Meeting

Draft Interim position statement on bisphenol A

This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

Introduction

1. In April 2023, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) established a new tolerable daily intake (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, mean and high level consumers for all age groups would exceed the new TDI by 2-3 orders of magnitude.

2. Both, the European Medical Agency (EMA) and the Bundesamt fuer Risikobewertung (BfR) provided comments to EFSA, highlighting diverging views.

3. The COT discussed the draft EFSA opinion at their extraordinary meeting in February 2022 and provided comments on the public consultation. The final EFSA opinion and diverging opinions by the EMA and the BfR were discussed at their May 2023 meeting.

4. Following the discussions at the May 2023 meeting, an interim position paper has been drafted, reflecting the comments and concerns by the Committee. This draft interim position paper can be found at Annex 1.

5. At the May meeting Members considered it possible that the TDI would need to be revised to account for new evidence. To ensure any risk management actions are sufficiently protective to consumers, i.e. whether there is a need to alter the specific migration limit (SML) or introduce a ban on BPA in food contact material (FCM) legislation, the establishment of a COT/UK TDI would be required by policy colleagues.

6. However, as Members did not consider doing a deep dive into the individual endpoints was worthwhile and the resource implications of doing our own review of the database is significant an appropriate way forward needs to be discussed.

7. Members considered that a weight of evidence analysis was lacking in the EFSA opinion. The Secretariat therefore proposes a weight of evidence approach of the relevant endpoints as an initial step, 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. Data integration may be possible using the SETE principles. It is hoped that this may then identify key endpoints, gaps and uncertainties and suggest a way forward on how to establish a TDI for BPA.

Question on which the views of the Committee are sought

i. Do Members have any comments on the draft interim position paper?

ii. Do the Committee agree with their previous conclusion that a COT/UK TDI is needed?

iii. Do the Committee agree with the Secretariats proposal of a weight of evidence approach, utilising the data on the relevant endpoints from the EFSA opinions and any newer published data?

iv. Or if the Committee consider a different approach preferable to the initial thoughts by the Secretariat, could Members please elucidate.

v. Does the Committee have any further comments?

Secretariat
July 2023

COT/2023/31 Annex 1

1. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) reviewed the scientific basis and implications for risk management of the new EFSA tolerable daily intake (TDI) for bisphenol A (BPA)

and considered that there was a substantial lack of evidence integration to derive a robust point of departure for the derivation of a health-based guidance value (HBGV). These concerns meant that the COT was unable to endorse the opinion.

2. The European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEF) considered the increase in percentage of TH17 cells in the immune system to be the most sensitive endpoint and hence the critical adverse effect of BPA and established a new TDI of 0.2 ng BPA/kg bodyweight (bw) per day. The new TDI was based on a human equivalent dose (HED) of 8.2 ng/kg bw per day to which EFSA applied an overall uncertainty factor (UF) of 5, the default UF of 2.5 and 10 for interspecies toxicodynamic differences and intraspecies variability in toxicokinetics and toxicodynamics, respectively. No uncertainty factor was applied for inter species variability in toxicokinetics as this was already accounted for in the conversion to the HED.

3. Although this new TDI is higher than the initially proposed level of 0.04 ng/kg bw, based on the 2015 exposure assessment, mean and high-level consumers of all age groups would exceed the new TDI by 2-3 orders of magnitude.

4. Both, the European Medical Agency (EMA) and the Bundesamt fuer Risikobewertung (BfR) provided comments to EFSA, highlighting diverging views, i.e on the use of an intermediate endpoint for the derivation of a HBGV, the approach and timeframe applied for consideration of studies and the risk assessment approach including the uncertainty analysis and clinical relevance/extrapolation from animals to humans and derivation of the HED. As the diverging views could not be resolved, according to the respective founding regulations, EFSA and the EMA/BfR are obliged to present a joint document to the European Commission (EC) clarifying the contentious scientific issue and identifying relevant uncertainties in the data.

5. The COT discussed the draft EFSA opinion at their extraordinary meeting in February 2022 and provided comments to the public consultation. The final EFSA opinion and diverging views by the EMA and BfR were discussed COT at their May 2023 meeting. The COT noted that the scientific issues raised by the EMA and BfR aligned with the concerns and comments highlighted by the COT during the public consultation and recent meeting.

6. The Committee did not agree with EFSA’s assessment that the increase in percentage of Th17 cells was a scientifically relevant and robust intermediate endpoint to be applied to the derivation of a new HBGV. While the Committee acknowledged that it would not be feasible to assess the full data base on BPA,

and other studies would likewise have uncertainties, the current EFSA protocol was extremely restricted in its data evaluation. Given the uncertainties over the endpoint a weight of evidence approach and evidence integration should have been applied to a wider dataset to derive a robust point of departure.

7. EFSA previously compared the temporary TDI (t-TDI) with exposure estimates and concluded that there was no health concern for any age group from dietary exposure and low health concern from aggregated exposure. In the current opinion EFSA was not explicitly asked to perform an exposure assessment and hence noted that the data used may not accurately reflect the current exposures to consumers. The COT agreed with this conclusion and noted that work has been undertaken by industry to lower exposures to BPA and hence, the previous data may not be reflective of the current exposures.

8. 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 derived by EFSA.

9. These considerations meant that the COT was unable to endorse the EFSA opinion and therefore considered it necessary to assess and integrate previous and recent evidence to derive a tolerable intake protective of UK consumers.