Committee on Toxicity

Committee on Carcinogenicity

Committee on Mutagenicity

Annual Report

2025

Committee on Toxicity of Chemicals in Food, Consumer, Products and the Environment Annual Report 2025

Contents

About the Committees

This is the 35th joint annual report of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) and the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC).

The aim of these reports is to provide a brief background to the Committees' decisions. Those seeking further information on a particular subject can obtain details from the Committee's statements and minutes, available from the websites listed below or from the Committee's administrative Secretary.

In common with other independent advisory committees, Committee members are required to follow a Code of Conduct which also gives guidance on how commercial interests should be declared. Members are required to declare any commercial interests on appointment and, again during meetings if a topic arises in which they have an interest.

If a member declares a specific interest in a topic under discussion, and it is considered to be a conflict of interest, he or she may, at the Chair's discretion be allowed to take part in the discussion but is excluded from decision making. Annex 1 contains the terms of reference under which the Committees were set up. The Code of Conduct is at Annex 2 and Annex 3 describes the Committees' policy on openness.

Annex 4 is the Good Practice Agreement for Scientific Advisory Committees. Annex 5 contains a glossary of technical terms used in the text. Previous publications of the Committees are listed at Annex 6. An alphabetical index to subjects and substances considered in previous reports is available on the COT website.

These three Committees also provide expert advice to other advisory committees, such as the Scientific Advisory Committee on Nutrition and the Advisory Committee on Novel Foods and Processes, and there are links with the FSA Science Council, Veterinary Products Committee and the Expert Committee on Pesticides (formerly the Advisory Committee on Pesticides), among others.

The Committees' procedures for openness include the publication of agendas, finalised minutes, agreed conclusions and statements. These are published on the internet at the following links:

Committee on Toxicity

Committee on Carcinogenicity

Committee on Mutagenicity

This report contains summaries of the discussions and links to the Committees' published statements. Paper copies are available upon request to the Secretariats.

Preface

COT Evaluations

Statement on the Safety of Ginger Supplement Use in Pregnancy (COT/2025/01)

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. To support this, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) were asked to review the risks of toxicity from chemicals in the maternal diet.

In May 2021, the COT considered the potential effects of ginger and ginger supplements during pregnancy and lactation and 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 to ginger.

Ginger (*Zingiber officinale*) is a flowering tropical plant originating in Southeast Asia. Ginger is commonly consumed as a spice in food or as a supplement. It is taken as fresh root, dried root powder and capsule (encapsulated dried powder) forms, as a liquid extract, preserved in syrup or sugar, and as a tea.

Ginger is growing in popularity as a natural remedy as it has been reported to modify the immune system to help the body respond to illness, and also to alleviate motion sickness and post-operative nausea and vomiting. Consuming ginger is one of the ways suggested by the NHS and NICE guidelines that might alleviate mild to moderate nausea and vomiting in pregnancy. It has also been used as a dietary supplement and a traditional remedy in many cultures for this and other purposes.

Several ginger supplements are commercially available, with varying amounts of ginger. In addition to this, concentrated ginger shots (liquid form), containing large amounts of pressed ginger, are becoming increasingly popular. The differences in composition of these supplements add uncertainty to estimates of the amount of ginger being consumed.

Generally, consumption of ginger in a traditional culinary manner within a diet is not considered a health concern. The Committee noted that from the evidence presented, the potential for contamination of ginger with heavy metals and/or mycotoxins cannot be excluded.

The COT concluded that there is no evidence to support changing the current NHS advice to pregnant women. This suggests that eating foods or drinks containing ginger might ease symptoms of morning sickness and states that during pregnancy a person should check with a pharmacist before taking ginger supplements.

The full statement can be found on the Committees website.

Statement of advice on the risk to human health from consumption of bivalve molluscs (shellfish) harvested from UK waters associated with marine biotoxins (COT/2025/02)

1.1 The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked by the Food Standards Agency (FSA) to evaluate whether emerging marine biotoxins found in shellfish harvested from United Kingdom (UK) waters may pose a risk to human health.

1.2 Marine biotoxins are naturally occurring toxic compounds produced by certain types of algae. These biotoxins can accumulate in shellfish, such as mussels and oysters, and may cause illness if consumed. The presence of some biotoxins in UK or EU waters is already known and work has begun to routinely monitor and regulate them in the UK. Others are considered "emerging marine biotoxins" because they have not previously been prevalent in UK waters but may become so due to several factors, including environmental changes, such as climate change and warming seas. These factors can alter the global distribution of marine biotoxin producing algae, increasing the likelihood that emerging marine biotoxins will be detected in UK waters and shellfish.

1.3 Groups of emerging marine biotoxins with related chemical structures and potencies have been identified through literature searches and by evaluating assessments by other authorities such as the European Food Safety Authority (EFSA) and Centre for Environment, Fisheries and Aquaculture Science (Cefas). As these biotoxins are not yet regulated or included in official monitoring programmes there is very little data on their current prevalence, levels, or distribution.

1.4 Toxicological data are also limited. As a result, the COT could not undertake a full risk assessment. Instead, the Committee developed a numerical risk-ranking approach to determine which emerging marine biotoxins could be of potential higher concern. This risk ranking approach is thus a prioritisation tool; it is not a measure of current risk to UK consumers and does not replace a formal risk assessment. The risk ranking will however support prioritisation of marine biotoxins and decision making by policy colleagues. The numerical risk ranking considered four different categories of evidence: (1) the extent to which each toxin is currently monitored; (2) the toxicological data based on animal studies; (3) documented reports of human illness or death; and (4) whether the toxin has been found in UK or European Union (EU) shellfish and waters, and if possible how frequent that occurrence is.

1.5 Using this approach, six groups of emerging marine biotoxins were successfully prioritised from highest to lowest risk: tetrodoxins (highest), palytoxins, microcystins, spirolides, brevetoxins, gymnodimines (lowest). Other toxins including azaspiracids, pteriatoxins and domoic acid analogues were also considered but were excluded from the risk ranking due to insufficient information. A “read across” (using data from similar toxins) approach was explored to generate temporary rankings for these toxins but the Committee found this method was too uncertain to provide robust scores.

1.6 The risk ranking approach in general is limited by a lack of data, including: (1) the absence of routine monitoring programmes, meaning that in most cases it was unclear whether these emerging biotoxins are already present in UK waters or shellfish; (2) the potential underreporting of human illness, especially in cases with only mild or moderate symptoms such as diarrhoea where individuals may not seek medical attention or report their symptoms; (3) missing information on human case reports that could influence the observed effects, such as pre-existing health conditions, possible exposure to multiple biotoxins and how long symptoms of illness lasted; (4) only a limited number of toxicological data were available on these emerging marine biotoxins, preventing the derivation of health-based guidance values (HBGVs). The lack of an HBGV further limits the conclusions that can be drawn on the potential risks to public health, as it is not possible to establish what an acceptable level of exposure at which no adverse effect occurs is.

1.7 Despite the uncertainties in the database, the risk-ranking approach applied in this assessment provides a useful prioritisation tool to support decision-making. As more data becomes available, the understanding of risks associated with these marine biotoxins may evolve.

1.8 The full statement can be found on the Committees website: 2025-statements and position papers | Committee on Toxicity. A lay summary will be published in 2026.

Statement on the Effects of Mercury on Maternal Health

1.9 The Scientific Advisory Committee on Nutrition (SACN) is reviewing the scientific evidence that informs the Government's dietary recommendations for women of childbearing age. As part of that process the COT was asked to review the risks of toxicity from certain chemicals in the maternal diet. As part of this programme of work, the possible risks from mercury in the diet of women of childbearing age was reviewed. Other chemical contaminants and excess nutrients will be considered separately.

1.10 Mercury occurs naturally in the earth's crust, chiefly as mercury (II) sulfide and is released into the environment from both natural and man-made sources. In the environment, mercury undergoes complex transformations and cycles between atmosphere, land, and aquatic systems where it can enter the food chain. Mercury exists in different forms, but evaluations show the most important form in relation to diet is methylmercury (MeHg), which accumulates in fish, especially large long-lived species such as shark, swordfish, and tuna. Other foods may contain mercury, but that it is usually in the form of inorganic mercury which is much less toxic, and the available data indicates that exposure to that form is insignificant.

1.11 The main concern with MeHg is its ability to affect the nervous system. MeHg can cross the placenta and the blood–brain barrier, so exposure during pregnancy may affect the developing brain of the foetus. MeHg also has bioaccumulative properties and a long half-life in the body, meaning that exposure before pregnancy can contribute to levels during pregnancy. Developmental and behavioural effects in children, including learning and coordination difficulties, have been observed at high exposure levels, in addition to increased risk of pregnancy complications such as preeclampsia and premature birth. For this reason, pregnant and breastfeeding women are considered sensitive groups.

1.12 Current UK advice already recommends that women who are pregnant or trying to conceive should avoid eating shark, swordfish, marlin, raw shellfish, and uncooked cold-smoked or cured fish, and limit oily fish to two portions per week and tuna steaks to no more than two per week. Following this dietary advice greatly reduces exposure to the harmful effects of MeHg.

1.13 In 2012 EFSA set health-based guidance values for MeHg (1.3 micrograms per kilogram of body weight per week) and inorganic mercury (4 micrograms per kilogram of body weight per week). COT reviewed UK exposure data from food, water, air, and soil. Even in high-consumption scenarios, the estimated combined exposures were below these guidance values. This means that, for most women and their babies, the risk from mercury in the diet is low.

1.14 In summary, mercury is present in the environment and can enter the diet, mainly through consumption of fish or shellfish. While MeHg can be harmful to the developing child's nervous system, current UK dietary advice provides effective protection and women of childbearing age should continue to follow this advice.

1.15 The full statement and lay summary can be found on the Committees website: 2025- statements and position papers | Committee on Toxicity.

Citrinin

1.16 The Scientific Advisory Committee on Nutrition (SACN) is reviewing the evidence that relates to the Government's dietary recommendations for women of childbearing age. The COT was asked to review the risks of toxicity from certain chemicals in the maternal diet. The following evaluation sets out the advice of the COT on whether UK exposures to citrinin would pose a risk to maternal health, i.e. adversely affect maternal outcomes during pregnancy, childbirth and up to 24 months after delivery.

1.17 Citrinin is a toxic substance produced by several species of fungi. It occurs mainly in grains but is also found in other products of plant origin e.g. beans, fruits, fruit and vegetable juices, herbs and spices as well as in spoiled dairy products. Its occurrence is generally due to the growth of fungi during the storage of crops after harvest.

1.18 In 2014, the Food Standards Agency (FSA) carried out a survey, the Total Diet Study, to calculate the background exposure of UK consumers to various chemicals, including citrinin, from the whole diet and to determine trends in exposure. Animal-derived foods were included in the Total Diet Study, but citrinin was not detected in any of the animal-derived food products analysed. Carryover of citrinin from animal feed into animal-based foods is not, therefore, considered in this assessment.

1.19 Citrinin has also been reported as a contaminant in certain fermentation products such as red yeast rice (RYR). However, the majority of packaging of RYR supplements either states that the product is not suitable for children and/or women who are pregnant or breast feeding or recommends that these groups should consult a general practitioner prior to consumption; RYR supplements are not, therefore, considered in this assessment.

1.20 Experimental studies in animals have linked citrinin to kidney and liver toxicity. In the kidney, the main adverse effects following citrinin administration were degeneration and tissue death, which were observed in all species tested. In the liver, a significant decrease in liver weight as a fraction of body weight (relative liver weight) has been reported.

1.21 Data from cell and animal studies also suggest that citrinin may be associated with reproductive toxicity, including adverse effects on the developing foetus during pregnancy. In experimental studies, however, these effects usually occur at doses that cause harm, including kidney damage, in the pregnant female. This suggests that any effects on the developing offspring are

secondary to maternal toxicity. Animal studies also suggest that citrinin can cross the placenta, although there is limited evidence to support this.

1.22 No epidemiological or human case report studies specific to the UK population were available. However, studies from non-UK countries (Belgium, Czech Republic, Portugal, Germany, Haiti, Bangladesh, Nigeria, Turkey, and Tunisia) that monitored citrinin levels in human urine did not indicate an association between higher maternal daily intakes of citrinin and duration of pregnancy, birth weight, birth length or head circumference at birth.

1.23 In 2012, EFSA assessed the risks to public and animal health related to the presence of citrinin in food and animal feed.

1.24 EFSA noted that citrinin does not seem to cause mutations in bacteria but that citrinin can induce chromosome changes in mammalian cells and in mice. These changes can be associated with the development of cancer.

1.25 Citrinin has been shown to cause kidney tumours in rats; however, EFSA could not predict whether citrinin might cause cancer in humans because of a lack of lifetime exposure studies in animals.

1.26 The evidence concerning potential DNA damage and the lack of human dietary exposure data led EFSA to conclude that establishing either a safety limit or following a margin of exposure approach for citrinin would not be appropriate. Instead, EFSA used the evidence from a study in rats to identify a “level of no concern” of 0.2 µg per kg body weight per day for kidney toxicity in humans. A level of no concern is not a safety limit; rather, it is a level of exposure below which there is no significant concern for adverse effects.

1.27 In 2015, the Netherlands Food and Consumer Product Safety Authority (NVWA) commissioned the National Institute for Public Health and Environment (RIVM) to find out whether any new studies on the toxic effects of citrinin had been published since 2011.

1.28 The RIVM selected two studies in rodents to identify the lowest dose of citrinin that is linked to a 5% increase in adverse effects (the Benchmark Dose Lower Confidence Limit, $BMDL_{05}$). The value they calculated was 48 µg per kg body weight per day for foetal growth restriction measured as decreased crown rump length, the length of a foetus from the top of the head to the rump (bottom), excluding the legs. This was 240 times higher than the dose set by EFSA as the level of no concern for kidney toxicity, suggesting that exposures below the level of no concern are very unlikely to cause adverse effects on foetal development and further supporting the idea that any effects on the developing offspring are likely to be secondary to maternal toxicity.

1.29 The COT agreed with EFSA's level of no concern of 0.2 µg per kg body weight per day for kidney toxicity and its justification for the recommended level. Whilst the $BMDL_{05}$ derived by the RIVM was specific to reproductive effects, EFSA's level of no concern was 240 times lower. Complying with the level of no concern would therefore provide protection against all the other forms of toxicity reported, including maternal and reproductive toxic effects, as well as adverse effects to the developing foetus during pregnancy.

1.30 Estimated exposures of women of childbearing age to citrinin were below the level of no concern set by EFSA. Therefore, the estimated exposures were not of concern for kidney or reproductive toxicity or for adverse effects to the developing foetus during pregnancy. In addition, citrinin was not detected above the lowest level that can be reliably measured in any of the food groups considered, further confirming that dietary exposure to citrinin is low and supporting the conclusion that levels of citrinin in the diet are not of concern to UK consumers.

1.31 Due to limitations in the database, the COT concluded that the risk of DNA damage or cancer cannot be ruled out. The COT agreed with EFSA and the RIVM that there is a need for further research to identify whether citrinin can damage DNA and/or increase the risk of cancer.

1.32 The full statement and lay summary can be found on the Committees website: 2025- statements and position papers | Committee on Toxicity.

Committee Procedures

Summary of the European Food Safety Authority's scientific opinion on the guidance on the use of read-across for chemical safety assessment in food and feed

The EFSA Scientific Committee (SC) published in July 2025 a Scientific Opinion on the guidance on the use of read-across for chemical safety assessment in food and feed. The document briefly reviews existing frameworks on read-across from organisations such as the European Chemicals Agency (ECHA) and the Organisation for Economic Cooperation and Development (OECD). The guidance goes on to describe a structured workflow to standardise and justify the read-across approach as a non-animal testing method for filling data gaps in chemical safety assessments, along with a discussion on the applicability domain and characterisation of the boundaries for read-across. The opinion also included a series of appendices on read-across processes, information on available in vitro methods for toxicological characterisation of chemical substances, an uncertainty assessment template, case study examples and a glossary of relevant terms and definitions.

The COT were asked to provide their comments on the EFSA read-across guidance.

It was agreed that the structured workflow was clear when approached as a review. However, no standard operating procedures (SOPs) were included, and the guidance was deliberately none-specific: this was noted during the public consultation period and confirmed by EFSA. The Committee noted that, without

experimental data, no New Approach Methodologies (NAMs) could be used to predict or read-across a toxicant.

While the aim of the guidance is to streamline processes, the quality of input data must be carefully considered, as it directly affects the quality of output.

The COT recommended that the read-across guidance should be reviewed by the COT Working Group on Guidance to avoid duplicating existing work in this area.

The European Food Safety Authority's draft scientific opinion on Δ8 THC – Derivation of a Health Based Guidance Value

1.33 In July 2025, EFSA published a draft opinion on deriving a health-based guidance value (HBGV) for Δ⁸-tetrahydrocannabinol (Δ⁸-THC) in food, considering its occurrence and co-existence with Δ⁹-THC. COT reviewed the draft opinion and provided comments for submission to the public consultation.

1.34 The COT noted that the draft opinion contained more evidence on Δ⁹-THC than Δ⁸-THC, despite the stated aim to evaluate Δ⁸-THC. EFSA proposed an acute reference dose (ARfD) applicable to the combined sum of Δ⁹-THC and Δ⁸-THC, based on a Lowest Observed Adverse Effect Level (LOAEL) of 2.5 mg/kg for Δ⁹-THC. The current UK position, which endorses a combined sum ARfD of 1 µg/kg bw/day for Δ⁹-THC and tetrahydrocannabinolic acid (THCA), may need to take into account the proposed grouping.

1.35 The lack of robust analytical methods for Δ⁸-THC, particularly regarding low detection limits and differentiation from other cannabinoids was noted; these limitations could undermine the reliability of occurrence and exposure data.

There are also challenges in distinguishing the pharmacological effects of Δ^8-THC from Δ^9-THC in complex mixtures.

1.36 There are significant data gaps, including limited information on pharmacokinetics, metabolism, and bioavailability of Δ^8-THC. While EFSA suggested there were no major differences in toxicokinetics between the two compounds, the COT considered the evidence insufficient to confirm this, particularly in the absence of human studies.

1.37 There are uncertainties around the potency estimates, which were based on a single human study of 19 adults. EFSA reported a point estimate for relative potency of Δ^9-THC to Δ^8-THC 1 to 1.4, with 95% confidence between 0.97 and 1.63 with data supported by quantitative analysis. These data were too limited to establish reliable potency comparisons. Additional concerns included data gaps in reproductive and developmental toxicity data and potential drug interactions via CYP-mediated metabolism.

1.38 Overall, the Committee supported EFSA's recommendations for further research but concluded that the evidence base does not yet allow for a confident HGBV for Δ^8-THC.

1.39 The final EFSA opinion was published in November 2025.

The European Food Safety Authority's draft update of its risk assessment on risks for human health related to the presence of plant lectins in food

1.40 In July 2025, EFSA released for public consultation a draft update of its risk assessment on risks for human health related to the presence of plant lectins in food.

1.41 The EFSA assessment only considered phytohemagglutinin (PHA) within the risk characterisation due to the evidence available. The Assessment concluded that due to limited data, establishing a health-based guidance

value would not be suitable, and a margin of exposure (MoE) approach was taken.

1.42 The EFSA Panel recommended that; analytical techniques are developed for the quantification of active and non-active lectins, occurrence data for different lectins should be collected, and the consideration of processing conditions and active and non-active lectins within the exposure assessment. The Panel also highlighted the need for human and rodent studies with regards to ADME, immunotoxicity, and gastrointestinal endpoints.

1.43 The COT were asked to provide comments on the draft opinion to be submitted to the EFSA public consultation.

1.44 It was agreed that the statement was detailed and covered important areas such as allergenicity and the autoimmune effects of lectins.

1.45 Further clarification should be included for the benefit of consumers to explain correct and incorrect processing.

1.46 The COT agreed that the data was not sufficient to calculate a health-based guidance value, and that a MoE approach was more suitable. The EFSA Panel concluded that an MOE of >100 would not raise a health concern and that if beans such as kidney beans were cooked properly there was no appreciable risk. The EFSA exposure assessment assumed that 50% of the lectins remain active in food matrixes, this would result in an MoE of 0.3 which was unusual for a highly consumed food product; clarification on the assumption supporting the 50% value should be included.

1.47 The COT recommended that the exposure assessment should consider vulnerable population groups such as those with irritable bowel syndrome, Crohn’s disease, ulcerative colitis and coeliac disease. It was further suggested that the EFSA Panel should consider the effect(s) of plant lectins on the gut microbiome.

1.48 The COT agreed with the recommendations for further work as suggested by the EFSA Panel.

1.49 The comments agreed by the Committee were submitted to EFSA as part of the public consultation process. The final EFSA opinion is yet to be published.

European Food Safety Authority public consultation on the risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food

1.50 In November 2025, EFSA published a draft opinion on the risk for animal and human health dioxins and dioxin-like polychlorinated biphenyls (PCBs) for public comment. This follows the re-assessment of dioxins by EFSA in 2018, and the publication of the revised toxic equivalency factors (TEFs) in 2022 by the FAO/WHO Joint Expert Committee on Food Additives (JECFA). The new EFSA opinion proposed a further reduction in the current (2018) Tolerable Weekly Intake (TWI) from 2 to 0.6 pg toxic equivalents (TEQ)/kg bw.

1.51 The COT discussed the draft EFSA and provided a number of comments to be submitted to EFSA.

1.52 The terms of reference of the current (2025) EFSA assessment stipulated that the assessment should apply to all 29 congeners, hence EFSA determined that human data could no longer be used as basis for establishing the TWI. The COT were unable to fully follow EFSA's reasoning to not use the Russian Children's Study and the two Seveso studies to establish a TWI, but instead use data from experimental animals, given that these were also only exposed to TCDD. The Committee also noted that EFSA did not consider any of the more recently published animal data in their assessment and would have liked a more detailed explanation as to their exclusion, along with more detail on the weighing of the total evidence. Instead of selecting one critical study, derivation of a point of departure across a number of studies may be

potentially more robust, especially as there may not be sufficiently robust scientific evidence to derive a reference point for the derivation of a health-based guidance value (HBGV) for dioxins and dioxin-like PCBs.

1.53 The actual exposures to dioxins and dioxin-like PCBS have not changed since the 2018 EFSA opinion, however the approach to the exposure assessment has changed along with the basis on which it is calculated. Hence, a more in-depth explanation would be useful, to understand EFSA's extrapolation from a point of departure based on TCDD only to an assessment based on the 2022 JECFA TEFs, for all 29 congeners. This was especially pertinent since TCDD does not appear to have the same effect in humans as in rats.

1.54 A preliminary analysis by the COT was able to reproduce EFSA's Bayesian model averaging approach. However, there appeared to be appreciable variability in the results between the current EFSA Bayesian approach, the previous EFSA PROAST version, another version of PROST and the online US Environmental Protection Agency (EPA) BMD software (BMDS) version in the size of POD/Benchmark doses. Changing the benchmark dose response/critical effect size (BMR/CES) from 10 to 15% also resulted in appreciable changes in the POD/Benchmark doses. The COT, noted that should the variability in the model results remain, this might raise questions regarding the use of the modelling, given the importance of the POD.

1.55 The COT would have also liked to have seen more detail on EFSA's recommendation on adverse outcome pathways (AOPs) and what work in particular would need to be done.

1.56 Comments were submitted to EFSA by the public consultation deadline.

EFSA Draft Guidance for Public Consultation: Draft guidance document on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption

1.57 In December 2024, EFSA's Food Ingredients & Packaging Unit (FIP) launched a public consultation on a draft guidance document concerning the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption.

1.58 The possible update of the existing document, “Guidance on the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption” (EFSA, 2010), was discussed at the 39th Plenary meeting of the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel). The update aimed to provide greater clarity on the data and information applicants should submit to EFSA.

1.59 The COT made a number of comments on the draft guidance, with a particular focus on the guidance document which described the requirements for toxicological testing.

1.60 The agreed comments were submitted to EFSA in February 2025 as part of the public consultation process.

COT Ways of Working

Ways of Working-Science and Research Special Topics Report

1.61 A template and format have been agreed to turn specific COT discussion papers into a “State of the Science” report or a “Science and Research Special Topics Report,” where the paper covered an individual scientific topic rather than being a risk assessment, where a statement would ultimately be published. Such papers have previously only been published in draft, as part of the media for discussion prior to the relevant meeting and are not citable.

1.62 The format will include a cover page summarising the paper, research recommendations and any other relevant information, notably the Committee’s recommendations. Certain documents could form part of the planned COT guidance package, where it was envisaged that the overarching guidance would be complemented by standalone papers on individual topics, as required. Furthermore, citation of such documents would be possible and promote the Committee’s work more widely.

1.63 Paper TOX/2025/09 on Novel Formulations of Supplement Compounds Designed to Increase Oral Bioavailability was used as an example as a formatted Science and Research Special Topics Report.

Ongoing work

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.

Other Committee Activities: Joint Expert Groups, Presentations and Workshop

Presentations FSA Postdoctoral Fellow and PhD student

1.108 The FSA and COT have been reviewing New Approach Methodologies (NAMs) to scope the best scientific methodologies available to be used in risk

assessment of chemicals in foods and the environment, and to understand how these can be incorporated and accepted in a regulatory context.

1.109 In 2021, the FSA started funding a 4-year computational toxicology postdoctoral fellow at the University of Birmingham and a four-year PhD Student (London Interdisciplinary Doctoral Program-LIDo-TOX AI) at King's College London.

1.110 The fellow and PhD student have been working alongside other government departments to understand how NAMs will improve indicative levels of safety in chemical risk assessment.

1.111 In addition, these new partnerships have helped with networking, research collaboration, training opportunities and furthering our knowledge in this area. The fellowship and studentship also compliment the work set out in the COT FSA UK NAMs Roadmap towards using new approach methodologies in chemical risk assessment.

1.112 The Postdoctoral Fellow and PhD student prepared a yearly review and gave a presentation to the Committee on their progress.

1.113 The PhD student provided an update on his research over the last year which involves the development of novel Quantitative Structure-Activity Relationship (QSAR) models using innovative artificial intelligence approaches. The aim of these models is to reliably predict the toxicological properties of molecules found in food and drink over a diverse range of endpoints of interest. Several case studies were presented which aimed to predict: 1) *in vivo* doses relevant to neurotoxicity, developmental toxicity and reproductive toxicity of brominated flame retardants; 2) Drug-Induced Liver Injury, Drug-Induced Renal Injury and Drug-Induced Cardiotoxicity of selective androgen receptor modulators and 3) the neurotoxicity and other toxicological effects of tropane alkaloids (TAs).

1.114 The postdoctoral fellow provided an overview on the latest international case study focusing on plant alkaloids of three large classes: tropane alkaloids (TAs), pyrrolizidine alkaloids (PAs), and glycoalkaloids (GAs). The first objective of this case study is to support the UK FSA's policy need to determine which TAs are the most potent (neuro)toxicants to prioritise specific substances and inform decisions on the UK's monitoring of these alkaloids in foods. An integral part of this aim is to confirm that neurotoxicity is the primary mode of action of these alkaloids. The second objective of this case study is to derive a HBGV for human exposure for the top priority, i.e. most potent substance within the class of TAs. This will utilise physiologically-based pharmacokinetic (PBPK) modelling and quantitative *in vitro* to *in vivo* extrapolation (QIVIVE). From a methodological perspective, a broader third objective of the case study is to evaluate and attempt to build confidence within the FSA in the application of a series of relevant NAMs that have been integrated in a manner to address policy needs. These NAMs are tiered and incorporate existing human *in vivo* data as well as new testing on human *in vitro* cell lines. The method in which to carry out this prioritisation is to utilise a tiered-testing strategy of *in silico*, *in vitro* and 'omics NAMs and use the outputs of this to derive a health-based guidance value to maximise the relevance and accuracy to human food safety.

1.115 The COT Members suggested the use of Organisation for Economic Co-operation and Development (OECD) reporting templates that provides a standardized structure for documenting PBPK models; it was noted that the fellow and PhD student had already started doing this.

1.116 The COT Members appreciated the work carried out and were impressed by the varied outputs.

Safety of Nitrates and Nitrites as Food Additives – Presentation from RSM UK Consulting LLP

1.117 Sodium and potassium nitrate, and sodium and potassium nitrites are salts commonly used as food additives for their antimicrobial properties, as well as their ability to maintain properties such as colour, texture and flavour. The safety of nitrates and nitrites as food additives was last evaluated by EFSA in 2017. In 2023, following an assessment on the safety of nitrosamines, the EU announced a decision to change the maximum permitted levels of nitrites and nitrates used as food additives to levels lower than those allowed in GB due to concerns regarding the additives' contribution to the formation of nitrosamines. This prompted a review of the current understanding of the safety of these additives in food sources in the context of GB legislation.

1.118 The RSM UK Consulting team delivered a presentation on the FSA-funded literature review of the safety of nitrates and nitrites as food additives. The presentation covered topics such as the research questions explored, the methodology used and the scope applied, as well as the findings resulting from the literature review and a brief discussion around these findings. RSM highlighted the uncertainties of the project, advised on ideas for future research and summarised the main conclusions of the literature review. The review had specifically focussed on the human and in vitro data.

1.119 The Committee made a number of comments on the review and thanked RSM for their hard work on this project and for delivering an insightful presentation.

AI in Risk Assessment Workshop

1.120 The COT held a workshop on AI in Chemical Risk Assessment in October 2025 in London, United Kingdom. The workshop included themed sessions consisting of short flash presentations followed by roundtable discussions. There was attendance from multiple stakeholders including academia, government and industry.

1.121 The workshop set out to explore the complex readiness of the data ecosystem and state of the art AI technologies. Opportunities as well as challenges associated with application of AI in chemical safety assessment were reviewed. The aim was to enable new insights and initiate discussions to determine how to best harness these technologies in future.

1.122 The finalised report will be published in due course.

Gut reactions: xenobiotics and the microbiome workshop

1.123 The COT held a workshop in October 2024 in London, United Kingdom on xenobiotics and the microbiome. The workshop included themed sessions consisting of short flash presentations followed by roundtable discussions. There was attendance from multiple stakeholders including academia, government and industry.

1.124 The workshop set out to explore the complex current state of the science of the microbiome pathophysiology and the possible impact of xenobiotics on host microbiome interactions and vice versa, including possible mechanisms and health implications, with a particular emphasis on the gut microbiome and dietary exposure. In addition, the aim was to enable new insights, review the science, initiate discussions to determine where the data gaps are in

research, what effects are of concern, and how might xenobiotics be evaluated practically for such effects in the future.

1.125 The four sessions were: Interactions of the host microbiome system; Gut microbiome and xenobiotics; Assessing the impact on the microbiome; Possible ways to evaluate in the short to medium term and microbiome interventions for maintaining health and treating disease and Future Directions

1.126 The workshop report is now available as HTML format and as a PDF. (DOI: https://doi.org/10.46756/sci.fsa.hew928)

Joint Expert Groups

AEJEG

AEJEG Assessments

1.127 The COT provides challenge and assurance on the outputs of the Joint Expert Groups (JEGs). As part of this they considered Committee Advice Documents prepared by the Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG) regarding the following regulated product applications:

- Committee Advice Document on the use of blue microalgae extract or blue Galdieria extract as a new food additive in the ‘colour’ functional class. (RP507).
- Committee Advice Document on the extension of use of curcumin (E 100) to a new food category “egg analogues” (RP41).

1.128 These documents are currently reserved as they cover draft AEJEG Committee Advice which is not currently published.

1.129 AEJEG Committee Advice Papers will be published in 2026.

FCM JEG

FCMJEG Assessments

1.130 The COT considered Risk Assessments prepared by the Joint Expert Group on Food Contact Materials (FCMJEG) regarding the following regulated product application:

- On the safety assessment on the evaluation of a post-consumer decontamination process, producing recycled poly(ethylene terephthalate) (PCR-PET) pellets for use in manufacture of materials and articles in contact with food. The COT endorsed the assessment made by the FCMJEG.

1.131 This item is currently reserved as the Committee Advice Paper is not currently published.

AEJEG Assessments

EFSA Draft Guidance for Public Consultation: Request for comment on EFSA's Public consultation on the EFSA Panel on Food Additive and Flavourings (FAF) 'Draft guidance on the preparation of an application for authorisation of a food additive submitted under 4 Regulation (EC) No 1331/2008

1.132 In December 2024, EFSA had proposed to update their 2012/2021 guidance (EFSA ANS Panel, 2012) on the preparation of an application for authorisation of a food additive submitted under Regulation (EC) No 1331/2008. The proposed update had reflected EFSA's intention to ensure that the guidance remained aligned with current regulatory expectations and continues to support the consistent and robust assessment of food additive applications across the European Union.

1.133 The update of the existing document had considered technical and scientific developments and practical experience by EFSA in the process of regulated products application submissions. EFSA had noted that there had been instances where scientific issues may be present that regulatory science had not been mature enough to include specific recommendations, noting potential effects on gut microbiota as an example. In such cases, the draft guidance had acknowledged scientific uncertainty while emphasising the importance of transparency, case-by-case evaluation, and the use of weight-of-evidence approaches where appropriate.

1.134 The draft guidance was discussed by COT and AEJEG and the agreed comments were submitted to EFSA in February 2025 as part of the public consultation process.

COT Working Groups

PFAS Subgroup

1.135 The COT subgroup on per- and poly-fluoroalkyl substances (PFAS) was set up in 2023 to provide guidance to UK Government Departments and Agencies to support human health risk assessments of per- and poly-fluoroalkyl substances (PFAS) where exposures to existing and legacy PFAS is occurring

through food, drinking water and other environmental media. This will include:

- Undertaking an independent review of toxicological and epidemiological data, focusing on a number of critical endpoints, and considering the biological relevance of the endpoints assessed.
- Considering the toxicokinetics of PFAS.
- Determining whether different PFAS can be grouped for assessment and how this can be done.
- Deriving a HBGV or a number of HBGVs as the data allow.

1.136 The subgroup considered of the evidence on liver and thyroid effects in 2023 and 2024. In 2025, the subgroup, along with additional experts on reproductive and developmental outcomes, had an update meeting in December, where the status of the evidence reviews for reproductive and developmental effects was provided.

1.137 These will be discussed in the next full subgroup meeting in 2026.

COT Guidance

1.138 The COT have agreed that their current guidance should be reviewed and updated as necessary. The existing guidance dates from 1983 but fell out of use as EFSA guidance was used in its place. The intention is to produce overarching guidance with more specific guidance where required, however, where other suitable guidance is available this could be referred to as appropriate. A working group was formed to start this task and met twice in 2025 to scope out the planned work.

Joint Working groups

Joint position paper from the Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT) on establishing a Safe Upper Limit for delta-9-tetrahydrocannabinol (Δ9-THC) and its precursor as contaminants of hemp-derived products and CBD novel foods

1.139 To support the assessment of cannabidiol (CBD) novel foods the Joint Advisory Committee on Novel Foods and Processes (ACNFP) and COT Subgroup developed a statement on a safe upper intake level for tetrahydrocannabinol (THC) as a contaminant of food.

1.140 The Committee reviewed the draft statement which summarises the position reached by the Subgroup and the evidence that underpins it.

1.141 The Joint position paper from the (ACNFP) & (COT) on establishing a Safe Upper Limit for delta-9-tetrahydrocannabinol (Δ9-THC) and its precursor as contaminants of hemp-derived products including CBD novel foods | Advisory Committee on Novel Foods and Processes was later published.

Plant-based drinks

1.142 Plant-based drinks are widely used as alternatives to animal milks such as cows' milk. They include drinks made from beans, peas, cereals, nuts and seeds.

1.143 While the availability and use of plant-based drinks in the UK have increased in recent years, they are still much less popular than cows' milk.

1.144 Oat drinks are currently the most popular plant-based drink in the UK, followed by soya and almond drinks.

1.145 Cows' milk is an important contributor to intakes of calcium and other minerals and vitamins ('micronutrients') and for children aged 1 to 5 years, cows' milk is also a major contributor to energy, protein and saturated fat intakes.

1.146 Both cows' milk and plant-based drinks may contain chemical contaminants or naturally occurring components. These could include organic chemicals, heavy metals and mycotoxins. Naturally occurring components include glycosides, isoflavones and naturally occurring oestrogens may also be present. Some of these components may have positive or negative health effects.

1.147 In England and Wales, the Nursery Milk Scheme allows childcare settings to reclaim the cost of providing one-third of a pint of milk per day to children in their care. Also, the Healthy Start scheme provides its recipients with weekly payments that can be spent on healthy foods, including cows' milk. To inform considerations about the inclusion of plant-based drinks in these schemes, and, to provide holistic advice to on plant-based drinks to consumers, the Scientific Advisory Committee on Nutrition (SACN) and the COT agreed to undertake an assessment of the nutritional and toxicological aspects of plant-based drinks.

Approach to the assessment

1.148 SACN and COT carried out a benefit-risk assessment comparing cows' milk with almond, oat and soya drinks, the most popular plant-based drinks in the UK at the time of the assessment. They also compared milk with water.

1.149 The assessment considered the impact of both nutritional intake and toxicological exposure on health outcomes. The full report includes details of the methods and processes used in the assessment.

1.150 The assessment had a specific focus on children aged 1 to 5 years. However, given the increasing availability and consumption of plant-based drinks, the assessment was expanded to also cover adults and children aged 5 years and over.

1.151 The assessment did not cover individuals or groups of people with specific dietary or nutrient requirements, except for those following a vegan diet (or a diet that is mostly free from animal products).

1.152 SACN and COT used the Benefit Risk Analysis for Foods (BRAFO) approach to compare cows' milk with almond, oat and soya drinks.

1.153 The assessment considered the impact of replacing cows' milk with almond, oat and soya drinks from a nutritional and toxicological perspective. The assessment was mainly informed by:

- Previous evaluations undertaken by SACN on nutrition and by COT on toxicology and health outcomes.
- UK dietary survey and purchasing data for information on total volumes of cows' milk consumed and the types of plant-based drinks available in the UK.
- A nutritional substitution analysis to consider the potential impact on nutrient intakes of replacing cows' milk with plant-based drinks or water. This is discussed in more detail in the main report.

Benefit risk assessment

1.154 SACN considered the following nutrients in the assessment:

- Energy,
- Protein,
- Saturated fat,
- Free sugars,
- Fibre,
- Vitamin A,

- Riboflavin,
- Vitamin B12,
- Vitamin D,
- Calcium,
- Potassium,
- Iodine,
- Zinc.

1.155 The rationale for the nutrients selected is discussed in the full report. SACN also considered salt.

1.156 COT considered a number of chemical contaminants and naturally occurring components and identified those for inclusion in the benefit-risk assessment based on:

- Their likely occurrence in cows' milk and plant-based drinks.

- Whether exposure was close to the relevant Health Based Guidance Value (the amount of chemical in food that a person can consume on a regular basis usually over a lifetime without any significant risk to health).

- Evidence on health outcomes and whether changes in exposure to chemical contaminants or naturally occurring components would likely be a public health concern.

1.157 COT included the following chemical contaminants or naturally occurring components in their assessment:

- Isoflavones,
- Lead,
- Dioxins and dioxin-like polychlorinated biphenyls (PCBs),
- Non-dioxin like PCBs,
- Per- and polyfluoroalkyl substances,
- Perchlorate,

- Mycotoxins (aflatoxin and ochratoxin A),
- Deoxynivalenol,
- Naturally occurring oestrogens (such as oestradiol).

Findings

1.158 At the time of the assessment, almond, oat and soya drinks available in the UK were not nutritionally equivalent to cows' milk. Replacing cows' milk with almond, oat or soya drinks would result in potential benefits and risks from both a nutritional and a toxicological perspective.

Nutritional benefits and risks

1.159 Replacing cows' milk with almond, oat and soya drinks may have nutritional benefits or risks, depending on whether they are typical, enhanced or 'unfortified and/or sweetened'. This is discussed in more detail in the main report.

Toxicological benefits and risks

1.160 For most toxicological chemical contaminants and naturally occurring components considered in the assessment, there was no clear difference between cows' milk and almond, oat or soya drinks. This was because either the chemical contaminants or naturally occurring components were not present in either cows' milk or plant-based drinks or were present at levels that posed little or no risk.

1.161 The only potential toxicological concern clearly identified relates to isoflavones from soya drinks in children aged 1 to 5 years following a vegan diet. This is because children are more highly exposed on a body weight basis than adults because of their smaller body size. Children following a vegan diet may

consume a higher amount of soya than other children. This risk could be partially mitigated by ensuring that children following a vegan diet consume a variety of non-animal protein sources rather than relying solely on soya products.

1.162 The ingredients used to make plant-based drinks may be at risk of fungal contamination, which can result in the presence of mycotoxins (naturally occurring toxins produced by fungi that can contaminate food and cause health problems). The limited data available suggests that this may not be a major concern in the UK, but it will be important to monitor the possible presence of these naturally occurring contaminants.

1.163 The full report provides detailed conclusions and recommendation for the general population, government and industry. It can be viewed at: Assessing the health benefits and risks of consuming plant-based drinks.

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) Annual Report 2025

Committee on Toxicity

2025