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TOX/2025/48

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

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

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

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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

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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

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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](#)).

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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](#)).

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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

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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.

Summary of the draft EFSA opinion on dioxins 2025

20. Following the publication of the new TEFs by JECFA, EFSA was asked by the European Commission (EC) to update its 2018 assessment, considering the potential impact the change in TEFs could have on the exposure assessment and derivation of the TWI. EFSA thereby took into account the updated TEFs for all 29 congeners and as such the sum of PCDD/F and DL-PCB TEQ. The assessment also included an update on exposure of food-producing animals and transfer of PCDD/Fs and DL-PCBs from these animals to animal derived food products.

21. Based on human milk samples from the WHO/UNEP monitoring program and individual milk samples from Germany, the application of the new TEFs resulted in consistently lower total TEQ concentrations, with an average decrease of 40%, compared to the previous (2005) TEFs.

22. EFSA applied a systematic approach to retrieve relevant information since their last (2018) assessment. No new essential data was identified on the toxicokinetics of dioxins, while effects reported in new experimental animal studies were considered not adverse and/or not suitable to derive a reference point (RP).

23. Numerous eligible epidemiological studies were identified, however, the number of studies per endpoint were limited and EFSA noted considerable

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heterogeneity, with few studies being prospective. Hence, EFSA did not identify any new evidence to change the previous conclusions.

24. EFSA continued to consider a decrease in sperm production in male offspring of rats upon exposure to TCDD (via the dams) as the most sensitive endpoint. Lower sperm concentrations were also observed in the three different human cohort studies, the two Seveso studies (TCDD), and the Russian Children's Study (significant associations between serum levels and TCC, PCDD-TEQ, PCDD/F-TEQ and sperm concentrations, but not for PCDF-97 TEQ, DL-PCB-TEQ or Total-TEQ).

25. As the current assessment was meant to apply all 29 congeners, EFSA concluded that the studies in humans could no longer be used as basis for establishing the TWI. The Russian Children's Study showed no statistically significant association for total TEQ and the two Seveso studies lacked information on exposure to other congeners than TCDD in both the exposed and control group. Thus, EFSA decided to use a study in rats (Faqi et al., 1998a), while the human studies were used as supportive evidence, including decisions on uncertainty factors (UF) to use.

26. In the critical study, dams were exposed to TCDD s.c. with a single dose of 25, 60 or 300 ng/kg bw two weeks prior to mating, followed by weekly injections of 5, 12 and 60 ng/kg bw during mating, pregnancy and lactation. The aim was a stable body burden. Three animals were killed on gestation day 21 (GD21) to confirm the intended body burden and male offspring were killed either postnatal day 70 (PND70) or PND170. Male pups showed reduced sperm production at both, 70 and 170 days.

27. At day 170 a near-maximum response was obtained at the lowest dose, corresponding to a body burden in the dams of 25.1 ng/kg bw. However, EFSA considered it more informative and scientifically robust to derive a RP from a benchmark dose (BMD) lower credible limit (BMDL) than extrapolating from a lowest observed adverse effect level (LOAEL) to a NOAEL. Hence, performing BMD modelling (EFSA Guidance, 2022) on the daily sperm production data from the Farqi et al. (1998) study, EFSA derived a maternal body burden of 1.7 ng TCDD/kg bw

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using a benchmark response (BMR) of 15% decreased sperm production. Although the BMDL₁₅ is based on TCDD, EFSA concluded that it should also apply to the sum of PCDD/Fs and DL-PCBs based on the TEQ concept.

28. EFSA did not apply the default UF for interspecies toxicokinetic variability as the starting point for the assessment was body burden. In addition, there is evidence demonstrating that humans are not more sensitive than rats. Therefore, the default UF for inter and intraspecies variability in toxicodynamics were not applied. The default UF of 3.16 for intraspecies variability in kinetics in humans, such as variations in maternal body fat content and amount of milk consumed by infants, however, was considered appropriate, while differences in metabolism likely play a minor role and absorption is almost complete.

29. The RP of 1.7 ng TEQ (2022)/kg bw correspond to a lipid-based level of 6.8 ng TEQ (2022)/kg body fat (based on 25% body fat) and using the concentration and age-dependent toxicokinetic model (concentration- and age-dependent (CADM) model) this lipid-based level would be reached after chronic exposure to 0.29 pg TEQ (2022)/kg bw per day. Applying the default UF of 3.61 for interspecies variability in kinetics, this results in a daily intake of 0.09 pg TEQ (2022)/kg bw per day or 0.63 pg TEQ (2022)/kg bw per week. EFSA rounded this to establish a TWI of 0.6 pg TEQ (2022)/kg bw per week for the sum of PCDD/Fs and DL-PCBs.

30. This TWI is lower than the TWI of 2 pg TEQ/kg bw/week established in 2018 and also lower than the TWI of 14 pg TEQ/kg bw/week that the SCF derived from the same study in 2001.

31. EFSA considered the TWI protective for the general population and all endpoints. Toxicokinetic modelling of chronic exposures at the TWI resulted in body burden in women age 35 years of 2.2 ng TEQ (2022)/kg fat, the highest body burden in women that does not raise a health concern for their sons. The fat-based levels in milk would be similar to the body burden. The TWI prevents woman of childbearing age reaching the body burden that could lead to in utero and lactational exposures associated with health concerns in offspring. EFSA recognised that infants have higher exposure per kg bw during breastfeeding than the TWI, resulting in a higher

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body burden. However, this was already taken into account when setting the TWI. Therefore, the TWI is not applicable for infants, and it is not appropriate to compare it to the exposure of infants.

32. EFSA noted that the differences in HBGVs (SCF, 2001; JECFA, 2002; EPA, 2012; EFSA 2018) were based on the selection of the critical studies, application of BMD modelling, toxicokinetic modelling and application of a correction factor for dosing regimens.

33. Exposures estimated with the new 2022 TEFs were between 27% and 35% lower than using the 2015 TEFs across all age groups. The non-ortho DL-PCBs showed the highest contribution (41%) to the total 2022-TEQ exposure, followed by PCDFs (27%), PCDDs (24%) and mono-ortho PCBs (9%).

34. When comparing the mean current dietary exposure to the 29 PCDD/Fs and DL-PCBs a 3- to 12-fold exceedance of the TWI was observed (lowest LB-highest UB) in 'Adolescents', 'Adults', 'Elderly' and 'Very Elderly'. At the P95, exceedances ranged from 6- to 30-fold (lowest LB-highest UB). For 'Toddlers' and 'Other Children', the mean dietary exposures exceeded the TWI by 6- to 27-fold and at the P95 from 11- to 55-fold. The exceedance for 'Toddlers' and 'Other Children' raised a concern for developmental effects.

Food producing animals

35. Ratios of 2022-TEQ vs 2005-TEQ concentration estimates for the 29 PCDD/Fs and DL-PCBs ranged from 0.8 to 1.2 for most food-producing animal species and categories considered. The variation in this ratio was largely driven by the congener pattern in the feed material or compound feed. The updated occurrence data and methodological refinements resulted in generally lower or comparable estimated concentrations of the 29 PCDD/Fs and DL-PCBs in the daily diets of food-producing animals compared to the 2018 Opinion based on the 2005 TEFs.

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36. EFSA used new studies to update the information and contribute better to the understanding on the transfer of PCDD/Fs and DL-PCBs in dairy cows, laying hens and pigs to milk and eggs and accumulation in liver, fat and meat of food producing animals. The change in TEFs does not affect the transfer rates of individual congeners but EFSA noted that it could impact total TEQ, and the extend of said impact may be evaluated based on a case-by-case basis and ideally using congener-specific toxicokinetic models that are available for some species.

37. EFSA noted a number of uncertainties, including the derivation of the RP from the critical study, the absorption, distribution, metabolism, excretion (ADME) and the toxicokinetic model, the relevance for humans of the new TEFs for DL-PCBs, the derivation of the TWI including the applicable UF, left-censored occurrence data and occurrence in foods of plant origin. Taking into consideration the uncertainties EFSA concluded with about 95% certainty that the TWI would be equal or higher than the value derived from the available data, if the identified uncertainties were resolved. EFSA considered it 99-100% certain that the mean exposure in adults would be higher than the TWI for all dietary surveys that were considered, if the identified uncertainties affecting the exposure assessment were resolved. Even taking into account the discrepancy between the exceedance of the TWI from dietary exposures and measured milk levels, EFSA considered it likely (80-90% certainty) that mean exposures would raise a health concern based on the new TEFs. For P95 exposures, the certainty was 95-99%. However, when uncertainties related to the new TEFs for DL-PCBs were also taken into account, the probability for health concerns were reduced (mean to 33-6%; P95 to 70-80%).

38. EFSA made a number of recommendations to reduce the uncertainties in the risk assessment, i.e. further development of approaches to compare animal- and human-based data, further data on occurrence levels in plant-derived foods, improvement of toxicokinetic models (including inclusion of other congeners (other than TCDD)), further biomonitoring data, also of other European populations, development of analytical methods, better understanding of the involvement of the AHR in regulation of sperm production and how it is disrupted by dioxins. The latter should contribute to the development of an adverse outcome pathway (AOP) for the AhR in relation to sperm production/effects on reproduction and development.

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Questions to the Committee

- i. Do the Committee have any comments on EFSA's (change in) approach to derive a TWI for dioxins, including but not limited to, the selection of the critical study/effect the BMD modelling and uncertainty analysis?
- ii. Do the Committee have any comments on the reduction of the TWI and its effect on human exposure?
- iii. Do the Committee have any other comments?

Secretariat

December 2025

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Abbreviations

ADME	Absorption, distribution, metabolism, excretion
AhR	Aryl hydrocarbon receptor
AOP	Adverse outcome pathway
BMD	Benchmark dose
BMDL	BMD lower credible limit
BMR	Benchmark response
CADM model	Concentration- and age-dependent model
GD	Gestation day
HBGV	Health based guidance value
LOAEL	Lowest observed adverse effect level
MoA	Mode of action
NOAEL	No observed adverse effect level
PND	Postnatal day
RP	Reference point
TEFs	Toxic equivalency factors
TEQ	Toxic equivalents
TWI	Tolerable weekly intake
UF	Uncertainty factors
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
EFSA	European Food Safety Authority
EC	European Commission
FSA	Food Standards Agency
JECFA	Joint FAO/WHO Expert Committee on Food Additives
SCF	Scientific Committee for Food
SETE	Joint COT and COC Synthesis and Integration of Epidemiological and Toxicological Evidence subgroup
UNEP	United Nations Environment Programme
WHO	World Health Organisation

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