Meeting

Draft supplementary statement to the COT’s position paper on bisphenol A (BPA)

Background

1. **In 2016**, EFSA received a mandate from the European Commission to re-evaluate the risk to public health related to the presence of BPA in foodstuffs; EFSA published a draft opinion in **December 2021** for public consultation and proposed a significant reduction to the temporary tolerable daily intake (TDI) of 4 µg/kg body weight (bw) to 0.04 ng/kg bw. This reduction would mean that both mean and high-level consumers for all age groups would exceed the new TDI by 2-4 orders of magnitude.

2. The COT discussed the draft EFSA opinion at an extraordinary meeting in **February 2022** (the full discussion can be viewed using this link: Final minutes of the extraordinary meeting on BPA 10th February 2022 | Committee on Toxicity). The Committee agreed that EFSA had approached the subject in a methodical and structured way. However, the Committee noted that there was no in-depth consideration of studies used in the previous (2015 EFSA) opinion. There was a large body of data missing and so the new opinion did not transparently encompass the totality of the available evidence. The Committee had reservations about the key endpoint selected by EFSA, i.e. an increase in Th17 cells, as this was an intermediate rather than an apical endpoint. The proposed TDI of 0.04 ng/kg bw per day derived from this endpoint would suggest that the whole population would be at risk, as all food consumption would lead to BPA exposures orders of magnitude above the recommended level and hence would be at risk of adverse effects. However, this did not seem to be supported by the available human data, and the use of the intermediate endpoint was conservative. Based on the evidence the Committee were not convinced that EFSA had reached an appropriate conclusion on an appropriate reference point. The Secretariat submitted the COTs comments and concerns within the deadline for public consultation.

3. Following public consultation, EFSA published the final opinion on the re-evaluation of BPA in **April 2023** (Re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs - - 2023 - EFSA Journal - Wiley Online Library) and established a TDI of 0.2 ng BPA/kg bw per day. Although this new TDI is higher than the initially proposed level of 0.04 ng.kg bw, it still means that both mean and high-level consumers for all age groups would exceed the new TDI by 2-3 orders of magnitude. Both, the European Medical Agency (EMA) and the German Federal Institute for Risk Assessment (BfR) provided comments to EFSA, setting out diverging views. As these diverging views could not be resolved, according to the respective founding regulations, EFSA and the EMA/BfR were obliged to present a joint document to the EC clarifying the contentious scientific issue and identifying relevant uncertainties in the data. These documents are required to be publicly available (and can be viewed using these links: ema-efsa-article-30.pdf, also this link: ema-efsa-article-30.pdf and Report on diverging views between EFSA and BfR on EFSA bisphenol A (BPA) opinion).

4. The BfR publishes their risk assessment on BPA in **April 2023** (Health assessment of Bisphenol A in foods - BfR).

5. The COT discussed the final EFSA opinion on BPA in **May 2023** (the full discussion can be viewed using this link: EFSA 2023 re-evaluation of the risk to public health from bisphenol A (BPA) in foodstuffs | Committee on Toxicity). The COT noted that while the EMA's approach to risk assessment differed from that of the COT and BfR in that it also considered benefit when reviewing human medicines, both the EMA and BfR raised similar scientific concerns as the COT, mainly with respect to the endpoint used by EFSA. The COT further agreed with the BfR's criticism that EFSA's predefined protocol restricted the data set assessed in the EFSA opinion and that there was a wider data set available for BPA, which should have been considered in the evaluation. The COT also questioned whether an intermediate endpoint of uncertain pathophysiological significance would be sufficiently robust. While this was a wider discussion, the Committee did not agree with EFSA that the change seen in Th17 cells was a sufficiently relevant and scientifically robust intermediate endpoint on which to base the establishment of a health-based guidance value (HBGV). In addition, given the uncertainties over the endpoint, a weight of evidence approach should have been clearly applied in the EFSA opinion to fully assess the data and derive a robust point of departure. The COT had previously agreed with EFSA's assessment of the safety of BPA in 2006, 2008 and 2015. However, while the Committee considered it possible that the TDI would need to be revised to

account for new evidence and ensure it was sufficiently protective, on balance the weight of evidence did not support the conclusions drawn by EFSA, or a TDI as low as that established by EFSA. It was agreed that an interim position paper, capturing the COT's view and the proposed next steps should be published.

6. In late spring/early summer 2023, the EC published a statement announcing a ban on the use of BPA in food contact materials (FCMs).

7. A first draft interim position statement was presented to the COT in **July 2023** (the full discussion can be viewed using this link: Final Minutes of the 11th July 2023 COT Meeting | Committee on Toxicity). The Committee agreed with the proposal to take a weight of evidence approach to the relevant endpoints, drawing on the data in the EFSA opinions (2006, 2008, 2015, 2023) and any data published since the cut-off point of the EFSA literature review. It was agreed that the SETE principles should be applied for data integration, where applicable, with the aim of identifying key endpoints, gaps and uncertainties and suggest a way forward in establishing a TDI for BPA, ensuring that the weight of evidence and data integration was reflected transparently in their assessment.

8. A second draft interim position statement was presented to the COT in **September 2023** (the full discussion can be viewed using this link: Final Minutes of the 5th September 2023 COT Meeting | Committee on Toxicity). Additional text was added, including recommendations how to take the work forward to establish a UK TDI. The UK TDI at the time of discussion was substantially above the new TDI established by EFSA and was based on changes in kidney weights. The Committee agreed at the meeting that it could not conclude on whether this endpoint should still be used while BPA was being evaluated as effects were apparent in other endpoints, suggesting the current TDI might no longer be appropriate. The COT considered it useful to identify and discuss HBGVs used elsewhere/by other authorities for BPA. The Secretariat stressed that due to resource constraints, a (full) review of BPA would need to be externally commissioned and would not return to the Committee before the middle of 2024.

9. A third draft interim position statement was presented to the COT in **October 2023** (the full discussion can be viewed using this link: Final Minutes of the 17th October 2023 COT Meeting | Committee on Toxicity), as well as information on HBGVs from other authorities. The Committee noted that the recent assessment of BPA by the BfR established a TDI lower than the previous EFSA TDI (2015) but higher than the new TDI (2023) and it would therefore be beneficial to consider the BfR approach in more detail as it was based on the same literature/data available to EFSA, and to establish how it differed from the

approach taken by EFSA.

10. In **December 2023**, the COT discussed the scientific evidence base, derivation and differences in approaches of the EFSA TDI and BfR TDI (the full discussion can be viewed using this link: Final Minutes of the 12th December 2023 COT Meeting | Committee on Toxicity). The BfR and COT agreed that the change in TH17 cells was not an appropriate endpoint to derive a point of departure for the derivation of a HBGV but instead the BfR used reproductive effects, i.e. sperm mobility/mortality in rodents, in their BMD modelling and derivation of a point of departure. While the BfR's approach was conservative, the overall assessment avoided unnecessary conservatism and after weighing the available evidence, the COT agreed with the endpoint selected by the BfR and the overall assessment. The COT therefore agreed to apply the TDI of 0.2 ug/kg bw per day derived by the BfR as an interim HBGV to their assessments until they have undertaken their own assessment/can reach a more considered position.

11. In **December 2024**, the EU adopted a ban on the use of BPA in FCMs, which took effect in **January 2025**, with an 18-month phase-out period for industry compliance.

12. Following the discussion of the BfR assessment at the December meeting the draft interim statement was updated and discussed by the COT in **February 2024** (the full discussion can be viewed using this link: Final minutes of the 6th February 2024 COT Meeting | Committee on Toxicity). FSA policy colleagues advised at the time, that the need for a UK TDI remains for risk management purposes. Given the extensive work and timelines of a full review of BPA and in light of the recent assessment by the BfR, the COT agreed that it was feasible to consider adopting assessments and HBGVs established by other authorities, rather than undertaking a (full) review themselves, where the Committee agreed with the approach and the scientific assessment of the database. In the case of BPA, the COT had previously assessed the EFSA opinion, the diverging opinions by the BfR and the European Medical Agency (EMA) and then the full assessment by the BfR. While the COT had significant reservations regarding the approach taken by EFSA and their subsequent derivation of the HBGV, they agreed with the BfR approach and considered it, while conservative, scientifically robust and more reasonable. **The COT therefore agreed to adopt the BfR TDI**.

13. While the COT were content to publish a condensed statement, in the interest of time, to reflect their decision to adopt the BfR TDI and to permit timely risk management, they stressed that a detailed supplementary statement would

be required. 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 thereby highlight the concerns regarding the EFSA TDI and the Committee's review of the relevant studies and approach taken by the BfR, including the modelling and studies selected to establish the HBGV. The supplementary statement should also include discussions of any relevant information that was published since the BfR assessment, and hence, a short literature search on the relevant endpoints should be included, from the BfR cut-off.

14. The draft interim statement was amended to reflect this development and form a draft position paper which was discussed by the COT at the **March 2024** meeting (Final Minutes of the 26th March 2024 COT Meeting | Committee on Toxicity) and **May 2024** meeting (Final Minutes of the 21st May 2024 COT Meeting | Committee on Toxicity). **The final position paper was published in May 2024**, and can be found at this link: Position paper on bisphenol A | Committee on Toxicity.

15. Following the publication of the COT position paper a small working group was formed, which met in **October 2024** and **December 2024**. The WG discussed the studies/information retrieved from the literature search, as well as the outline and (level of) information to be included in the supplementary statement.

16. With thanks to the WG the following supplementary statement (Annex A) provides the transparent weighing of evidence presented in the EFSA and BfR assessments, and retrieved literature, with a focus on immunotoxicity and reproductive and developmental effects as endpoints of BPA exposure. The paper further includes the discussions and considerations that resulted in the COT adopting the TDI set by the BfR, and considering this TDI sufficiently protective of UK consumers, although lower than the EFSA TDI.

17. Please note, the supplementary statement is not an independent piece of work or a statement by itself but is the underlying scientific weighing of all information that resulted in the COT adopting the TDI of TDI of 0.2 µg/kg bw per day.

18. Please also note, the working group has signed off on the statement in **November 2025**.

Questions to the Committee

i) Do the Committee agree with the structure of the supplementary statement.

ii) Do the Committee consider the supplementary statement sufficiently detailed and transparent to reflect how they reached the conclusion to adopt the BfR TDI.

iii) Do the Committee have any other comments.

COT Secretariat

November 2025