as reserved.

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1. Dr Alison Yeates noted a potential conflict of interest due to her involvement with the School Milk and Nursery Alliance. It was agreed that she could contribute to discussions but would not participate in agreeing conclusions. Dr Meera Cush also noted a conflict of interest as she had been involved in a project for an infant formula manufacturer where she had provided toxicology data on the safety of isoflavones for use in medical foods for the elderly; the company concerned had commented on the draft report. It was agreed that she could contribute to discussions but would not participate in agreeing conclusions. No other interests were declared.

2. Members were reminded that the draft report of joint COT and Scientific Advisory Committee on Nutrition (SACN) Working Group on assessing the health benefits and risks of consuming plant-based drinks was published for peer review in July 2024.

3. The aim of this discussion was to review the comments received from the parties who had responded. The COT were specifically requested to consider the main areas related to toxicological aspects of the report, these were isoflavones, naturally occurring oestrogens, vitamin A and iodine. SACN and the SACN Subgroup on Maternal and Child Nutrition (SMCN) would be addressing the comments related to nutritional issues and the feeding of infants and young

children respectively.

4. For isoflavones, Members noted there were little or no data available to confirm the risk(s) of isoflavones in human cases, thus it was not possible to determine the potential health risks of isoflavones present in soy drinks for children. It was agreed that the uncertainty in the database was known and acknowledged in both the draft plant-based drink report and the supporting COT reviews from 2003, 2013 and 2021. The advice is precautionary since exposure to isoflavones from soya formula or, from soya drinks plus other dietary sources of soya on a body weight basis is approaching the levels associated with adverse effects in some animal studies, though this has not been observed in human epidemiological studies.

5. The literature was last reviewed in 2021 to support the COT review of plant-based drinks but should be updated to see if any new evidence was available that might affect the current assessment.

6. With respect to the claimed beneficial effects of soya/isoflavones, whilst these were not in the remit of the COT, it was noted that beneficial effects had not been substantiated sufficiently to support, for example, health claims with the exception of the limited support for isoflavones made by NICE.

7. Regarding naturally oestrogens, it was questioned whether a comparison of the oestrogen levels present in human breast milk and cows' milk had been previously considered. The Secretariat confirmed that in their 2023 risk assessment of cows' milk, the COT compared exposure to oestrogens in cows' milk to the endogenous production rates of prepubescent boys and girls under the age of 8. Uncertainties on these rates were further discussed. In the assessment of cows' milk, a comparison had also been drawn on exposure against the acceptable daily intake for 17 B-oestradiol which had been set by JECFA in 2000.

8. While the adverse effects of vitamin A were noted, Members pointed out this was associated with pre-formed retinol and not pro-vitamin A in the form of carotenoids. It seemed unlikely that pre-formed retinol would be used for fortification, but that could be clarified. It was agreed that it would be sensible to expand on the toxicity of the different forms of vitamin A in the report in more detail.

9. Members noted that the potential adverse effects of iodine were considered as part of the cows' milk risk assessment and not thought to be of

concern. Population iodine intakes were not thought to be high, and nothing concerning was identified in the review of iodine in the maternal diet. It was suggested that additional detail should be provided in the report in the context of potential fortification.

10. The Committee had no comments on the other responses received from interested parties.