Committee Procedures

In this guide

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

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 Δ^8-tetrahydrocannabinol (Δ^8-THC) in food, considering its occurrence and co-existence with Δ^9-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 Δ^9-THC than Δ^8-THC, despite the stated aim to evaluate Δ^8-THC. EFSA proposed an acute reference dose (ARfD) applicable to the combined sum of Δ^9-THC and Δ^8-THC, based on a Lowest Observed Adverse Effect Level (LOAEL) of 2.5 mg/kg for Δ^9-THC. The current UK position, which endorses a combined sum ARfD of 1 µg/kg bw/day for Δ^9-THC and tetrahydrocannabinolic acid (THCA), may need to take into account the proposed grouping.

1.35 The lack of robust analytical methods for Δ^8-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 as 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.