

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

Introduction and Background

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

Introduction

1. In November 2025 EFSA published a draft opinion on dioxins 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 JECFA. The new EFSA opinion would further reduce the current (2018) tolerable weekly intake (TWI) from 2 to 0.6 pg toxic equivalents (TEQ)/kg bw.

2. The COT commented on the EFSA opinion in 2018 and had a number of reservations, particularly with respect to the key study which was the Russian Children's study which reported decreased sperm concentrations. The 7-fold reduction in the TWI to 2 pg/kg bw was possibly too conservative and the COT therefore recommended that a review of the evidential base and derivation of a health-based guidance value (HBGV) based upon this should be undertaken.

3. The timelines and work undertaken by EFSA and the COT are set out below, along with other developments such as the revised TEFs.

4. The public consultation closes on 26th January 2026. Could Members please send any additional comments to the Secretariat by **Thursday 22nd January 2026**

Background

5. In 2018, EFSA launched a public consultation on the “Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food”. Following a review of available animal and epidemiological data EFSA decided that the human risk assessment should be based on effects observed in humans and with the animal data being used as supportive evidence. EFSA selected the Russian Children’s Study as the most appropriate for dose-response modelling and established a TWI of 2 pg TEQ/kg bw/week; in this study, the key endpoint was sperm concentration. The TWI was based on a no observed adverse effect level (NOAEL), with a median serum level of 7.0 pg TEQ/g fat for the sum of PCDD/F TEQ in the lowest quartile. EFSA concluded that the data suggested that the long-term intake should remain below 0.25 pg TEQ/kg bw per day or 1.75 pg TEQ/kg bw per week to ensure that serum levels in boys remain below the NOAEL for effects on sperm concentrations of 7.0 pg TEQ/g fat, also when breastfed for 12 months. The value of 1.75 was rounded to 2 considering the uncertainty in the estimation of the critical serum level and corresponding daily intake. EFSA decided not to apply additional uncertainty factors (UFs), since the HBGV was based on a NOAEL obtained in a study with a relatively large number of boys (n = 133) and repeated semen sampling.

6. Although the TWI was based on PCDD/F-TEQ only, EFSA concluded that the TWI should apply to the sum of PCDD/Fs and DL-PCBs. However, they highlighted that the studies indicated that the current TEFs required re-evaluation. In particular, PCB-126, which contributes most to the DL-PCB-TEQ level, may be less potent in humans than indicated by the TEF-value of 0.1.

7. EFSA noted that the TWI was based on serum levels sampled from boys at the age of 8–9 years, however the critical window for the effects on sperm may actually be at younger age or during puberty. The TWI was considered protective for the general population and that it would prevent women from reaching a concentration in the blood that could lead to harmful pre- and postnatal effects.

8. In October 2018, the COT discussed the draft EFSA opinion and noted that the initial reservations regarding the observations made in the Faqi et al. (1998) study in rats that formed the basis for the establishment of the TWI in previous evaluations (i.e. SCF, 2001) resulted in the FSA funded studies by Bell et al. (2007a;b;c), which were performed using the same strains of animals and under the same conditions as the Faqi et al. study without, however, reproducing the same effects. The COT therefore questioned the lack of discussion regarding possible weighing of the discrepancies observed, especially since the Faqi. et al study has been used by EFSA to argue and/or justify causality for the associations observed with sperm quality in the human studies, that formed the basis for the HBGV. The COT also noted the lack of discussion of the evidence analysis regarding the associations between TCDD exposure during infancy/prepuberty and impaired semen quality observed in the Seveso incident studies and the Russian Children's study that were considered causal. The Committee considered that due to the lack of detailed discussion the evidence synthesis was not robust. The significant associations observed between PCDD-TEQ and PCDF-TEQ but not for DL-PCB-TEQ or Total -TEQ in the Russian Children's study was considered surprising by the COT, given the mode of action (MoA) of these chemicals. If correct, it might suggest a revision of the TEFs was necessary. It was also noted that a discussion on the possible explanation for the associations observed, or lack thereof, was also absent. The COT agreed with the selection of the critical endpoint for the establishment of an HBGV and accepted that, if possible, human data should be used for this purpose but was unable to conclude this was robust. Discussing the TWI established, the Committee questioned its applicability to the whole population ([COT discussion paper](#), [COT minutes](#)).

9. In the November 2018, EFSA published their scientific opinion on the risks for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food, establishing a TWI of 2 pg TEQ/kg bw which is significantly lower than the TDI previously established by WHO of 1-4 TEQ pg/kg bw ([Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food](#)).

10. The COT discussed the final opinion on dioxins in September 2019 and noted that all three epidemiological studies looked at by EFSA were small with significant loss-to-follow up and very difficult to compare directly. Due to the low number of participants in the Russian Children's study, results had to be considered in quartiles to give sufficient power, and pre- and postnatal exposure were not compared. In the Seveso cohort, effects on sperm quality were only observed in children exposed before puberty, with boys who had been breastfed

by exposed mothers showing a marked decrease in sperm quality compared to boys from exposed mothers who were formula-fed. Some of the analysis could be improved in these studies, but generally the studies supported each other. The COT noted that EFSA concluded that the animal studies did support the epidemiological evidence but concluded that the end-points measured were too different between the human and animal studies. Overall, the Committee considered that, whilst the data available were limited, it was not reasonable to dismiss the conclusions of EFSA regarding acceptable intake ([COT discussion paper](#), [COT minutes](#)).

11. In September 2020, the COT discussed the implications of the new TWI for risk management at the FSA and on the UK population. Exposures for most of the population prior to the new TWI being established were below the then level of health concern but could be now at or above the new level of health concern. This suggests that current risk management measures for dioxin in food, which include regulatory limits and precautionary advice to consumers and are based on the previous TDI, may be inadequate. The COT took another look at the animal and human data and considered whether the newly proposed TWI was relevant to all consumers and to place the various risks associated with exposure into perspective against other health risks, as well as nutritional benefits from food consumption. The COT noted again that while there was a high degree of uncertainty, the studies used by EFSA could not be dismissed. However, the Committee questioned the use of the Russian Children's Study to derive the new TWI as they considered that the study provided only a weak data set. Hence, the COT considered the 7-fold reduction in the TWI as possibly being too conservative. The COT recommended that a review of the evidential base and derivation of a HBGV based upon this should be undertaken. However, COT acknowledged that a full systematic review of the dioxins database was neither feasible nor practicable. The Committee noted that there was a need to examine both the epidemiological data and the animal data to determine the synergies and divergencies within the database. The Committee considered that the work of the SETE subgroup ([SETE | Committee on Toxicity](#)) might provide a suitable framework for this ([COT discussion paper](#), [COT minutes](#)).

12. In October 2020, the COT discussed the approach for the review of the dioxin HBGV, including resource implications, approaches for undertaking the review and ongoing work by the SETE working group. The COT noted that it was unlikely that the Committee would identify critical endpoints of toxicity different to those already identified by other authorities, hence rather than performing a systematic review of the entire literature, it would be more pragmatic and

feasible to draw on existing work on dioxins and narrow the literature search to the specific endpoints underpinning the TDI. The COT highlighted it would be necessary to consider the mode of action and available toxicokinetic models and stressed the need for a clear formulation of the scientific questions, including consideration of all risk management concerns. By applying the SETE guidance, the review of dioxins would establish a future approach where compounds were assessed in a clear and transparent way taking into account the entire scientific evidence base. It was agreed for a small subgroup to be formed to discuss the requirements/problem formulation in more detail ([COT discussion paper](#), [COT minutes](#)).

13. In December 2020, the COT discussed the approach for the review of dioxins, following the meeting of a small subgroup. The proposal included a systematic review of the epidemiological evidence and toxicological evidence for the critical endpoint identified by EFSA, namely effects on the reproductive system, focussing on changes in the male reproductive system parameters.

14. The COT also discussed the draft position paper on dioxins highlighting that the review of dioxins will be an extensive and lengthy undertaking. Given that an immediate reduction in the TDI would take decades to take effect, due to the nature of dioxins especially the long half-life in humans, and as the current TDI was based on the most sensitive endpoint in the animal studies and is intended to protect the most sensitive population group, it will be protective for all population groups. Thus, while the re-assessment of dioxin is a necessary and important piece of work going forward the COT does not consider it necessary in the meantime to alter its current advice on dioxins ([COT discussion paper](#), [COT minutes](#)).

15. The COT position paper on dioxins was published in March 2021 and can be viewed using this link: [Dioxin Interim Position Statement](#).

16. In September 2023, the COT discussed the report of the commissioned systematic review of the literature on dioxins. The review and subsequent report thereby focused on male reproductive toxicity and immunotoxicity. Literature on and assessment of the mechanism of action of dioxins via the aryl hydrocarbon receptor (AhR) were also included to investigate species differences related to male reproductive toxicity and immunotoxicity, where possible. The literature review further included a non-systematic look at data on potential carcinogenicity of dioxins and dioxin-like PCBs and whether it involved a genotoxic mechanism. The report provided to the FSA also includes evidence integration and visualisation of the conclusions following the SETE guidelines. The COT noted that

using the Newcastle scoring system only high scoring papers were included in the literature review and this could lead to papers of lesser quality but still with relevant information being omitted; this was a concern also discussed by the SETE sub-group. The COT considered that it would be of value to see the relevant information from the papers that did not meet the quality criteria included in the next review. The COT agreed that the most critical effects from this review and previous reviews should be identified. Converting the doses to body burden should also be considered.

17. The Committee agreed that following the systematic literature review, there currently was not sufficient evidence to identify a key study or studies on which to establish a health based guidance value and further consideration would be required ([COT discussion paper](#), [COT minutes](#)).

18. In 2024, JECFA published its 2022 re-evaluation of human and mammalian toxic equivalency factors for dioxins. The new TEFs were no longer rounded based on a half-log scale but directly based on observed relative potencies. Much more weight was given to *in vivo* studies and toxicological endpoints in experimental animals. TEFs for almost all congeners were changed, apart from mono-ortho PCBs, for which the 2005 WHO-TEFs were retained due to limited and heterogenous data. Applying the new TEFs to a limited set of dioxin-like chemical concentrations measured in human milk and seafood indicated that the total toxic equivalents will tend to be lower than when using the 2005 TEFs. A comparison of the 2005 and 2022 Tefs can be found in Table 1 using this link: [The 2022 world health organization reevaluation of human and mammalian toxic equivalency factors for polychlorinated dioxins, dibenzofurans and biphenyls - ScienceDirect](#).

19. Following the publication of the JECFA derived TEFs, EFSA published a draft update to their risk assessment of dioxins for public consultation in November 2025 ([Public Consultation](#)). The following paragraphs provides a brief summary of the draft EFSA opinion.