Ongoing work

In this guide

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

Derivation of a health-based guidance value for antimony

1.64 The UK Health Security Agency (UKHSA) sought advice from the COT with respect to an appropriate health-based guidance value (HBGV) for antimony. UKHSA advises the Drinking Water Inspectorate (DWI) on the potential risks from chemicals in drinking water. Following the UK exit from the European Union, the DWI had undertaken a review of the regulatory standards for some chemicals in drinking water, including antimony.

1.65 The World Health Organization (WHO), the US Agency for Toxic Substances and Disease Registry (ATSDR) and Health Canada all used the same study (Poon et al., Food and Chemical Toxicology, 36:21-35, 1998) to derive

different HBGVs. The differences were primarily due to variations in the interpretation of the study findings, particularly in the choice of the No Observed Adverse Effect Level (NOAEL). The COT assessed the Poon et al. (1998) study and its interpretations, as well as other available evidence to determine an appropriate HBGV to support an update to the antimony drinking water standard in the UK.

1.66 The COT agreed that the Poon et al. (1998) study was the most appropriate study to use to derive a HBGV for antimony. The COT determined that the NOAEL of 6,000 micrograms per kilogram of body weight per day (µg/kg bw/day), based on decreased body weight gain and reduced food and water consumption in adult rats, was the point of departure. An uncertainty factor (UF) of 300 was recommended, resulting in a tolerable daily intake (TDI) of 20 µg/kg bw/day as a HBGV for antimony.

1.67 The Committee considered a draft statement on this topic and agreed it could be approved by Chair’s action

1.68 The statement will be finalised in 2026.

Derivation of a health-based guidance value for boron

1.69 The UK Health Security Agency (UKHSA) advises the Drinking Water Inspectorate (DWI) on potential health risks from chemicals in drinking water. Following EU exit, the DWI is reviewing the regulatory standards for some chemicals in drinking water, including boron. UKHSA sought advice from the COT with respect to an appropriate health-based guidance value (HBGV) for boron.

1.70 The toxicity studies on boron by Heindel et al. (Fundamental and Applied Toxicology, 18: pp.266-277, 1992), Price et al. (Fundamental and Applied Toxicology, 32:179-193, 1996) and Weir and Fisher (Toxicology and Applied Pharmacology, 23: 351-364, 1972) have been used by several authoritative bodies (WHO, Health Canada, EFSA, EVM, ATSDR and ECETOC), including the COT in 1995, as the critical studies for their health-based guidance values (HBGVs). The differences in the HBGVs derived by these bodies are due to differences in the choice of the points of departure (POD) from these critical studies, and uncertainty factors applied.

1.71 The COT reviewed these studies, along with the other available animal and human epidemiological evidence. The Committee agreed that the Price et al., 1996 rat developmental toxicity study was the most appropriate basis for a HBGV. A dose of 10.0 mg B/kg bw/day was identified as an appropriate POD, consistent with the COT's previous assessment in 1995. The COT agreed that a total uncertainty factor of 100 was appropriate, resulting in a Tolerable Daily Intake (TDI) of 0.1 mg/kg bw/day as the HBGV for boron.

1.72 The Committee reviewed a draft statement on boron and agreed it could be approved by Chair's action.

1.73 The statement will be finalised in 2026.

Ongoing Work

Review of the safety of ashwagandha in food, drinks and food supplements (Reserved)

1.74 The Committee are in the process of reviewing the safety of ashwagandha in food, drinks and food supplements. This item is currently being treated as reserved as some data are commercially sensitive.

1.75 This work is ongoing, and a final statement is expected in 2026.

Risk Assessment of T2 and HT2 mycotoxins in food

1.76 Throughout 2025, COT continued their comprehensive evaluation of the risks posed by T-2 and HT-2 mycotoxins in food, prompted by recent changes in European Union legislation that introduced lower maximum levels for the sum of these toxins.

1.77 The COT considered a revised exposure assessment, focussing on refined estimates of dietary exposure in different population groups and their relationship to health-based guidance values (HBGVs). Using 97.5th percentile exposure values is conservative and while these often-exceeded HBGVs, mean exposures generally remained below them. Concerns were raised about high contamination levels in oats compared to new EU limits, and the reliability of exposure data for ready-to-eat foods given small sample sizes. The Committee

also examined methodological issues, potential double counting in exposure calculations, and the absence of data on animal products, recommending that these gaps be addressed in subsequent drafts.

1.78 Members subsequently considered draft statements consolidating previous discussion papers and setting out their conclusions.

1.79 This work is ongoing, and a final statement is expected in 2026.

Liquorice in the maternal diet

1.80 Following a request from SACN, the COT agreed to add liquorice to the list of substances to review as part of the programme of work on the maternal diet. It was noted that liquorice contains numerous active chemical constituents, and clarification would be required on whether the assessment should focus on liquorice extract as a whole or its individual chemical constituents.

1.81 The Committee noted that the main adverse effect associated with high liquorice consumption was hypertension.

The potential health effects of *Echinacea* in the maternal diet

1.82 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.

1.83 The scoping paper focused on herbal dietary supplements regulated as foods, excluding those classified as traditional herbal medicines under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). Among the supplements considered was Echinacea, commonly marketed for immune support and for the prevention and treatment of colds and flu-like symptoms.

1.84 A discussion paper (TOX/2024/43) presented to the COT in December 2024 reviewed the available *in vitro*, animal, and human data on *Echinacea*, including mechanisms of action, drug-herb interactions, contaminants, toxicity (including genotoxicity), reproductive and developmental endpoints, and adverse

effects in humans. The Committee had concluded that that deriving a point of departure for *Echinacea* would be challenging due to variability in preparations, extracts, doses, and limited high-quality data.

1.85 The first draft statement on the potential effects of *Echinacea* in the maternal diet was presented to the Committee in December 2025 (TOX/2025/45).

1.86 This set out the background to the issue and the COT's conclusions.

1.87 Members made a number of comments, and a revised version of the statement is expected to be presented to the Committee in 2026.

Calcidiol supplementation in the maternal diet

1.88 As part of the ongoing programme of work on the maternal diet, the Committee were asked to assess the effects of calcidiol supplements in the maternal diet.

1.89 Calcidiol is a novel source of vitamin D3 (cholecalciferol), which is formed via chemical synthesis from cholestatrienol. Calcidiol is a synthetic form of 25(OH)D, which is an inactive precursor to the biologically active form of vitamin D known as 1,25-dihydroxyvitamin D (1,25 (OH)2D) and thus is commonly referred to as a pre-hormone. Calcidiol is considered to be 2.5 times more bioavailable than vitamin D3.

1.90 The Committee agreed with EFSA's conclusion on the level established as safe for calcidiol supplements (i.e. 10 µg) and agreed that, at present, there was no evidence that there was excess exposure to vitamin D in the population.

1.91 The COT requested a new draft position statement that provides an overview of calcidiol in the maternal and signposts all previous COT work on all other Vitamin D derivatives. The COT also requested a short supplementary paper that specifically addresses calcidiol in the maternal diet and identifies data gaps.

1.92 The position statement and supplementary papers are to be presented to the COT in 2026.

AI in Risk Assessment State of the Science Discussion paper (Reserved)

1.93 In the horizon scanning paper presented to COT Members in February 2025, Members agreed that Artificial Intelligence (AI) would be a suitable topic for the next COT Annual Workshop 2025. The workshop would be a first step towards reviewing the current state of the art of AI technologies relevant to chemical risk assessment as well as discussing the opportunities and the challenges associated with the application of AI in chemical safety assessment. As part of the background to the workshop, a scoping paper on AI in risk assessment considering these points would be presented to the COT.

1.94 The scoping paper set out a brief history of AI, the different areas of AI and their applications in chemical risk assessment. It reviewed current state-of-the-art AI tools and discussed the opportunities and challenges of using these technologies. The paper also explored the complexity of data ecosystems which would be part of AI integration in chemical risk assessment in the regulatory setting.

1.95 This topic forms part of the COT's work on integrating New Approach Methodologies (NAMs) in risk assessment and continuing to develop a UK NAMs Roadmap.

1.96 It is intended that the scoping paper will be reworked into a state of the science report.

1.97 This item is currently being treated as reserved ahead of possible publication.

Scoping paper on the potential risk(s) of Garcinia cambogia

1.98 In 2025, the COT considered a scoping paper (TOX/2025/41) on the potential risk(s) of *Garcinia cambogia* (*G. cambogia*) in food supplements. In the UK, there are currently no HBGVs or limits established for the use of *G. cambogia* in food and drinks, including in food supplements.

1.99 In March 2025, an opinion was published by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) on their assessment of the adverse reactions to the consumption of food supplements containing *G. cambogia*. ANSES advised consumers to not consume food supplements containing *G. cambogia*.

1.100 In response, the FSA and FSS requested the COT to review the ANSES opinion and assess the risk(s) associated with consumption of *G. cambogia* in food supplements. In addition, the COT was asked to consider whether a safe intake level or maximum limit of *G. cambogia* for use in food and drink, including food supplements, could be derived based on the available data.

1.101 COT Members were unable to agree or disagree with the conclusions reached by ANSES on the safety of *G. cambogia* food supplements.

1.102 The COT Members noted a number of uncertainties with respect to composition and confounding factors and requested additional information on vulnerable groups and potential long-term health effects. This will be presented at a future COT meeting.

1.103 The medicinal status of Garcinia food supplements containing hydroxycitric acid (HCA) was also noted. These would not be in the remit of the FSA.

Supplementary Statement on Bisphenol A (BPA)

1.104 Following extensive review and discussion of the scientific evidence of the new EFSA tolerable daily intake (TDI) for bisphenol A (BPA), and the subsequent assessment by the German Federal Institute for Risk Assessment (BfR) in 2023, the COT adopted the tolerable daily intake (TDI) of 0.2 µg/kg bw per day set by the BfR in May 2024.

1.105 While the COT were content to publish a condensed position statement in the interests of allowing timely risk management, it was agreed that to reflect their decision to adopt the BfR TDI, a detailed supplementary statement would be required.

1.106 This statement was considered essential to provide the scientific basis of the Committee’s conclusion to adopt the BfR TDI, demonstrating how their decision was protective of UK consumers. The supplementary statement should highlight the concerns regarding the establishment of the EFSA TDI and the Committee’s review of the relevant studies and approach taken by the BfR, including the modelling and the studies which were selected to establish the HBGV. The supplementary statement should also include discussions of any relevant information that was published since the BfR assessment.

1.107 The supplementary statement is in the process of being finalised and will be published early in 2026.